

PROSPECTUS SUPPLEMENT
(to Prospectus dated December 14, 2016)

3,428,572 American Depositary Shares Representing 3,428,572 Ordinary Shares



Kitov Pharma Ltd.

We are offering 3,428,572 American Depositary Shares (“ADSs”) representing 3,428,572 of our ordinary shares, no par value (“Ordinary Shares”). Each ADS represents one Ordinary Share. In a concurrent private placement, we are selling to such investors warrants to purchase up to 2,571,430 ADSs (the “warrants”). The warrants and the ADSs representing ordinary shares issuable upon the exercise of the warrants are not being registered under the Securities Act of 1933, as amended, (the “Securities Act”), are not being offered pursuant to this prospectus supplement and are being offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder and Regulation S under the Securities Act.

Our ADSs are listed on NASDAQ Capital Market (“NASDAQ”) under the symbol “KTOV.” The warrants being issued in the concurrent private placement are not listed on any securities exchange and we do not expect to list the warrants on any national securities exchange or other trading market. On January 16, 2019, the last reported sale price of our ADSs on NASDAQ was \$1.60 per ADS. Our Ordinary Shares are also listed on the Tel Aviv Stock Exchange (“TASE”) under the symbol “KTOV.” On January 16, 2019, the last reported sale price of our Ordinary Shares on the TASE was NIS 8.00, or \$2.18 per Ordinary Share (based on the exchange rate reported by the Bank of Israel on such date).

We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to comply with certain reduced public company reporting requirements for future filings.

As of January 16, 2019, the aggregate market value of our outstanding ordinary shares held by non-affiliates, or public float, was approximately \$43,177,714 based on issued and outstanding ordinary shares or ADSs held by non-affiliates represented by an equivalent of 15,420,612 ADSs, at a price of \$2.80 per ADSs, which was the last reported sale price of our ADSs on NASDAQ on January 15, 2019, a date that is within 60 days of filing this prospectus supplement. As of the date hereof, we have sold or offered 3,260,000 ADSs for a total of \$8,150,000 pursuant to General Instruction I.B.5 of Form F-3 during the prior 12 calendar month period that ends on and includes the date hereof but excluding this offering. Pursuant to General Instruction I.B.5 of Form F-3, in no event will we sell securities registered on this registration statement of which this prospectus supplement forms a part in a public primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below \$75.0 million.

Investing in these securities involves a high degree of risk. Please read “Risk Factors” beginning on page S-10 of this prospectus supplement, on page 7 of the accompanying prospectus and in the documents incorporated by reference into this prospectus supplement.

None of the United States Securities and Exchange Commission, the Israeli Securities Authority, any state securities commission or any other regulatory body, has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

We have retained H.C. Wainwright & Co., LLC to act as our exclusive placement agent. The placement agent has agreed to use its “reasonable best efforts” to arrange for the sale of the securities offered by this prospectus supplement. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. We have agreed to pay the placement agent fees set forth in the table below, which assumes that we sell all of the securities we are offering.

	PER ADS	TOTAL
Offering price	\$ 1.75	\$ 6,000,001
Placement agent fees (1)	\$ 0.105	\$ 360,000
Proceeds to us, before expenses	\$ 1.645	\$ 5,640,001

- (1) We will pay the placement agent a cash commission fee equal to 6% of the aggregate gross proceeds to us from the sale of the securities in the offering and a management fee equal to 1% of the aggregate gross proceeds. We will pay the placement agent a non-accountable expense allowance of \$65,000. In addition, we have agreed to issue to the placement agent unregistered warrants to purchase up to 240,000 ADSs (which represents 7% of the aggregate number of ADSs sold in this offering) at an exercise price of \$2.1875 per ADS (which represents 125% of the offering price per ADS sold in this offering). See “Plan of Distribution” on page S-59 of this prospectus supplement for more information regarding the placement agent’s compensation.

We anticipate that delivery of the ADS will be made on or about January 18, 2019.

H.C. Wainwright & Co.

Prospectus Supplement dated January 16, 2019.

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ABOUT THIS PROSPECTUS SUPPLEMENT

You should rely only on the information provided in this prospectus supplement and the accompanying prospectus, all information incorporated by reference herein and therein, as well as the additional information described under “Incorporation by Reference” on page S-62 of this prospectus supplement. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus supplement and the accompanying prospectus do not constitute an offer to sell, or a solicitation of an offer to purchase, the securities offered by this prospectus supplement and the accompanying prospectus in any jurisdiction where it is unlawful to make such offer or solicitation. You should not assume that the information contained in this prospectus supplement or the accompanying prospectus, or any document incorporated by reference in this prospectus supplement or the accompanying prospectus, is accurate as of any date other than the date on the front cover of the applicable document. Neither the delivery of this prospectus supplement nor any distribution of securities pursuant to this prospectus supplement shall, under any circumstances, create any implication that there has been no change in the information set forth or incorporated by reference into this prospectus supplement or in our affairs since the date of this prospectus supplement. Our business, financial condition, results of operations and prospects may have changed since that date.

This prospectus supplement and the accompanying prospectus are part of a registration statement (No. 333-215037) that we filed with the Securities and Exchange Commission, or the SEC, using a “shelf” registration process. Under the shelf registration process, from time to time, we may sell any of the securities described in the base prospectus in one or more offerings, subject to General Instruction I.B.5. of Form F-3, according to which in no event will we sell securities with a value exceeding more than one-third of our “public float” (the market value of our ordinary shares and any other equity securities that we may issue in the future that are held by non-affiliates) in any 12-calendar month period so long as our public float remains below \$75.0 million. This document comprises two parts. The first part is this prospectus supplement, which describes the specific terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference herein. The second part, the accompanying prospectus, gives more general information, some of which may not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. If the description of the offering varies between this prospectus supplement and the accompanying prospectus or the documents incorporated herein by reference filed prior to the date of this prospectus supplement, you should rely on the information contained in this prospectus supplement. However, if any statement in one of these documents is inconsistent with a statement in another document having a later date — for example, a document incorporated by reference in the accompanying prospectus — the statement in the document having the later date modifies or supersedes the earlier statement.

Before purchasing any securities, you should carefully read both this prospectus supplement and the accompanying prospectus, together with the additional information described under the headings, “Where You Can Find More Information” and “Incorporation by Reference,” on pages S-61 and S-62 of this prospectus supplement.

Unless the context otherwise requires, all references to:

- the terms “Registrant,” “Company,” “we,” “us,” “our,” and similar designations refer to Kitov Pharma Ltd., together with its wholly-owned subsidiary, Kitov Pharmaceuticals, and its majority owned subsidiary, TyrNovo, except where otherwise stated or where it is clear that the terms mean only Kitov Pharma Ltd. exclusive of its subsidiaries,
- “Kitov” refers to the Registrant, together with its wholly-owned subsidiary, Kitov Pharmaceuticals, until completion of the merger between the Registrant and Kitov Pharmaceuticals in December 2017, pursuant to which Kitov Pharmaceuticals merged with and into the Registrant and was dissolved,
- “Kitov Pharma”, refers to the Registrant, exclusive of its subsidiaries,

- “Kitov Pharmaceuticals” refers to Kitov Pharmaceuticals Ltd., the wholly owned subsidiary of the Registrant until completion of the merger with the Registrant in December 2017, pursuant to which Kitov Pharmaceuticals merged with and into the Registrant and was dissolved,
- “TyrNovo” refers to TyrNovo Ltd., the majority owned subsidiary of the Registrant,
- the terms “shekels”, “Israeli shekels” and “NIS” refer to New Israeli Shekels, the lawful currency of the State of Israel,
- the terms “dollar”, “US\$” or “\$” refer to U.S. dollars, the lawful currency of the United States of America,
- the terms “Euro” or “€” refer to the Euro, the lawful currency of the European Union member states,
- “ordinary shares,” “our shares” and similar expressions refer to the Registrant’s Ordinary Shares, no par value per share,
- “ADS” refer to the Registrant’s American Depositary Shares,
- “public warrants” or “Series A warrants” refer to the Registrant’s warrants listed on the NASDAQ Capital Market under the symbol KTOVW,
- the “Companies Law” are to Israel’s Companies Law, 5759-1999, as amended,
- the “SEC” are to the United States Securities and Exchange Commission,
- “NASDAQ” are to the NASDAQ Capital Market except where otherwise stated or where it is clear that the terms mean any of the NASDAQ exchanges, and
- the “TASE” are to the Tel Aviv Stock Exchange.

Glossary of Industry Terms

Additionally, for convenience, the following terms used in this prospectus supplement are defined as follows:

“API”	Active Pharmaceutical Ingredient – any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug product, becomes one active ingredient in the drug product.
“approved product”	A product that has been approved for commercialization by a regulatory authority.
“CMC”	Chemistry Manufacturing and Controls – The methods by which a drug substance and product are synthesized, purified, assayed, and packaged.
“cGMP”	Current Good Manufacturing Practice – minimum requirements of the FDA and other regulatory authorities for the methods, facilities, and controls used in the manufacturing, processing, and packing of a drug product that is intended for human use to ensure that the product is safe for use and has the ingredients and strength that it claims to have.
“Clinical”	Pertaining to human studies.
“Drug Product”	For the purposes of this disclosure – a drug product that has been approved by the FDA for marketing and sales within the United States.

“FDA”	United States Food and Drug Administration.
“Formulation”	All the active and inactive materials contained in a final medical product.
“Generic Product”	A product developed by others than the original innovator, yet contains the same active substance as the original product both qualitatively and quantitatively. Limits of the difference from the original product within which the product may be recognized by the regulations as generic are determined separately for each product by the related regulatory authorities during the approval process. Regulatory recognition of a product as a generic product is performed through the majority of approval procedures adapted to this type of product, which differ from the approval procedures applied to a new chemical entity (NCE).
“NCE”	New Chemical Entity - a drug that contains no active moiety that has been approved by the FDA in any other application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act.
“NDA”	New Drug Application - an application submitted to the FDA to approve marketing a new drug.
“PDX”	An animal model in which patient-derived tumor tissue at low passage are implanted in animals, used to conserve original tumor characteristics and to provide relevant predictive insights into clinical outcomes when evaluating new cancer therapies.
“Preclinical”	Drug development studies performed outside of a human living organism or cell, using living cells, or appropriate animal models. The studies begin before trials in humans and assess safety, toxicity, and efficacy. Since drug development is dynamic, Preclinical studies are performed throughout the drug development lifecycle.
“Pharmacokinetics” “PK”	The study of the absorption, distribution, metabolism and excretion of a drug from the body; the pharmacokinetic indices provide, among other things, information on the extent and time of the patient’s exposure to the material. It is the study of how the body affects the drug.
“therapeutic candidate”	A product that is undergoing development, preclinical trials, clinical trials and/or has a pending NDA in review by the FDA or similar marketing application being reviewed by a foreign regulatory authority but has not been approved for commercialization.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

We are offering to sell, and seeking offers to buy, ADSs representing our Ordinary Shares only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the ADSs in certain jurisdictions may be restricted by law. Persons outside the U.S. who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the ADSs and the distribution of this prospectus supplement and the accompanying prospectus outside the U.S. This prospectus supplement does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights selected information about us, this offering and information contained in greater detail elsewhere in this prospectus supplement, the accompanying prospectus, and in the documents incorporated by reference. This summary is not complete and does not contain all of the information that you should consider before investing in our ADSs. You should carefully read and consider this entire prospectus supplement, the accompanying prospectus and the documents, including financial statements and related notes, and information incorporated by reference into this prospectus supplement, including the financial statements and “Risk Factors” starting on page S-10 of this prospectus supplement, before making an investment decision. If you invest in our securities, you are assuming a high degree of risk.

Overview

We are a pharmaceutical company currently focused on the development and commercialization of:

- (i) Consensi™, a combination drug recently approved by the FDA for the simultaneous treatment of two clinical conditions: pain caused by osteoarthritis and hypertension (high blood pressure), which can be pre-existing or caused by the treatment for osteoarthritis; and
- (ii) NT219, a therapeutic candidate which is a small molecule that targets two pathways highly involved in cancer drug resistance.

In addition, we may consider the acquisition of therapeutic candidates at various stages of development in various therapeutic areas or the acquisition of approved drug products. We currently have no binding agreements or commitments to complete any transaction for the possible acquisition of new therapeutic candidates or approved drug products.

We intend to seek FDA approval for the commercialization of our NT219 therapeutic candidate. Where applicable, we also intend to seek corresponding regulatory paths for approval in other foreign jurisdictions. We have one drug product, Consensi™, which successfully completed its Phase III clinical trial and which was approved by the FDA on May 31, 2018, following the successful filing of a completed 505(b)(2) NDA. Our current drug pipeline consists of one therapeutic candidate, NT219, which is in preclinical stage but will likely be subject to review and approval by the FDA upon filing a completed 505(b)(1) NDA, if at all. Upon and subject to receipt of the requisite approvals, if any, we intend to commercialize NT219 through licensing and/or other commercialization arrangements with pharmaceutical companies on a global and/or territorial basis. We may also evaluate, on a case by case basis, co-development and similar arrangements, as well as independent commercialization of our therapeutic candidates.

Our competitive strengths

The pharmaceutical market is characterized by large international pharmaceutical companies that develop a wide range of products, both generic and NCEs, which operate alongside smaller companies, such as ours, that develop a specific drug or a combination of drugs. Therefore, many small companies enter into agreements with such global companies during the drug development stage in order to continue the development or marketing of the drug, taking advantage of the financial, marketing and/or other resources available to such global companies. At the same time, the global companies tend to enter into agreements with smaller companies in order to save development time and resources. The global drug sector is a highly developed market with a turnover of hundreds of billions of U.S. dollars and intense competition. If we are to develop other therapeutic candidates and one or more of those therapeutic candidates are approved by the FDA to be commercialized as drugs, most of those drugs are expected to have competing drugs or other therapies, developed at the same time by other companies and organizations. We are therefore exposed to competition in our field of operation. Although we believe that our therapeutic candidate NT219 has advantages which our competitors' products lack, there is a constant risk in the drug development field that a competing party will complete the development stages before we are able to develop our therapeutic candidates intended for the same disease. Moreover, a constant threat in our market is presented by new drugs that have already completed all the development stages and have already entered the market and are competing with the treatments and drugs previously available on the market.

We also believe that our approved drug, Consensi™, has several distinct advantages over competitor drugs, such as:

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

NT219 is a small molecule, and small molecules typically are less expensive to develop and have less complex CMC as compared to large proteins or antibodies. In addition, NT219 has the potentially advantageous effect of:

- overcoming drug resistance acquired by cancer, prevent or delay such resistance; and
- working in combination with multiple approved cancer therapies.

Our strategy

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

Key elements of our strategy are to:

- develop our therapeutic candidate NT219 with clinical and commercial advantages and obtain approval thereof from the FDA and other foreign regulatory authorities;
- commercialize our FDA-approved drug Consensi™ in the United States and to obtain approval of Consensi™ in other foreign jurisdictions;
- expand our line of therapeutic candidates through the acquisition or in-licensing of technologies, products and drugs intended to meet clinical needs, thereby utilizing the skills, knowledge and experience of our personnel to develop and enhance the value of additional products, and bring them to market efficiently;

- cooperate with third parties to both develop and commercialize our NT219 or other therapeutic candidates that we may develop in the future in order to share costs and leverage the expertise of others; and
- enter into sub-license agreements with international companies for potential or future therapeutic candidates based on potential upfront and milestone payments, royalties and/or other marketing arrangements, depending on product and market conditions.

Recent Developments

Unique Mechanism of Action and Anti-Cancer Effect of NT219

On January 15, 2019, we announced new findings from our ongoing collaboration with researchers from the Hebrew University of Jerusalem. The data revealed NT219's high affinity and selective binding to its target proteins. Researchers demonstrated that NT219 binds directly to Insulin Receptor Substrates (IRS) 1/2 and to the Signal Transducer and Activator of Transcription 3 (STAT3), both known modulators of tumor survival, metastasis and drug resistance. Data showed that a short exposure of cancerous cells to NT219 was sufficient to trigger irreversible shutdown of these pathways, resulting in a long-term anti-cancer effect.

Based on these findings, we extended our collaboration agreement with Yissum Research and Development Company of the Hebrew University of Jerusalem Ltd. ("Yissum"), the Technology Transfer company of the Hebrew University of Jerusalem, in order to deepen the understanding of NT219's efficacy in overcoming tumors' resistance to immunotherapy.

FDA Approval of Consensi™

The FDA approved our NDA on May 31, 2018 for our Consensi™ drug product. Consensi™ is a combination of two APIs: amlodipine besylate, a calcium channel blocker; and celecoxib, a nonsteroidal anti-inflammatory drug (NSAID). Consensi™ was approved on May 31, 2018 for patients suffering from hypertension and from osteoarthritis for whom treatment with amlodipine for hypertension and celecoxib for the treatment of osteoarthritis are appropriate. The New Drug Application for Consensi™ included the positive results from our Phase III clinical trial. These data demonstrated that the study met its primary endpoint of showing that the drug lowers daytime systolic blood pressure by at least 50% of the reduction in blood pressure achieved in patients treated with amlodipine besylate only, with statistical significance of $p=0.001$. We also submitted, as an amendment to the NDA, the positive results from its randomized double-blind, placebo-controlled renal function Phase III/IV clinical trial of Consensi™. Data from this study validated the primary efficacy endpoint achieved in the completed Phase III clinical trial. This study also demonstrated that treatment with Consensi™ led to a statistically significant reduction of serum creatinine, a marker of renal function, from its baseline value ($p=0.0005$), demonstrating improved renal function in patients treated with the combination. In contrast, neither amlodipine besylate nor placebo lowered creatinine to a statistically significant level.

We anticipate that treating the symptoms of hypertension and osteoarthritis will lower blood pressure and by so doing, will reduce the risk of fatal and nonfatal cardiovascular events such as strokes or myocardial infarctions. Consensi™ is available in tablets and is to be administered orally once per day. Consensi™ tablets are formulated according to the following strengths (amlodipine/celecoxib): 2.5 mg/200 mg, 5 mg/200 mg, and 10 mg/200 mg tablets.

In connection with our Consensi™ drug product, we are subject to post-marketing requirements and post-marketing commitments. Post-marketing requirements and post-marketing commitments are studies that sponsors conduct after FDA approval to gather additional information about a product's safety, efficacy, or optimal use. Post-marketing requirements are required studies, whereas a sponsor voluntarily commits to conduct post-marketing commitments. We are required by the FDA to comply with reporting requirements including but not limited to submitting serious unexpected adverse drug experiences no later than 15 calendar days from initial receipt of the information and also to provide a periodic report quarterly for the first three years of approval and then annual after the first three years. The FDA waived a requirement to conduct a pediatric assessment under the Pediatric Research Equity Act because Consensi™ is intended to treat indications that are rarely experienced in pediatric populations.

We have also committed to conducting additional supplementary CMC studies on our Consensi™ drug product, including an elemental impurities assessment and a dissolution method and acceptance criteria development study.

Now that Consensi™ has been approved for marketing in the United States, and following our execution of a marketing and distribution agreement for the commercialization of Consensi™ in the United States, we intend to shift the focus of our clinical and regulatory teams to our NT219 therapeutic candidate that is currently in development for various oncology indications. We intend to leverage the teams' drug development expertise gained from the Consensi™ approval process.

Acquisition of Additional Stake in TyrNovo

On June 17, 2018, we closed the transaction for the acquisition of an additional approximately 3.1% stake in our majority-owned subsidiary, TyrNovo Ltd. ("TyrNovo"), pursuant to an agreement with Taoz – Company for Management and Holdings of Companies Ltd. ("Taoz"), previously announced on June 15, 2018. Taoz was the final remaining unaffiliated minority shareholder of TyrNovo, and with whom we had entered into a shareholders' agreement in February 2017. Pursuant to this new share exchange agreement with Taoz, in exchange for Taoz's entire holding in TyrNovo and the termination of the existing shareholder and investment agreements amongst us, TyrNovo and Taoz, we issued to Taoz 2,816,900 newly issued ordinary shares (equivalent to 2,816,900 ADSs).

After the closing of this new share exchange transaction, we now hold approximately 97.57% of TyrNovo's issued and outstanding ordinary shares. Approximately 2.41% of TyrNovo's issued and outstanding ordinary shares are owned by Dr. Hadas Reuveni Ph.D., the founder and Chief Technology Officer of TyrNovo. Dr. Reuveni's shares at present are held by a trustee and do not have any voting rights pursuant to a recently issued tax ruling by the Israeli Tax Authority, and as such we hold 100% of the voting rights in TyrNovo.

Consensi™ Commercialization Agreement for United States

On January 3, 2019, we announced that we signed an exclusive marketing and distribution agreement with Coeptis Pharmaceuticals ("Coeptis") for the commercialization of our FDA-approved drug Consensi™ in the U.S. market. The agreement provides for total milestone payments from Coeptis of \$3.5 million, of which we have already received the initial milestone upon execution of the agreement, and additional milestone payments are due upon completion of an agreed Chemistry, Manufacturing, Control (CMC) plan and upon first commercial sales in the U.S. In addition, we are entitled to 40% to 60% of Coeptis' net profit on Consensi™ sales. The agreement is for a term of fifteen years and may be extended for additional two-year terms.

Consensi™ Commercialization Agreement for China

In May 2018 we have signed a definitive License, Development and Commercialization Agreement for our FDA-approved drug Consensi™ for the territory of China with Hebei Changshan Biochemical Pharmaceutical Co., Ltd. (Changshan Pharma), a Chinese public company traded on the Shenzhen Stock Exchange. Upon receipt of marketing authorization in China, Changshan Pharma will have the exclusive right and license to import, manufacture, distribute and sell Consensi™ in China, Taiwan, Hong Kong and Macao. Changshan Pharma will be responsible for seeking marketing authorization in China for Consensi™ in China. Under the terms of the agreement, we are entitled to receive up to an aggregate of \$3.5 million for U.S. FDA approval of Consensi™, and for China regulatory milestones, of which \$1 million became payable upon FDA approval of Consensi™ and \$2.5 million will become payable upon achievement of certain regulatory milestones in China; up to an aggregate of \$6.0 million for predefined commercial milestones; and up to 12% royalties on net sales. The initial term of the definitive agreement with Changshan Pharma is for ten years from the date of first commercial sale and shall automatically renew for additional one-year terms.

Reverse Share Split

On January 4, 2019, we effected a reverse share split of our ordinary shares, or the reverse share split, at an exchange ratio of 1-for-20. The reverse share split applied to all of our outstanding ordinary shares and therefore did not affect any shareholders' relative ownership percentage. Our Annual Report on Form 20-F for the year ended December 31, 2017 and our condensed consolidated unaudited interim financial statements as of June 30, 2018 that are incorporated by reference into the prospectus supplement and the accompanying prospectus are presented without giving effect to the reverse share split. All shares and price per share numbers set forth in this prospectus supplement are presented after giving effect to the reverse stock split. The reverse share split was not a reverse split of our ADSs. Our ADSs continue to trade as before the reverse share split and represent the same underlying portion of our share capital as they did prior to the reverse share split, however, after the reverse share split, our ADSs represent one ordinary share as compared to 20 ordinary shares prior to the reverse share split.

Corporate information

Kitov was incorporated under the laws of the State of Israel (under a previous name) on August 12, 1968 and its ordinary shares were originally listed for trading on the TASE in 1978. In November 2015, we completed an initial public offering of our ADSs and Series A warrants on NASDAQ. Our principal executive offices are located at One Azrieli Center, Round Tower, 19th Floor, 132 Menachem Begin Road, Tel Aviv 6701101, Israel, and our telephone number is 972-3-933-3121. Our website is www.kitovpharma.com. The information contained therein or connected thereto shall not be deemed to be incorporated into this prospectus supplement and the accompanying prospectus.

THE OFFERING

ADSs offered by us in the offering	3,428,572 ADSs representing 3,428,572 Ordinary Shares
Total Ordinary Shares outstanding immediately after this offering	19,437,836 Ordinary Shares (not including one Ordinary Share held in treasury) (such number of ordinary shares would be represented by 19,437,836 ADSs.)
The ADSs	<p>Each ADS represents one Ordinary Share. The ADSs initially will be evidenced by American Depositary Receipts ("ADRs"), executed and delivered by The Bank of New York Mellon, as depositary (the "Depositary").</p> <p>The Depositary, as depositary, will be the holder of the Ordinary Shares underlying your ADSs and you will have rights as provided in the Deposit Agreement dated as of November 25, 2015, among us, The Bank of New York Mellon, as Depositary, and all owners and holders from time to time of ADSs issued thereunder (the "Deposit Agreement"), a form of which has been filed as Exhibit 1 to the Registration Statement on Form F-6 filed by the Depositary with the SEC on November 6, 2015.</p> <p>Subject to compliance with the relevant requirements set out in the prospectus, you may turn in your ADSs to the Depositary in exchange for Ordinary Shares underlying your ADSs.</p> <p>The Depositary will charge you fees for such exchanges pursuant to the Deposit Agreement.</p>
Offering Price	The offering price is \$1.75 per one ADS.

Use of Proceeds	<p>We intend to use the net proceeds of this offering to fund the development of NT219, the possible acquisition of new therapeutic candidates and for general working capital purposes. We currently have no binding agreements or commitments to complete any transaction for the possible acquisition of new therapeutic candidates, though we are currently exploring possible candidates.</p> <p>See “Use of Proceeds” for additional information.</p>
Listing	<p>Our ADSs are listed on NASDAQ under the symbol “KTOV” and our Ordinary Shares currently trade on the TASE in Israel under the symbol “KTOV”. The warrants being issued in the concurrent private placement are not listed on any securities exchange and we do not expect to list the warrants on NASDAQ, the TASE or any other national securities exchange or any other recognized trading system, and we do not expect a market to develop. Warrant holders are prohibited from listing any warrants on any such exchange or trading system or on any other trading platform.</p>
Risk factors	<p>Before deciding to invest in our ADSs, you should carefully consider the risks related to our business, the offering and our securities, and our location in Israel. See “Risk Factors” on page S-10 of this prospectus supplement.</p>
Concurrent private placement	<p>In a concurrent private placement, we are selling to the purchasers of our ADSs in this offering warrants to purchase three-fourths of the number of the ADSs purchased by such investors in this offering, or up to 2,571,430 ADSs. We will receive gross proceeds from the concurrent private placement transaction solely to the extent such warrants are exercised for cash. The warrants will be immediately exercisable when issued at an exercise price of \$2.00 per ADS and will expire 5.5 years from the date on which first exercisable. The warrants and the ADSs issuable upon the exercise of the warrants are not being offered pursuant to this prospectus supplement and are being offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder and Regulation S under the Securities Act. See “Concurrent Private Placement of Warrants.”</p>
Dividend Policy	<p>We have never declared or paid any cash dividends to our shareholders, and we currently do not expect to declare or pay any cash dividends in the foreseeable future. See “Dividend Policy.”</p>
Depository	<p>The Bank of New York Mellon.</p>
<p>The number of ADSs to be outstanding after this offering excludes:</p> <ul style="list-style-type: none"> • 1,243,507 ordinary shares issuable at a weighted average exercise price of NIS 0.16 (approximately \$0.04) per share issuable to holders of our options issued, as applicable, under our 2013 Option Plan, as amended, or our 2016 Equity Incentive Plan, (such number of ordinary shares would be represented by 1,243,507 of our ADSs); • 7,134,790 ordinary shares underlying the ADSs issuable upon exercise of the Series A warrants and the representative’s warrants issued in our initial public offering, and the Series A warrants and the placement agent warrants issued as part of our offering in July 2016 (such number of ordinary shares would be represented by 7,134,790 of our ADSs); • 529,427 ordinary shares underlying ADSs issuable upon exercise of the warrants issued in connection with our July 2017 private placement of warrants and the placement agent warrants issued as part of our July 2017 public offering (such number of ordinary shares would be represented by 529,427 of our ADSs); • 1,858,000 ordinary shares underlying ADSs issuable upon exercise of the warrants issued in connection with our June 2018 private placement of warrants and the placement agent warrants issued as part of our June 2018 public offering (such number of ordinary shares would be represented by 1,858,000 of our ADSs); and • 2,571,430 ordinary shares issuable upon exercise of the warrants offered in our concurrent private placement with an exercise price of \$2.00 and 240,000 ordinary shares underlying ADSs issuable upon exercise of placement agent warrants with an exercise price of \$2.1875 issued to the placement agent as compensation with respect to this offering. <p>Unless otherwise stated, outstanding share information throughout this prospectus supplement excludes such outstanding securities.</p>	

RISK FACTORS

You should carefully consider the risks described below and in our annual report on Form 20-F for the year ended December 31, 2017, as well as the other information included or incorporated by reference in this prospectus supplement, including our financial statements and the related notes, before you decide to buy our securities. The risks and uncertainties described below and incorporated by reference in this prospectus supplement are not the only risks facing us. We may face additional risks and uncertainties not currently known to us or that we currently deem to be immaterial. Any of the risks described below or incorporated by reference in this prospectus supplement, and any such additional risks, could materially adversely affect our business, financial condition or results of operations. In such case, you may lose all or part of your original investment.

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™ which have been commercialized in the US 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 stages, and has not been approved for marketing and are 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 have regulatory approval for NT219 or any other therapeutic candidate that we may develop 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 June 30, 2018 of approximately \$43.3 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; and successfully commercialize and sell our FDA-approved drug Consensi™ in the United States and obtain the required regulatory approvals in various territories 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.

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. 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. 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 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 or our FDA-approved drug Consensi™, we will need to raise substantial additional funds to develop and/or commercialize our NT219 therapeutic candidate 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 NT219 therapeutic candidates in its 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 NT219 therapeutic candidate, 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 NT219 therapeutic candidate 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 issues that may arise 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 Consensi™ 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 NT219 therapeutic candidate, 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 three 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 NT219 therapeutic candidate 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, CMC, and clinical trials may involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We and/or our potential commercialization partners will not be able to commercialize our therapeutic candidates without completing such trials.

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

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

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

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

If we do not establish collaborations for our 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 and the potential commercialization of our NT219 therapeutic candidate, or any other therapeutic candidates that we may develop in the future and our commercialization of Consensi™ 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 NT219 therapeutic candidate, 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 United States independently will have an adverse effect on our business, financial condition and results of operation.

Any collaborative arrangements that we establish may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. We do not control third parties with whom we have or may have collaborative arrangements, and we rely on them to achieve results which may be significant to us. In addition, any future collaboration arrangements may place the development, 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;
- should a collaborator fail to comply with applicable laws, rules, or regulations when performing services for us, we could be held liable for such violations;
- our collaborators may experience financial difficulties or changes in business focus;

- our collaborators may experience quality or regulatory issues that negatively affect our therapeutic candidates;
- our collaborators may fail to secure adequate commercial supplies in a timely manner of 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 the development and may increase the cost of developing our therapeutic candidates.

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

Our current business model is based largely upon the development and commercialization of NCEs that have 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 NCEs that have 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 a clinical trial 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 the 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, we cannot be certain whether NT219 will be safe and efficacious. In addition, we cannot be certain that the FDA or any foreign regulatory body will consider our NT219 therapeutic candidate, 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. 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 on third parties to conduct our CMC, preclinical and clinical trials, and those third parties may not perform satisfactorily, including, but not limited to, failing to meet established deadlines for the completion of such clinical trials.

We do not have the ability independently to conduct CMC, preclinical or clinical trials for our product candidates, and we rely on third parties, such as contract manufacturing organizations, contract research organizations, medical institutions, contract laboratories, current and potential development or commercialization partners, clinical investigators and independent study monitors, to perform these functions. Our reliance on these third parties for development activities reduces our control over these activities.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Although we have, in the ordinary course of business, entered into agreements with these third parties, we continue to be responsible for confirming that each of our preclinical and clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA requires us to comply with regulations and standards, commonly referred to as 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. 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, it 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 and clinical trial data that we present to regulatory authorities in order to obtain marketing authorizations. Although we attempt to audit and control the quality of third party data, we cannot guarantee the authenticity or accuracy of such data, nor can we be certain that such data has not been fraudulently generated. There is no assurance that these third parties will pass FDA or regulatory audits, which could delay or prohibit regulatory approval or revoke already approved marketing authorization.

If third parties do not manufacture our NT219 therapeutic candidate or any other therapeutic candidate that we may develop in the future in sufficient quantities in the required timeframe, and at an acceptable cost, clinical development and commercialization of our therapeutic candidates would be delayed.

We do not currently own or operate manufacturing facilities, and we rely, and expect to continue to rely, on third parties to manufacture preclinical, clinical and commercial quantities of our 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.

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 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 therapeutic candidate 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 any of our NT219 therapeutic candidate.

To date, our NT219 has been manufactured in relatively small quantities by third-party manufacturers. We are also in discussions with third-party manufacturers for the manufacturing of NT219 under cGMP conditions. Once our NT219 therapeutic candidate 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 they 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 or we may not meet our post marketing commitments to the FDA for Consensi™.

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 that 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 manufactured sufficient quantities of Consensi™ for formulation development, PK studies, clinical trials, and the required large scale production in support of our NDA package that we submitted to the FDA for the purposes of approving Consensi™ for marketing and commercial sale in the United States. We anticipate that we will continue to rely on our third-party manufacturers to manufacture our Consensi™ drug product at commercial scale under cGMP conditions. These third-party manufacturers may not be able to successfully increase the manufacturing capacity for our Consensi™ drug product to meet the demand in the United States. Any changes to the manufacturing process to increase the manufacturing capacity for Consensi™ or for any other reason may require additional validation studies, which the FDA must review and approve. If they are unable to successfully increase the manufacturing capacity for Consensi™ or 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 NT219 therapeutic candidate if 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 or if we obtain regulatory approvals for our NT219 therapeutic candidate or any other therapeutic candidate that we may develop in the future will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and applicable foreign laws, regulations and guidelines, we could lose those approvals, and our business would be seriously harmed.

Our FDA-approved Consensi™ drug product is subject to ongoing post-marketing surveillance programs and regulatory review. In addition, if our NT219 therapeutic candidate 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, if any and as applicable, are subject to ongoing reporting obligations, including pharmacovigilance, and the manufacturing operations 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 the manufacturing operations or the imposition of labeling or marketing limitations. Since many more patients are exposed to drugs following their marketing approval, unanticipated adverse reactions or serious adverse reactions that were not observed in preclinical and/or clinical trials may be observed during the commercial marketing of 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 manufacturing facilities that we or our commercialization partners, if any, use or will 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 obtains regulatory approval resulting in decreased or lost revenue from milestones, product sales or royalties and could also result in 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 prescription or promotion of off-label uses 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 use of Consensi™ departs from the approved use may increase the risk of injury or other adverse events to the patients and product liability claims brought against us. Additionally, 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, and 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.

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

Modifications to our Consensi™ drug product, NT219 therapeutic candidate or to any other therapeutic candidates 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, if necessitated by a problem with a marketed product, may result in the recall or suspension of marketing of the previously approved and marketed product until clearances or approvals of the modified product are obtained. The FDA and other foreign regulatory authorities require manufacturers of approved drugs to make and document a determination of whether or not a modification requires a 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 to 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 depend on our ability to identify and acquire or in-license therapeutic candidates to achieve commercial success.

Kitov Pharma own the rights to FDA-approved drug Consensi™ which we acquired as a therapeutic candidate, and our NT219 therapeutic candidate were all acquired by us from third parties. We evaluate internally and with external consultants each potential therapeutic candidate. However, there can be no assurance as to our ability to accurately or consistently select therapeutic candidates that have the highest likelihood to achieve commercial success.

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

In addition, Yisum is responsible under the license agreement for the filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If Yisum does not meet its obligations in a timely manner or if other events occur that are not within Yisum's control, which impact Yisum'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, Yisum 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 Yisum discontinues maintaining such patents, we may not be able to enforce rights for our therapeutic candidates or protect our therapeutic candidates from competition in those territories.

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

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

Our growth and success also depend on our ability to attract and retain additional highly qualified scientific, technical, business development, marketing, managerial and finance personnel. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to liability from their former employers. In addition, if we elect to independently commercialize any therapeutic candidate, we will need to expand our marketing and sales capabilities. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel. Compensation packages for 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. Any such 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. 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. The requirements and restrictions for such grants are found in the Encouragement of Research, Development and Technological Innovation in Industry Law 5744-1984 (formerly known as the Law for the Encouragement of Research and Development in Industry 5744-1984), or the Innovation Law, the IIA's rules and guidelines and the terms of these grants.

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

The technologies licensed to TyrNovo by Yisum were developed, at least in part, with funds from IIA grants, and accordingly is obligated to pay royalties on sales of any of its IIA funded products and related services. In addition, the Government of Israel may from time to time audit sales of products which it claims incorporate technology and know-how funded via IIA programs and this may lead to additional royalties being payable on additional products. As of June 30, 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. These are generally described in the risk factor below under “The IIA grants which TyrNovo’s technology has received for research and development expenditures restrict its ability to manufacture products and transfer (including by way of license for R&D purposes) know-how outside of Israel and require it to satisfy specified conditions. In addition, we may encounter difficulties partnering TyrNovo’s therapeutic candidates with entities outside of Israel due to certain restrictions regarding manufacturing and transferring of know-how (including by a way of license for R&D purposes) outside of Israel imposed due to the receipt of the IIA grants.”

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

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

Under the IIA’s rules and guidelines, TyrNovo is generally prohibited from manufacturing products developed using the IIA funding outside of the State of Israel without the prior approval of the IIA and subject to payment of increased royalties. TyrNovo may not receive the required approvals for any proposed transfer of manufacturing activities. This restriction may impair TyrNovo’s ability to outsource manufacturing rights abroad.

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

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

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

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

Risks Related to Our Industry

Even 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 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 NT219 therapeutic candidate. 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 NT219 therapeutic candidate.

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 NT219 noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Some of these technologies may have an entirely different platform or means of treating the same indications as Consensi™, NT219, or other therapeutic candidates that we may develop in the future. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities, human resources and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing and other resources.

For example, since 2010, the opioid epidemic in the United States has increasingly been recognized as a major cause of death. The CDC estimates that from 2010 to 2016 over 600,000 Americans died from opioid overdoses. As a result, individuals, corporations, and the FDA have increasingly sought to decrease the over utilization of opioids. One method for decreasing the use of opioids is to increase the use of other analgesics. We believe that Consensi™ could potentially replace opioids for many types of chronic pain. However, it is possible that new drugs and new treatments that have been developed or that are in the process of being developed by others in order to reduce the use of 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 NT219 therapeutic candidate to receive widespread acceptance.

If third-party payers do not adequately reimburse customers for our Consensi™ drug product, or our NT219 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 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. However, there may be significant delays in obtaining coverage for newly approved therapeutic candidates. Moreover, eligibility for coverage does not necessarily signify that a therapeutic candidate will be reimbursed in all cases or at a rate that covers our costs, including 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 therapeutic candidates 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 therapeutic candidate is, among others:

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

Obtaining reimbursement approval for a therapeutic candidate or an approved drug from each government or other third-party payer is a time-consuming and costly process that could require us or our current or potential development and commercialization partners to provide supporting scientific, clinical and cost-effectiveness data for the use of our therapeutic candidates to each payer. Even when a payer determines that a therapeutic candidate is eligible for reimbursement, the payer may impose coverage limitations that preclude payment for some uses that are approved by the FDA or other foreign regulatory authorities. Reimbursement rates may vary according to the use of the therapeutic candidate and the clinical setting in which it 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 therapeutic products. If the price we are able to charge for any therapeutic candidates we develop, if approved, or the reimbursement provided for such therapeutic candidates, if approved, is inadequate in light of our development and other costs, our return on investment could be adversely affected.

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

In the U.S., there have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services which may affect payments for our Consensi™ drug product in the U.S. We believe that legislation that reduces reimbursement for our Consensi™ drug product 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 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. Third-party payers often follow Medicare coverage policy and payment limitations government and private 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 therapeutic candidates, if approved. 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 (commonly 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. 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.

Several states and private entities initially mounted legal challenges to the Healthcare Reform Law, and have continued to litigate various aspects of the legislation. On July 26, 2012, the United States Supreme Court generally upheld the provisions of the Healthcare Reform Law at issue as constitutional. However, the U.S. Supreme Court held that the legislation improperly required the states to expand their Medicaid programs to cover more individuals. As a result, the states have a choice as to whether they will expand the number of individuals covered by their respective state Medicaid programs. Some states have determined that they will not expand their Medicaid programs and will develop other cost-saving and coverage measures to provide care to currently uninsured individuals. Many of these efforts to date have included the institution of Medicaid managed care programs. The manner in which these cost-saving and coverage measures are implemented could have a material adverse effect on our business, financial condition and results of operations.

The Healthcare Reform Law sparked one of the most comprehensive and significant reforms in the history of the U.S. healthcare industry and has significantly changed the way healthcare is financed by both governmental and private insurers and impacted the scope of healthcare insurance and incentives for consumers and insurance companies, among others. Pharmaceuticals represent a significant portion of the cost of providing care. 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 therapeutic candidates 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 approved therapeutic candidates, if any, is substantially reduced or otherwise adversely affected in the future, or rebate obligations associated with them are substantially increased, it could have a material adverse effect on our business, financial condition, and 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 those therapeutic candidates currently being developed by us or our development or commercialization partners), or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for, any therapeutic candidate for which we receive marketing approval in the future could have a material adverse effect on our business, financial condition and results of operations.

Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Judicial challenges as well as legislative initiatives to modify, limit, or repeal the Healthcare Reform Law have been initiated and continue to evolve following the 2017 changes in the U.S. presidential administrations and U.S. Congress. There is still uncertainty with respect to the impact the current administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold. Such reforms could have an adverse effect on anticipated revenues from therapeutic candidates that we may successfully develop and for which we may obtain regulatory approval 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 future arrangements with third-party payers and customers 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 therapeutic candidates, if approved. The laws that may affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under government healthcare programs such as the Medicare and Medicaid programs;
- the federal Anti-Inducement Law (also known as the Civil Monetary Penalties Law), which prohibits a person from offering or transferring remuneration to a Medicare or State healthcare program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State healthcare program;
- the Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients for certain designated health services where that physician or family member has a financial relationship with the entity providing the designated health service, unless an exception applies;
- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government healthcare programs that are false or fraudulent;
- the so-called federal "Sunshine Act", which requires certain pharmaceutical and medical device companies to monitor and report certain financial relationships with physicians and other healthcare providers to CMS for disclosure to the public;
- the federal 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 provision, which imposes 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 Acts, 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 and false claims 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 with third parties 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. Although effective compliance programs can help mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. 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.

The Healthcare Reform Law, via the Sunshine Act, also imposed reporting requirements on certain medical device and pharmaceutical manufacturers, among others, to make annual public disclosures of certain payments and other transfers of value to physicians and teaching hospitals and ownership or investment interests held by physicians or their immediate family members. This information is subsequently made publicly available in a searchable format on CMS's "Open Payments" website. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value, or ownership or investment interests that are not reported.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing, medical directorships, and other purposes. For example, some states impose a legal obligation on companies to adhere to voluntary industry codes of behavior (e.g., the PhRMA Code and the AdvaMed Code of Ethics), which apply to pharmaceutical and medical device companies' interactions with healthcare providers, and 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.

Most recently, there has been a trend in federal and state legislation aimed at requiring pharmaceutical companies to disclose information about their production and marketing costs, and ultimately lowering costs for drug products. Several states have passed or introduced bills that would require disclosure of certain pricing information for prescription drugs that have no threshold amount or are above a certain annual wholesale acquisition cost, and in June 2016 Vermont became the first state to pass legislation requiring certain drug companies to disclose information relating to justification of certain price increases, followed by New York, Maryland, Nevada, Louisiana, and California in 2017. Each law imposes different requirements related to the disclosure of confidential and proprietary cost information. The U.S. Congress has also introduced bills targeting prescription drug price transparency. These laws and any other such implementation of legislation requiring publication of drug costs could materially and adversely impact our business, financial condition, and results of operations by promoting a reduction in drug prices. As such, patients may choose to use other low-cost, established drugs or therapies.

The scope and enforcement of these laws are uncertain and subject to change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and 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. We currently have a clinical trial liability policy that includes coverage for our clinical trials. Should we decide to seek additional insurance against such risks before our product sales commence, there is a risk that such insurance will be unavailable to us, or if it can be obtained at such time, that it will be available only at an unaffordable cost. Even if we obtain insurance, it may prove inadequate to cover claims or litigation costs, especially in the case of wrongful death claims. Product liability claims or other claims related to our Consensi™ drug product, or our NT219 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 NT219 therapeutic candidate 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 NT219 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 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 these infringements and other legal challenges could have a material adverse effect on our business, results of operations and financial condition.

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

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

From time to time, we may also be involved in various lawsuits and legal proceedings other than intellectual property infringement actions, concerning such laws as corporate and securities laws, business laws, product liability laws, and environmental laws. On December 3, 2015, we announced that we received a lawsuit and motion to approve the lawsuit as a class action lawsuit pursuant to the Class Action Lawsuits Law 5766-2006 which was filed against us and our directors at the Tel Aviv District Court (Economic Division). The Motion asserts claims for damages to the holders of our securities listed on the TASE, arising due to the initial public offering of our securities in the U.S. during November 2015. A separate, similar claim in the amount of NIS 1.1 million was recently filed against us 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, 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 the period ended June 30, 2018, we incurred legal expenses of approximately \$900,000 in connection with the ISA Investigation and ongoing class actions. Although we maintain directors' and officers' liability insurance, with an extension to cover the Company as well, and which is expected to cover much of our expected costs (legal and otherwise) in connection with the ISA Investigation and ongoing class actions 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 \$293,000, most of which amount has already been paid by us as of the date of this prospectus supplement.

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. 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, is expected to 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 proposed settlement to have a material impact on the Company's statement of operations. The proposed 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 proposed 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 proposed settlement, with no additional costs to us or to the other defendants. Upon the effectiveness of the proposed 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 proposed settlement is subject to the completion of final documentation, preliminary and final approval by the District Court for the Southern District of New York and dismissal by the plaintiffs with prejudice of the state actions, funding of the \$2.0 million in cash by our insurance carriers, and other customary closing conditions. Further, we have the right to terminate the settlement if class members timely and validly requesting exclusion from the class meet the conditions set forth in a confidential supplemental agreement with the lead plaintiffs. There can be no assurance that the settlement will be finalized and approved and, even if approved, whether the conditions to closing will be satisfied, and the actual outcome of this matter may differ materially from the terms of the settlement described herein.

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 proposed 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. To our knowledge no hearing has been held yet with respect to these motions involving Dr. Waymack.

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 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. Political uprisings and civil resistance demonstrations in various countries in the Middle East have affected the political stability of those countries. It is not clear how this instability, will develop and how it will affect the political and security situation in the Middle East. This instability may lead to deterioration of the political relationships that exist between Israel and these countries, and have raised concerns regarding security in the region and the potential for armed conflict. The tension between Israel and Iran or extremist groups in the region, such as Hamas in Gaza and Hezbollah in Lebanon, may escalate in the future and turn violent, which could affect the Israeli economy generally and us in particular. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations. Parties with whom we may do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. The conflict situation in Israel could cause situations where medical product certifying or auditing bodies could not be able to visit manufacturing facilities of our subcontractors in Israel in order to review our certifications or clearances, thus possibly leading to temporary suspensions or even cancellations of our product clearances or certifications. The conflict situation in Israel could also result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

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

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

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

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

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for certain transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. These provisions of Israeli law may delay, prevent or make difficult an acquisition of us, which could prevent a change of control and therefore depress the price of our shares,

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.

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

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

As described in our Annual Report for 2016 on Form 20-F, under “Item 15 - Controls and Procedures,” based on our evaluation of whether our 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, we cannot assure you that we will not identify additional material weaknesses in our internal control over financial reporting in the future, nor that our disclosure controls and procedures will detect or uncover all failures of persons within the Company to disclose material information otherwise required to be set forth in our reports. The occurrence of or failure to remediate any material weaknesses may adversely affect our reputation and business and the market price of our ordinary shares, public warrants and any other securities we may issue.

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

Kitov Pharma’s ADSs and public warrants have been traded on The NASDAQ Capital Market since November 20, 2015. As a public company whose securities are listed in the United States, we incur accounting, legal and other expenses, including costs associated with our reporting requirements under the Exchange Act. We also incur costs associated with corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act, as well as rules implemented by the SEC and NASDAQ, and provisions of Israeli corporate law applicable to public companies.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act and the related rules adopted by the SEC and the Public Company Accounting Oversight Board, our management is required to report on the effectiveness of our internal control over financial reporting. In addition, once we no longer qualify as an “emerging growth company” under the JOBS Act and lose the ability to rely on the exemptions related thereto discussed above and depending on our status as per Rule 12b-2 of the Exchange Act, our independent registered public accounting firm may also need to attest to the effectiveness of our internal control over financial reporting under Section 404.

The process of determining whether our existing internal controls over financial reporting systems are compliant with Section 404 and whether there are any material weaknesses or significant deficiencies in our existing internal controls, requires the investment of substantial time and resources, including by our chief financial officer and other members of our senior management. As a result, this process may divert internal resources and take a significant amount of time and effort to complete.

We cannot predict the outcome of evaluations we will conduct, and whether we will need to implement additional remedial actions in order to implement effective controls over financial reporting. The determination and any remedial actions required could result in us incurring additional costs that we did not anticipate, including the hiring of outside consultants. Irrespective of compliance with Section 404, any failure of our internal controls could have a material adverse effect on our stated results of operations and harm our reputation. As a result, we may experience higher than anticipated operating expenses, as well as higher independent auditor fees during and after the implementation of these changes. If we are unable to implement any of the required changes to our internal control over financial reporting effectively or efficiently or are required to do so earlier than anticipated, it could adversely affect our operations, financial reporting and/or results of operations and could result in an adverse opinion on internal controls from our independent auditors and cause the market price of Kitov Pharma's ordinary shares, ADSs and public warrants to decline.

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

We may be classified as a Passive Foreign Investment Company, or PFIC, for U.S. federal income tax purposes in 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.

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

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

- announcements of technological innovations or new therapeutic candidates by us or by others;
- announcements by us of significant acquisitions, strategic partnerships, in-licensing, out-licensing, joint ventures or capital commitments;
- expiration or terminations of licenses, research contracts or other development or commercialization agreements;
- public concern as to the safety of drugs that we, our current or potential development and commercialization partners or others develop;
- the volatility of market prices for shares of biotechnology companies generally;
- success or failure of research and development projects;
- departure of key personnel;

- developments concerning intellectual property rights or regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if Kitov Pharma's ordinary shares or ADSs or public warrants are covered by analysts;
- changes in government regulations or patent decisions;
- developments by our current or potential development and commercialization partners; and
- general market conditions and other factors, including factors unrelated to our operating performance.

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

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

Future sales of Kitov Pharma's ordinary shares or ADSs or other warrants or convertible securities could reduce the market price of its ordinary shares and ADSs and other listed securities.

As of December 31, 2018, we had an aggregate of 16,009,264 issued and outstanding ordinary shares (including 1 dormant ordinary shares held in treasury) (such number of ordinary shares would be represented by 16,009,264 of Kitov Pharma's ADSs), no non-voting senior preferred shares, 6,835,669 Series A or public warrants, representative's warrants to purchase 157,945 of its ADSs, which were granted to the underwriters as part of Kitov Pharma's initial U.S. offering in November 2015, placement agent's warrants to purchase 141,176 of its ADSs, which were granted to the placement agent as part of its follow-on U.S. offering in July 2016, non-listed warrants to purchase 359,205 of its ADSs, which were granted to the investors in conjunction with its registered direct offering in July 2017, placement agent's warrants to purchase 170,722 of its ADSs, which were granted to the placement agent as part of its registered direct offering in July 2017, and non-tradable options and RSUs to purchase 1,243,507 ordinary shares, (such number of non-tradable options or RSUs and their underlying ordinary shares would be represented by 1,243,507 of its ADSs).. 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.

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our ADSs 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. We currently have no binding agreements or commitments to complete any transaction for the possible acquisition of new therapeutic candidates. There is no certainty that we will be able to complete any transactions for the possible acquisition of new therapeutic candidates. However, our management will have broad discretion in the application of the net proceeds from our previous offerings. Our shareholders may not agree with the manner in which our management chooses to allocate the net proceeds from the public offerings. The failure by our management to apply these funds effectively could have a material adverse effect on our business, financial condition and results of operations. Pending their use, we may invest the net proceeds from the public offerings in a manner that does not produce income. The decisions made by our management may not result in positive returns on any investment by shareholders and shareholders will not have an opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

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

We are an “emerging growth company,” as defined in the JOBS Act, and we may take advantage of certain exemptions from various requirements that are applicable to other public companies that are not “emerging growth companies.” Most of such requirements relate to disclosures that we would only be required to make if we also ceased to be a foreign private issuer in the future, for example, the requirement to hold shareholder advisory votes on executive and severance compensation and executive compensation disclosure requirements for U.S. companies. However, as a foreign private issuer, we would still be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. We are exempt from such requirement for as long as we remain an emerging growth company, which may be up to five fiscal years after the date of our November 2015 initial public offering. We will remain an emerging growth company until the earliest of: (a) the last day of our fiscal year during which we have total annual gross revenues of at least \$1.07 billion; (b) the last day of our fiscal year following the fifth anniversary of the closing of our initial U.S. offering; (c) the date on which we have, during the previous three-year period, issued more than \$1 billion in non-convertible debt; or (d) the date on which we are deemed to be a “large accelerated filer” under the Exchange Act. When we are no longer deemed to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act discussed above. We cannot predict if investors will find our ordinary shares, ADSs, or warrants less attractive as a result of our reliance on exemptions under the JOBS Act. If some investors find our ordinary shares, ADS, or warrants less attractive as a result, there may be a less active trading market for our ordinary shares, ADS, and warrants and our share price may be more volatile.

Risks Related to The Offering

ADSs representing a substantial percentage of our outstanding shares may be sold in this offering and in the concurrent private placement, which could cause the price of our ADSs and Ordinary Shares to decline.

Pursuant to this offering, we will sell 3,428,572 ADSs representing 3,428,572 Ordinary Shares, or approximately 21.42 % of our outstanding Ordinary Shares as of December 31, 2018. In addition, pursuant to the concurrent private placement, we will sell warrants to purchase up to an additional 2,571,430 ADSs representing 2,571,430 Ordinary Shares, representing approximately 16.06% of our outstanding Ordinary Shares as of December 31, 2018. These sales and any future sales of a substantial number of ADSs and/or warrants 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.

Our management team will have immediate and broad discretion over the use of the net proceeds from this offering and may not use them effectively.

We currently intend to use the net proceeds of this offering to fund the pre-clinical and clinical development of NT219, possible acquisition of new therapeutic candidates and for general working capital purposes. See “Use of Proceeds.” However, our management will have broad discretion in the application of the net proceeds. Our shareholders may not agree with the manner in which our management chooses to allocate the net proceeds from this offering. The failure by our management to apply these funds effectively could have a material adverse effect on our business, financial condition and results of operation. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income. The decisions made by our management may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

The offering may not be fully subscribed, and, even if the offering is fully subscribed, we will need additional capital in the future. If additional capital is not available, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely.

The placement agent in this offering will offer the securities on a “best-efforts” basis, meaning that we may raise substantially less than the total maximum offering amount. We will not provide any refund to investors if less than all of the securities are sold. We have incurred losses in each year since our inception. If we continue to use cash at our historical rates of use and proceed with potential acquisitions or in-licensing transactions we will need significant additional financing, which we may seek to raise through, among other things, public and private equity offerings and debt financing. Any equity financings will likely be dilutive to existing shareholders, and any debt financings will likely involve covenants restricting our business activities. Additional financing may not be available on acceptable terms, or at all.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus, and the information incorporated by reference herein and therein may include forward looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. In addition, certain sections of this prospectus supplement, the accompanying prospectus, and the information incorporated by reference herein contain information obtained from independent industry and other sources that we have not independently verified. You should not put undue reliance on any forward-looking statements. Unless we are required to do so under U.S. federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements.

Our ability to predict our operating results or the effects of various events on our operating results is inherently uncertain. Therefore, we caution you to consider carefully the matters described under the caption “Risk Factors” on page S-10 of this prospectus supplement, and certain other matters discussed in this prospectus supplement, the accompanying prospectus, and the information incorporated by reference herein and therein, and other publicly available sources. Such factors and many other factors beyond our control could cause our actual results, performance or achievements to be materially different from any future results, performance or achievements that may be expressed or implied by the forward-looking statements.

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

- the initiation, timing, progress and results of our research, manufacturing, preclinical studies, clinical trials, and other therapeutic candidate development efforts, as well as the extent and number of additional studies that we may be required to conduct;
- our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials;
- our receipt of regulatory clarity and approvals for our therapeutic candidates and the timing of other regulatory filings and approvals;
- 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.;
- a delay or rejection of an NDA for one or more of our therapeutic candidates;
- the regulatory environment and changes in the health policies and regimes in the countries in which we operate including the impact of any change in regulation and legislation that could affect the pharmaceutical industry, and the difficulty of predicting actions of the FDA or any other applicable regulator of pharmaceutical products;
- the research, manufacturing, preclinical and clinical development, commercialization, and market acceptance of our therapeutic candidates;
- our ability to successfully acquire, develop or commercialize our pharmaceutical products;
- the ability of our commercialization partners to successfully achieve substantial sales for our drug products;
- our ability to establish and maintain corporate collaborations;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials;
- the implementation of our business model, strategic plans for our business and therapeutic candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, future revenues capital requirements and our needs for additional financing;
- the uncertainty surrounding an investigation by the Israel Securities Authority into our historical public disclosures and the potential impact of such investigation on the trading and price of the Company’s securities or on our clinical, commercial and other business relationships, or on receiving the regulatory approvals necessary in order to commercialize our products;
- the impact of competitive companies, technologies and our industry; and
- the impact of the political and security situation in Israel, the U.S. and other countries we may obtain approvals for our products on our business.

USE OF PROCEEDS

We estimate that our net proceeds from this offering will be approximately \$5.4 million, after deducting the placement agent fees and estimated offering expenses payable by us.

We intend to use the net proceeds of this offering to fund the pre-clinical and clinical development of NT219, the possible acquisition of new therapeutic candidates and the development of such therapeutics candidates, and for general working capital purposes. We currently have no binding agreements or commitments to complete any transaction for the possible acquisition of new therapeutic candidates, though we are currently exploring possible candidates. There is no certainty that we will be able to complete any transactions for the possible acquisition of new therapeutic candidates.

Our expected use of net proceeds from the offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus supplement, we cannot predict with certainty any or all of the particular uses for the net proceeds we received upon the completion of the offering, or the amounts, if any, that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including, the progress of the pre-clinical and clinical development of NT219, our ability to identify additional therapeutic candidates to be acquired or developed, and our ability to finalize any negotiations and enter into definitive agreements in connection with the possible acquisition of new therapeutic candidates, and to close such transactions. As a result, our management will have broad discretion in the application of the net proceeds, which may include uses not set forth above, and investors in our securities will be relying on our judgment regarding the application of the net proceeds from the offering.

CAPITALIZATION AND INDEBTEDNESS

The following table sets forth our total capitalization as of June 30, 2018:

- on an actual basis; and
- on an as-adjusted basis to reflect the sale of 3,428,572 ADSs representing 3,428,572 Ordinary Shares in this offering at the offering price of \$1.75 per one ADS and the receipt by us of net proceeds of approximately \$5.4 million, after deducting placement agent fees and estimated offering expenses payable by us in connection with this offering and the concurrent private placement (assuming no exercise of the warrants offered in the concurrent private placement and no proceeds, if any, from the exercise of warrants issued in the concurrent private placement).

The information set forth in the following table should be read in conjunction with and is qualified in its entirety by reference to the audited and unaudited financial statements and notes thereto incorporated by reference in this prospectus supplement and the accompanying prospectus.

<i>(In thousands, except share data)</i>	As of June 30, 2018	
	<u>Actual</u>	<u>As Adjusted</u>
Cash and cash equivalents and short-term deposits	11,830	17,246
Shareholders' equity:		
Ordinary shares		
Share premium	44,437	49,853
Capital reserves	9,030	9,030
Accumulated deficit	(43,325)	(43,325)
Total Shareholders' equity	10,142	15,558
Non-controlling interest		
Total capitalization	<u>10,142</u>	<u>15,558</u>

The number of ADSs to be outstanding after this offering excludes:

- 1,243,507 ordinary shares issuable at a weighted average exercise price of NIS 0.17 (approximately \$0.05) per share issuable to holders of our options issued, as applicable, under our 2013 Option Plan, as amended, or our 2016 Equity Incentive Plan, (such number of ordinary shares would be represented by 1,243,507 of our ADSs);
- 7,134,790 ordinary shares underlying the ADSs issuable upon exercise of the Series A warrants and the representative's warrants issued in our initial public offering, and the Series A warrants and the placement agent warrants issued as part of our offering in July 2016 (such number of ordinary shares would be represented by 7,134,790 of our ADSs); and
- 529,427 ordinary shares underlying ADSs issuable upon exercise of the warrants issued in connection with our July 2017 private placement of warrants and the placement agent warrants issued as part of our July 2017 public offering (such number of ordinary shares would be represented by 529,427 of our ADSs); and
- 1,858,000 ordinary shares underlying ADSs issuable upon exercise of the warrants issued in connection with our June 2018 private placement of warrants and the placement agent warrants issued as part of our June 2018 public offering (such number of ordinary shares would be represented by 1,858,000 of our ADSs); and
- 2,571,430 ordinary shares issuable upon exercise of the warrants offered in our concurrent private placement with an exercise price of \$2.00 and 240,000 ordinary shares underlying ADSs issuable upon exercise of placement agent warrants with an exercise price of \$2.1875 issued to the placement agent as compensation with respect to this offering.

DILUTION

If you invest in our ADSs and warrants, your interest will be diluted immediately to the extent of the difference between the public offering price per one ADS and the as-adjusted net tangible book value per ADS after this offering and the concurrent private placement of warrants.

The net tangible book value of our ADSs as of June 30, 2018 was approximately \$4.5 million, or approximately \$0.0003 per ADS. Net tangible book value per ADS represents the amount of our total tangible assets less total liabilities divided by the total number of our Ordinary Shares outstanding as of June 30, 2018.

After giving effect to the sale of our ADSs offered by this prospectus supplement at the public offering price of \$1.75 per one ADS in connection with this offering and the sale of the warrants in connection with our concurrent private placement, and after deducting the placement agent fees and estimated offering expenses payable by us in connection with this offering and our concurrent private placement of warrants, our as adjusted net tangible book value as of June 30, 2018 would have been approximately \$9.9 million, or approximately \$0.001 per ADS. This calculation assumes that none of the warrants issued in the concurrent private placement is exercised and excludes the proceeds, if any, from the exercise of warrants issued in the concurrent private placements. This represents an immediate increase in net tangible book value of approximately \$1.75 per ADS to our existing security holders and an immediate dilution in as-adjusted net tangible book value of approximately \$1.7498 per ADS to purchasers of our ADSs in this offering, as illustrated by the following table:

Offering price per ADS	\$ 1.750
Net tangible book value per ADS as of June 30, 2018	\$ 0.0003
Increase in net tangible book value per ADS attributable to this offering and the concurrent private placement	\$ 1.75
As-adjusted net tangible book value per ADS as of June 30, 2018 after giving effect to this offering and the concurrent private placement	\$ 0.001
Dilution per ADS to the new investors purchasing our ADSs in this offering	\$ 1.7498

The number of Ordinary Shares to be outstanding after this offering is based on 15,809,723 Ordinary Shares outstanding as of June 30, 2018, and excludes as of such date

- (i) 1,082,724 ordinary shares issuable at a weighted average exercise price of NIS 0.17 (approximately \$0.05) per share issuable to holders of our options issued, as applicable, under our 2013 Option Plan, as amended, or our 2016 Equity Incentive Plan, (such number of ordinary shares would be represented by 1,082,724 of our ADSs);
- (ii) 7,134,790 ordinary shares underlying the ADSs issuable upon exercise of the Series A warrants and the representative's warrants issued in our initial public offering, and the Series A warrants and the placement agent warrants issued as part of our offering in July 2016 (such number of ordinary shares would be represented by 7,134,790 of our ADSs);
- (iii) 529,427 ordinary shares underlying ADSs issuable upon exercise of the warrants issued in connection with our July 2017 private placement of warrants and the placement agent warrants issued as part of our July 2017 public offering (such number of ordinary shares would be represented by 529,427 of our ADSs);
- (iv) 1,858,000 ordinary shares underlying ADSs issuable upon exercise of the warrants issued in connection with our June 2018 private placement of warrants and the placement agent warrants issued as part of our June 2018 public offering (such number of ordinary shares would be represented by 1,858,000 of our ADSs); and
- (v) 2,571,430 ordinary shares issuable upon exercise of the warrants offered in our concurrent private placement with an exercise price of \$2.00 and 240,000 ordinary shares underlying ADSs issuable upon exercise of placement agent warrants with an exercise price of \$2.1875 issued to the placement agent as compensation with respect to this offering.

The as-adjusted information discussed above is illustrative only. Our net tangible book value following the completion of the offering is subject to further adjustment based on the actual offering price of our ADSs and other terms of this offering.

PRINCIPAL TRADING MARKET OF AMERICAN DEPOSITARY SHARES AND OUR ORDINARY SHARES

Our ordinary shares are currently traded on the TASE under the symbol “KTOV”. Our ADSs are currently traded on NASDAQ under the symbol “KTOV”.

DIVIDEND POLICY

We have never declared or paid any cash dividends to our shareholders. 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.

MATERIAL TAX CONSIDERATIONS

Taxation

Israeli Tax Considerations

General

The following is a summary of the material tax consequences under Israeli law concerning the purchase, ownership and disposition of Ordinary Shares and ADSs of our company.

This discussion does not purport to constitute a complete analysis of all potential tax consequences applicable to investors upon purchasing, owning or disposing of Ordinary Shares and ADSs of our company. In particular, this discussion does not take into account the specific circumstances of any particular investor (such as tax-exempt entities, financial institutions, certain financial companies, broker-dealers, investors that own, directly or indirectly, 10% or more of our outstanding voting rights, all of whom are subject to special tax regimes not covered under this discussion). To the extent that issues discussed herein are based on legislation, which has yet to be subject to judicial or administrative interpretation, there can be no assurance that the views expressed herein will accord with any such interpretation in the future.

Potential investors are urged to consult their own tax advisors as to the Israeli or other tax consequences of the purchase, ownership and disposition of the Ordinary Shares or ADSs being offered hereby, including, in particular, the effect of any foreign, state or local taxes.

General Corporate Tax Structure in Israel

The Israeli corporate tax rate applicable to Israeli resident companies is 23% in 2018 and thereafter.

Taxation of Shareholders

Capital Gains

Capital gains tax is imposed on the disposal of capital assets by an Israeli resident and on the disposal of such assets by a non-Israeli resident if those assets are either (i) located in Israel; (ii) shares or a right to a share in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel, unless an exemption is available or unless an applicable double tax treaty between Israel and the seller's country of residence provides otherwise. The Israeli Income Tax Ordinance distinguishes between "Real Gain" and the "Inflationary Surplus." Real Gain is the excess of the total capital gain over Inflationary Surplus computed generally on the basis of the increase in the Israeli Consumer Price Index between the date of purchase and the date of disposal. Inflationary Surplus is not subject to tax.

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

Corporate and individual shareholders dealing in securities in Israel are taxed at the tax rates applicable to business income which is 23% in 2018 and thereafter, and a marginal tax rate of up to 47% for individuals.

Notwithstanding the foregoing, capital gains generated from the sale of our Ordinary Shares or ADSs by a non-Israeli shareholder may be exempt from Israeli tax under the Israeli Income Tax Ordinance provided that the following cumulative conditions are met: (i) the Ordinary Shares or ADSs were purchased upon or after the registration of the Ordinary Shares or ADSs on the stock exchange and (this condition will not apply to shares purchased on or after January 1, 2009) (ii) the seller does not have a permanent establishment in Israel to which the generated capital gain is attributed. However, non-Israeli resident corporations will not be entitled to the foregoing exemption if Israeli residents: (i) have a 25% or more interest in such non-Israeli corporation or (ii) are the beneficiaries of, or are entitled to, 25% or more of the income or profits of such non-Israeli corporation, whether directly or indirectly. In addition, such exemption would not be available to a person whose gains from selling or otherwise disposing of the Ordinary Shares or ADSs are deemed to be business income.

In addition, the sale of the Ordinary Shares or ADSs may be exempt from Israeli capital gains tax under the provisions of an applicable double tax treaty. For example, the Convention between the Government of the U.S. and the Government of the State of Israel with respect to Taxes on Income (the “U.S.- Israel Double Tax Treaty”) exempts a U.S. resident (for purposes of the treaty) from Israeli capital gains tax in connection with the sale of the Ordinary Shares or ADSs, provided that: (i) the U.S. resident owned, directly or indirectly, less than 10% of the voting power of the company at any time within the 12 month period preceding such sale; (ii) the U.S. resident, being an individual, is present in Israel for a period or periods of less than 183 days during the taxable year; and (iii) the capital gain from the sale was not derived through a permanent establishment of the U.S. resident in Israel; however, under the U.S-Israel Double Tax Treaty, the taxpayer would be permitted to claim a credit for such taxes against the U.S. federal income tax imposed with respect to such sale, exchange or disposition, subject to the limitations under U.S. law applicable to foreign tax credits. The U.S-Israel Double Tax Treaty does not relate to U.S. state or local taxes.

Payers of consideration for the Ordinary Shares or ADSs, including the purchaser, the Israeli stockbroker or the financial institution through which the Ordinary Shares or ADSs are held, are obligated, subject to certain exemptions, to withhold tax at a rate of 25% upon the sale of Ordinary Shares or ADSs.

Upon the sale of traded securities, a detailed return, including a computation of the tax due, must be filed and an advanced payment must be paid to the Israeli Tax Authority on January 31 and July 31 of every tax year in respect of sales of traded securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Israeli Income Tax Ordinance and regulations promulgated thereunder, such return need not be filed and no advance payment must be paid. Capital gains are also reportable on annual income tax returns.

Dividends

Dividends distributed by a company from income, which is not attributed to a Preferred Enterprise as defined in the Israel’s Encouragement of Capital Investment Law (1959), to a shareholder who is an Israeli resident individual will be generally subject to income tax at a rate of 25%. However, a 30% tax rate will generally apply if the dividend recipient is a Controlling Shareholder, as defined above, at the time of distribution or at any time during the preceding 12-month period. If the recipient of the dividend is an Israeli resident corporation, such dividend will generally not be subject to tax provided that the income from which such dividend is distributed, derived or accrued within Israel. A distribution of dividend by a company from income attributed to a Preferred Enterprise will generally be subject to withholding tax in Israel at the following tax rates: Israeli resident individuals - 20% with respect to dividends to be distributed as of 2014; and Israeli resident companies – 0%.

Dividends distributed by an Israeli resident company from income, which is not attributed to a Preferred Enterprise, to a non-Israeli resident (either an individual or a corporation) are generally subject to Israeli withholding tax on the receipt of such dividends at the rate of 25% (30% if the dividend recipient is a Controlling Shareholder at the time of distribution or at any time during the preceding 12-month period). Dividends distributed by an Israeli resident company from income, which is attributed to a Preferred Enterprise, to a non-Israeli resident (either an individual or a corporation) are generally subject to withholding tax at a rate of 20%. These rates may be reduced under the provisions of an applicable double tax treaty. For example, under the U.S.-Israel Double Tax Treaty, the following tax rates will apply in respect of dividends distributed by an Israeli resident company to a U.S. resident: (i) if the U.S. resident is a corporation which holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding shares of the voting stock of the Israeli resident paying corporation and not more than 25% of the gross income of the Israeli resident paying corporation for such prior taxable year (if any) consists of certain types of interest or dividends the tax rate is 12.5%; (ii) if both the conditions mentioned in clause (i) above are met and the dividend is paid from an Israeli resident company’s income which was entitled to a reduced tax rate under The Law for the Encouragement of Capital Investments, 1959, the tax rate is 15%; and (iii) in all other cases, the tax rate is 25%. The aforementioned rates under the U.S.-Israel Double Tax Treaty will not apply if the dividend income is attributed to a permanent establishment of the U.S. resident in Israel.

Excess Tax

Individual holders who are subject to tax in Israel (whether any such individual is an Israeli resident or non-Israeli resident) and who have taxable income that exceeds a certain threshold in a tax year NIS 649,560, linked to the Israeli Consumer Price Index), which is approximately \$176,033, based on the representative U.S. dollar – NIS rate of exchange of 3.69 on January 17, 2019), will be subject to an additional tax at the rate of 3% on his or her taxable income for such tax year that is in excess of such amount. For this purpose, taxable income includes taxable capital gains from the sale of securities and taxable income from interest and dividends, subject to the provisions of an applicable double tax treaty.

Estate and Gift Tax

Israeli law presently does not impose estate or gift taxes.

U.S. Federal Income Tax Considerations

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

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

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

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

For purposes of this description, the term “U.S. Holder” means a beneficial owner of our ADSs that, for U.S. federal income tax purposes, is (i) a citizen or resident of the United States, (ii) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income tax regardless of its source or (iv) a trust (x) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions or (y) that has elected to be treated as a domestic trust for U.S. federal income tax purposes.

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

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

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

Tax Basis of each ADS

The ADSs will be sold together with an accompanying warrant. The initial basis in your ADSs’ will be equal to the amount paid for the ADSs’ less the fair market value of their accompanying warrant. The initial basis in the accompanying warrant will equal its initial fair market value.

Exchange of ADSs for Ordinary Shares

In general, if you hold ADSs, you will be treated as the holder of the underlying ordinary shares represented by those ADSs for U.S. federal income tax purposes. Accordingly, gain or loss generally will not be recognized if you exchange ADSs for the underlying ordinary shares represented by those ADSs. In addition, you will receive a basis in your ordinary shares equal to the basis of your ADSs exchanged for such shares.

Taxation of Dividends and Other Distributions on Our ADSs

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

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

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

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

- you conduct a trade or business in the U.S. and such income is effectively connected with that trade or business (and, if required by an applicable income tax treaty, the dividends are attributable to a permanent establishment or fixed base that such holder maintains in the U.S.); or
- you are an individual and have been present in the U.S. for 183 days or more in the taxable year of such sale or exchange and certain other conditions are met.

Sale, Exchange or Other Disposition of Our ADSs

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

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

- such gain is effectively connected with your conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment or fixed base that you maintain in the United States); or
- you are an individual and have been present in the United States for 183 days or more in the taxable year of such sale or exchange and certain other conditions are met.

Passive Foreign Investment Company Consequences

We may be classified as a Passive Foreign Investment Company (PFIC) for the 2019 tax year. If we are indeed so classified for 2019 or in any other taxable year, a U.S. Holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

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

- at least 75% of its gross income is “passive income”; or
- at least 50% of the average quarterly value of its total gross assets (which may be determined in part by the market value of our ADSs, which is subject to change) is attributable to assets that produce “passive income” or are held for the production of passive income.

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

Our PFIC status determination is based on our income, assets and activities for the entire taxable year and therefore it is not possible to determine whether we will be characterized as a PFIC for the 2018 taxable year until after the close of the year. In addition, our status as a PFIC may depend on how quickly we utilize the cash proceeds from this offering in our business, which we cannot currently determine with certainty.

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

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

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

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

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

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

U.S. Holders should consult their tax advisors regarding application of the PFIC rules.

Medicare Tax

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

Certain Reporting Requirements with Respect to Payments of Offer Price

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

Backup Withholding Tax and Information Reporting Requirements

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

Foreign Asset Reporting

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

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PROSPECTIVE INVESTOR. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN OUR ADSs IN LIGHT OF THE INVESTOR’S OWN CIRCUMSTANCES.

PLAN OF DISTRIBUTION

Pursuant to an engagement letter dated as of January 16, 2019, we have engaged H.C. Wainwright & Co., LLC (“Wainwright”), as our exclusive placement agent for this offering. Wainwright is not purchasing or selling any shares, nor are they required to arrange for the purchase and sale of any specific number or dollar amount of shares other than the use their “reasonable best efforts” to arrange for the sale of share by us. Therefore, we may not sell the entire amount of shares being offered.

Upon the closing of this offering, we will pay the placement agent a cash commission fee equal to 6% of the aggregate gross proceeds to us from the sale of the securities in the offering and a management fee equal to 1% of the aggregate gross proceeds. We will pay the placement agent a non-accountable expense allowance of \$65,000. We estimate the total expenses of this offering, excluding the placement agent fees, will be approximately \$600,000.

In addition, we agreed to issue to the placement agent compensation warrants to purchase up to 240,000 ADSs (which represent 7% of the ADSs sold to the investors in this offering). The compensation warrants will have an exercise price of \$2.1875 per ADS (which represents 125% of the offering price per ADS) and shall be immediately exercisable and have a term of five (5) years from the date of this prospectus. Pursuant to FINRA Rule 5110(g), the compensation warrants and any shares issued upon exercise of the compensation warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security:

- by operation of law or by reason of reorganization of our company;
- to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period;
- if the aggregate amount of securities of our company held by the holder of the compensation warrants or related persons do not exceed 1% of the securities being offered;
- that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or
- the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction set forth above for the remainder of the time period.

In addition, we have agreed to give the placement agent a right of first refusal to act as our sole book-running manager, underwriter or placement agent during the six-month period following consummation of this offering if we or any of our subsidiaries decides to raise funds by means of a public offering or a private placement of equity or debt securities outside Israel using an underwriter or placement agent. In addition, the placement agent has a right to a tail fee equal to the compensation in this offering if certain investors whom the placement agent contacted with respect to this offering or introduced, directly or indirectly, to us during the term of the placement agent’s engagement, provides us with further capital during the period beginning on the date of our engagement letter with the placement agent and ending three months following the expiration of the aforementioned right of first refusal period.

We and our executive officers and directors have agreed, subject to certain exceptions, not to offer, sell, agree to sell, directly or indirectly, or otherwise dispose of any ordinary shares, ADSs or warrants or any other securities convertible into or exchangeable for ordinary shares for a period of 45 days (and generally extended to 90 days in the case of executive officers and directors) after the consummation of this offering.

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any commissions received by it and any profit realized on the sale of the securities by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The placement agent will be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

The engagement letter agreement provides that we will indemnify the placement agent against specified liabilities, including liabilities under the Securities Act.

The foregoing description of the engagement agreement is only a summary, does not purport to be complete and is qualified in its entirety by reference to such, a copy of which will be attached as an exhibit to our Report on Form 6-K being filed with the SEC in connection with this offering and is incorporated herein by reference.

From time to time, the placement agent may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions. The placement agent in this offering participated in the offering we consummated in June 2018, for which it received compensation. However, except as disclosed in this prospectus, we have no present arrangements with the placement agent for any further services.

The depositary for the ADSs to be issued in this offering is The Bank of New York Mellon.

CONCURRENT PRIVATE PLACEMENT OF WARRANTS

Concurrently with the closing of the sale of ADSs in this offering, we also expect to issue and sell to the investors warrants to purchase an aggregate of up to 2,571,430 ADSs. The following summary of certain terms and provisions of the warrants offered in our concurrent private placement is not complete and is subject to, and qualified in its entirety by the provisions of the warrant and the form of which will be filed with the SEC by us as an exhibit to a Report on Form 6-K in connection with this offering.

Exercisability. Each warrant shall be immediately exercisable on the issuance date and have a term of exercise equal to five and a half (5.5) years from the date on which first exercisable. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of ADSs purchased upon such exercise, together with applicable charges and taxes. Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to such exercise. If at any time after the 6th month anniversary of the issuance date, a registration statement registering the issuance of the ADSs underlying the warrants under the Securities Act is not then effective or available, the holder may exercise the warrant through a cashless exercise, in whole or in part, in which case the holder would receive upon such exercise the net number of ADSs determined according to the formula set forth in the warrant. No fractional ADSs are to be issued upon the exercise of the warrants. If any fractional share of an ADS would be deliverable upon the exercise of the warrants, we, in lieu of delivering such fractional ADS, may elect to either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by then current exercise price or round up to the next whole ADS.

Transfer. Such securities will be issued and sold without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(a)(2) of the Act and/or Regulation D and/or Regulation S promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the investors may exercise those warrants and sell the underlying shares only pursuant to an effective registration statement under the Securities Act covering the resale of those shares, an exemption under Rule 144 under the Securities Act, or another applicable exemption under the Securities Act.

Exercise Price. The initial exercise price per ADS purchasable upon exercise of the warrants is equal to \$2.00 per full ADS (which may be adjusted as set forth below). In addition to the exercise price per ADS, other applicable charges and taxes are due and payable upon exercise.

Adjustment Provisions. The exercise price and the number of ADSs issuable upon exercise are subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, rights offerings, stock subdivisions and combinations, reclassifications or similar events affecting our ADSs.

Exchange Listing. There is no established public trading market for the warrants, and we do not intend to apply to list the warrants on any securities exchange or automated quotation system.

Fundamental Transaction. If, at any time while the warrants are outstanding, (1) we, directly or indirectly, consolidate or merge with or into another person, (2) we, directly or indirectly, sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets, (3) any direct or indirect purchase offer, tender offer or exchange offer (whether by us or another person) is completed pursuant to which holders of our ordinary shares are permitted to sell, tender or exchange their ordinary shares for other securities, cash or property and has been accepted by the holders of 50% or more of our outstanding shares of ordinary shares, (4) we, directly or indirectly, effect any reclassification, reorganization or recapitalization of our ordinary shares or any compulsory share exchange pursuant to which our ordinary shares are converted into or exchanged for other securities, cash or property, or (5) we, directly or indirectly, consummate a stock or share purchase agreement or other business combination with another person whereby such other person acquires more than 50% of our outstanding ordinary shares, each, a “Fundamental Transaction”, then upon any subsequent exercise of the warrants, the holders thereof will have the right to receive the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of ADSs then issuable upon exercise of the warrant, and any additional consideration payable as part of the Fundamental Transaction.

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

LEGAL MATTERS

Certain matters concerning this offering will be passed upon for us by Haynes and Boone, LLP, New York, New York. The validity of the securities being offered by this prospectus will be passed upon for us by Gross, Kleinhendler, Hodak, Halevy, Greenberg & Co., Tel Aviv, Israel.

EXPERTS

The consolidated financial statements of Kitov Pharma Ltd. as of December 31, 2017 and 2016 and for each of the years in the three-year period ended December 31, 2017, have been incorporated by reference herein in reliance upon the report of Somekh Chaikin, a Member Firm of KPMG International, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form F-3 under the Securities Act relating to the offering of our securities offered hereby. This prospectus does not contain all of the information contained in the registration statement. The rules and regulations of the SEC allow us to omit certain information from this prospectus that is included in the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we filed any of these documents as an exhibit to the registration statement, you may read the document itself for a complete description of its terms.

We are required to file reports and other information with the SEC under the Exchange Act, and the regulations thereunder applicable to foreign private issuers. We also furnish to the SEC under cover of Form 6-K material information required to be made public in Israel, filed with and made public by any stock exchange or distributed by us to our shareholders. You may read the registration statement, including the related exhibits and schedules, and any document we file with the SEC without charge at the SEC's web site at <http://www.sec.gov>.

In addition, since our ordinary shares are traded on the TASE, in the past we filed Hebrew language periodic and immediate reports with, and furnished information to, the TASE and the Israel Securities Authority, or the ISA, as required under Chapter F of the Israel Securities Law, 1968. In accordance with Section 35XXXIII of the Israel Securities Law, and pursuant to the prior approvals of our securities holders to change to reporting in accordance with the U.S. securities laws and regulations, we presently report to ISA and the TASE in accordance with 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. Our major shareholders are required to make applicable ownership disclosures in accordance with U.S. securities laws and reporting requirements. We generally initially file or furnish our reports, as applicable, to the SEC. We then submit copies of the SEC filings and submissions to ISA and TASE, including any filings made by our major shareholders with respect to their holdings in Kitov Pharma, in accordance with the Dual-Listed Reporting Requirements. Such copies can be retrieved electronically through the websites for listed company reports of ISA (www.magna.isa.gov.il) and TASE (www.maya.tase.co.il).

As a foreign private issuer, we will be exempt from the rules under the Exchange Act relating to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. As permitted under the Companies Law, and the Notice Regulations which were enacted pursuant to such law, and as set forth in Kitov's amended and restated articles of association, Kitov is not required to physically deliver a notice of a shareholders meeting, a proxy statement or a voting slip. Kitov prepares notices of general meetings of its shareholders, as well as the accompanying proxy statements, voting slips and voting instruction forms, (collectively, the "Proxy Materials") in accordance with applicable laws, rules and regulations and disclosure requirements in the State of Israel, as such are applicable to a company whose shares are traded on both the TASE and the NASDAQ, and which reports to the SEC as a foreign private issuer and to ISA and the TASE in accordance with the Dual-Listed Reporting Requirements. Our Proxy Materials may not necessarily be mailed to our beneficial shareholders in Israel, or to our beneficial ADS holders in the U.S. We will furnish to the SEC on Form 6-K the forms of our Proxy Materials, and they will be made available to the public on the SEC's website at www.sec.gov. We will also submit the Proxy Materials to ISA and TASE and they will be made available to the public on their respective websites for listed company reports: www.magna.isa.gov.il and www.maya.tase.co.il. We will also include the Proxy Materials on our corporate website, to the extent required under the Companies Law and the applicable regulations enacted thereunder governing publication of notices of general meetings of our shareholders and the distribution of the Proxy Materials. The circulation of by us of any Proxy Materials should not be taken as an admission that we are subject to the proxy rules under the Exchange Act, nor as an admission that in doing so we are not availing, nor that we may not avail, ourselves of any, or all of, the exemptions set forth under Regulation 3 of the Companies Regulations (Relief Regulations for Companies Whose Securities are Listed for Trading on an Exchange Outside of Israel), 5760-2000. Furthermore, nothing in the form or content of, and/or the language in, any of our Proxy Materials should be taken as an admission by us with respect to that which is stated under Regulation 5 of the Notice Regulations concerning the applicability (or lack thereof) of instructions under relevant non-Israeli law as to the content our Proxy Materials, insofar as such may apply to certain matters on the agenda of the applicable meeting of securities holders.

In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we intend to file with the SEC, within 120 days after the end of 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 the 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.

We maintain a corporate website at www.kitovpharma.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference. We will post on our website any materials required to be posted on such website under applicable corporate or securities laws and regulations, including posting any notices of general meetings of our shareholders.

INCORPORATION BY REFERENCE

The SEC allows us to incorporate by reference the information we file with or furnish to the SEC, which means that we can disclose important information to you by referring you to another document filed or furnished separately with the SEC. The information incorporated by reference is considered to be part of this prospectus. Any information that we file or furnish later with the SEC and that is deemed incorporated by reference will also be considered to be part of this prospectus and will automatically update and supersede the information in this prospectus. In all cases, you should rely on the later information over different information included in this prospectus. This prospectus incorporates by reference the documents listed below, and any future Annual Reports on Form 20-F that we file with the SEC and certain Reports on Form 6-K that we furnish to the SEC (but only to that extent that such Form 6-K states that it is incorporated by reference herein), in each case, between the date of the initial registration statement and the effectiveness of the registration statement and following the effectiveness of the registration statement until the offering of the securities under the registration statement is terminated:

- The description of our ordinary shares, no par value per share, and the American Depositary Shares representing the ordinary shares, contained in Item 1 of the Registration Statement on Form 8-A (File No. 001-37643) filed with the Commission on November 18, 2015;
- our Annual Report on Form 20-F for the fiscal year ended on December 31, 2017, filed with the SEC on March 5, 2018; and
- our reports on Form 6-K furnished to the SEC on March 15, 2018, May 11, 2018 (excluding Exhibit 99.1 thereto), May 31, 2018, June 1, 2018, June 5, 2018, June 15, 2018 (excluding Exhibit 99.1 thereto), June 18, 2018, July 30, 2018 (excluding Exhibit 99.1 thereto), August 29, 2018, September 17, 2018, September 19, 2018, October 11, 2018, November 9, 2018, December 19, 2018, December 28, 2018, January 3, 2019, January 15, 2019, January 16, 2019 and January 18, 2019.

We will provide, free of charge, to each person, including any beneficial owner, to whom this prospectus is delivered, a copy of any or all information that has been incorporated by reference into this prospectus, but which has not been delivered with the prospectus, upon written or oral request to us at the following address:

Kitov Pharma Ltd.
One Azrieli Center, Round Tower, 19th Floor
132 Menachem Begin Rd.
Tel Aviv 6701101, Israel
Tel: +972-3-9333121
Attention: Chief Financial Officer

PROSPECTUS

\$200,000,000

**American Depositary Shares representing Ordinary Shares,
Ordinary Shares, Preferred Shares,
Warrants, Overallotment Purchase Rights,
Subscription Rights, Units, Capital Notes, and/or Debt Securities**



KITOV PHARMA LTD.

We may offer to the public from time to time in one or more series or issuances American Depositary Shares, or ADSs, ordinary shares, preferred shares, warrants, overallotment purchase rights, subscription rights, units, capital notes and/or debt securities consisting of two or more of these classes or series of securities. Each ADS represents 20 of our ordinary shares.

We refer to the ADSs, ordinary shares, preferred shares, warrants, overallotment purchase rights, subscription rights, units, capital notes and debt securities collectively as “securities” in this prospectus.

Each time we sell securities pursuant to this prospectus, we will provide a supplement to this prospectus that contains specific information about the offering and the specific terms of the securities offered. This prospectus may not be used to consummate a sale of securities by us unless accompanied by the applicable prospectus supplement. You should read this prospectus and the applicable prospectus supplement carefully before you invest in our securities.

We may, from time to time, offer to sell the securities, through public or private transactions, directly or through underwriters, agents or dealers, on or off The NASDAQ Capital Market or Tel Aviv Stock Exchange Ltd., or the TASE, as applicable, at prevailing market prices or at privately negotiated prices. If any underwriters, agents or dealers are involved in the sale of any of these securities, the applicable prospectus supplement will set forth the names of the underwriter, agent or dealer and any applicable fees, commissions or discounts.

Our ordinary shares are currently traded on the TASE under the symbol “KITOV.” The last reported sale price of our ordinary shares on the TASE on December 11, 2016, was NIS 0.651, or \$0.171, per share (based on the exchange rate reported by the Bank of Israel on that date, which was NIS 3.818 = \$1.00).

Our ADSs and Series A warrants (issued to public investors in connection with our November 2015 initial public offering and our July 2015 follow-on public offering) are currently listed on The NASDAQ Capital Market under the symbols “KITOV” and “KITOVW”, respectively. The last reported sale price of our ADSs and public warrants on The NASDAQ Capital Market on December 9, 2016 was \$3.44 and \$1.47, respectively.

On December 11, 2016, the aggregate market value worldwide of our outstanding voting and non-voting common equity held by non-affiliates was approximately \$25.7 million, based on 150,954,226 ordinary shares outstanding and a per ordinary share price of \$0.171 based on the closing sale price of our ordinary shares on the TASE, and the exchange rate reported by the Bank of Israel, on December 11, 2016. We have not offered any securities pursuant to General Instruction I.B.5 on Form F-3 during the prior 12 calendar month period that ends on and includes the date of this prospectus.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act) and will be subject to reduced public company reporting requirements.

Investing in these securities involves a high degree of risk. Please carefully consider the risks discussed in this prospectus under “Risk Factors” beginning on page 7 and in any applicable prospectus supplement for a discussion of the factors you should consider carefully before deciding to purchase these securities.

Neither the Securities and Exchange Commission, or the SEC, the Israeli Securities Authority, or ISA, nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2016

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a “shelf” registration process. Under this process, we may offer and sell our securities under this prospectus.

Under this shelf registration process, we may sell the securities described in this prospectus in one or more offerings up to a total price to the public of \$200,000,000. Furthermore, so long as the aggregate market value worldwide of our outstanding voting and nonvoting common equity held by non-affiliates (the “public float”) is less than \$75 million, the aggregate market value of securities sold by us pursuant to this shelf registration statement during the period of 12 calendar months immediately prior to, and including, the sale shall be no more than one-third of the public float. The offer and sale of securities under this prospectus may be made from time to time, in one or more offerings, in any manner described under the section in this prospectus entitled “Plan of Distribution.” This shelf registration statement is not being filed by us in connection with any presently contemplated securities offering. We note that in connection with our follow-on public offering which we completed on July 5, 2016, we agreed with our placement agent for the offering, H.C. Wainwright & Co., LLC (the “placement agent”), that during a period ending 180 days following July 5, 2016, we will not sell or transfer any ADSs or ordinary shares or securities convertible into, or exchangeable or exercisable for, ADSs or ordinary shares, in a transaction in which the primary purpose is raising capital or a transaction which results in the issuing of securities to an entity whose primary business is investing in securities, without first obtaining the written consent of the placement agent.

This prospectus provides you with a general description of the securities we may offer. Each time we sell securities we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus, and may also contain information about any material federal income tax considerations relating to the securities covered by the prospectus supplement. You should read both this prospectus and any prospectus supplement together with additional information under the headings “Where You Can Find More Information” and “Incorporation of Certain Documents by Reference.”

When used herein, unless the context requires otherwise, all references to (i) “Kitov Pharma,” refers to Kitov Pharma Ltd. (formerly known as Kitov Pharmaceuticals Holdings Ltd. prior to an official name change in January 2018) and (ii) “we,” “us,” “our,” and similar designations refer to Kitov Pharma Ltd., together with its former wholly-owned subsidiary, Kitov Pharmaceuticals Ltd.

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

KITOV PHARMA LTD.

This summary does not contain all of the information you should consider before investing in our securities. Before making an investment decision, you should carefully read the entire prospectus and our other filings with the SEC. This summary contains forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that may cause or contribute to such differences include those discussed in “Risk Factors” and “Forward-Looking Statements” below.

Overview

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

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

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

We are currently focusing on our development efforts for KIT-302, which has recently completed its Phase III clinical study. We are currently not developing KIT-301, for which we have an active IND, due to our need to allocate resources for advancing the development of KIT-302. The Science and Technology Committee of our Board of Directors has recently considered whether we should continue the further development of KIT-301. In the Committee's view, KIT-301 can be categorized as an inferior earlier generation combination drug, as compared to KIT-302, and taking into account the progress we have made with KIT-302's development and in preparing our anticipated New Drug Application, or NDA, to be submitted to the U.S. Food and Drug Administration, or the FDA, for KIT-302, the Committee determined to recommend to our Board of Directors to consider removing KIT-301 from our development pipeline, and if so determined, to also to consider directing management to update the FDA at an appropriate time about any such discontinuation of development of KIT-301.

In addition, we may consider the acquisition of therapeutic candidates or existing drug products, at various stages of development, which are not necessarily related to the treatment of pain caused by osteoarthritis or treatment of hypertension. We currently have no binding agreements or commitments to complete any transaction for the possible acquisition of new therapeutic candidates, though we are involved in negotiations with a number of possible candidates. There is no certainty that we will be able to complete any transactions for the possible acquisition of new therapeutic candidates. We may not be able to identify suitable acquisition candidates, complete acquisitions or integrate acquisitions successfully. In this regard, acquisitions involve numerous risks, including difficulties in the integration of the acquired therapeutic candidates and the diversion of management's attention from other business concerns. Although we will endeavor to evaluate the risks inherent in any particular transaction, there can be no assurance that we will properly ascertain all such risks. In addition, acquisitions could result in the incurrence of substantial additional indebtedness and other expenses or in potentially dilutive issuances of equity securities. There can be no assurance that difficulties encountered with acquisitions will not have a material adverse effect on our business, financial condition and results of operations.

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

Developments Since Our NASDAQ Listing

Initial Public Offering on The NASDAQ Capital Market

On November 25, 2015, we completed an underwritten public offering of 3,158,900 ADSs, each representing 20 of our ordinary shares, and public warrants to purchase up to 3,158,900 ADSs. The ADSs and public warrants were issued in a fixed combination of one ADS and one warrant to purchase one ADS for a combined price to the public of \$4.13. In addition, the underwriters of the offering partially exercised their option to purchase an additional 220,074 warrants to purchase 220,074 ADSs. The public warrants had an initial per ADS exercise price of \$4.13, were exercisable immediately, and have a term of five years from the date of issuance. The gross proceeds to us from this offering were approximately \$13 million, prior to deducting underwriting discounts, commissions and other offering expenses. The public warrants were subject to "weighted average" ratchet anti-dilution provisions as set forth in the Warrant Agent Agreement, providing that until November 25, 2016, upon issuances of our ADSs or an equivalent number of ordinary shares (or securities convertible or exercisable into ADSs or an equivalent number of ordinary shares), subject to specified exceptions, at a price less than the exercise price then in effect, the exercise price would be reduced based on the "weighted average" formula set forth in the Warrant Agent Agreement. The "weighted average" ratchet provision of the public warrants was triggered by our July 5, 2016 follow-on public offering (described below), and upon closing of the follow-on public offering on July 5, 2016, the exercise price of all the public warrants was reduced in accordance with its terms to \$3.78.

Phase III Clinical Trial Results

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

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

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

The trial results showed that in patients treated with amlodipine besylate only, there was a mean reduction in daytime systolic blood pressure of 8.8 mm Hg. In patients treated with KIT-302, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg. Therefore, the primary efficacy endpoint of the study has been successfully achieved with a p value of 0.001.

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

On May 12, 2016, we announced that we received the minutes from the FDA for the pre-NDA submission meeting held during April 2016. The FDA requested that the clinical study results be reviewed to check and make sure no patients suffered adverse consequences from the enhanced blood pressure reduction resulting from the synergy of celecoxib and amlodipine. We are unaware of any such events occurring and intend to include a detailed review in the safety section of our NDA. In addition, to further establish safety, the FDA requested a literature search related to animal studies of celecoxib and amlodipine be included in the NDA. The FDA also requested documentation of a clinical need for KIT-302, such as by identifying how many patients receive celecoxib on a chronic basis. We intend to provide this documentation by using one or more of the various computerized patient care databases or pharmacy benefit managers. Finally, the FDA requested that the statistical calculation for the primary efficacy endpoint be performed using an alternate mathematical technique. Our statistician has already conducted this calculation and determined that the primary efficacy endpoint was successfully met with the new calculation method.

The final and complete analyses, including the clinical study report, are expected to be completed during the first quarter of 2017. We plan to submit our NDA for marketing approval of KIT-302 with the FDA in the coming months.

In addition, in connection with our Development Services Agreement with Dexcel, pursuant to which Dexcel developed the formulation for KIT-302 and is performing the subsequent stability testing and manufacturing scale-up in quantities adequate for submission of an NDA to the FDA, Dexcel performed a pilot clinical bioequivalence trial, or the Pilot PK Study, and subsequently performed a final conclusive pharmacokinetic (PK) bioequivalence (BE) study, or the Final PK Study. The objective of these two studies was to check the pharmacokinetics of the combination drug in order to show that the blood levels achieved with our combination are equivalent to those obtained with the individual components. The Pilot PK Study was performed during April and May 2015, after completion of the formulation of two prototypes of KIT-302; during June 2015, we obtained the successful results of the Pilot PK Study. The Final PK Study was performed during March and April 2016, and on May 10, 2016 we announced that we, together with Dexcel, had successfully completed the Final PK Study. The Final PK Study compared the PK of KIT-302 which is a fixed dose combination consisting of celecoxib (200 mg), indicated for osteoarthritis pain, and amlodipine (10 mg), indicated for high blood pressure, to off-the-shelf branded 200 mg celecoxib capsules and 10 mg amlodipine tablets. These evaluations were conducted under both fed and fasted conditions. The results demonstrated that for both the C_{max} (the maximum blood level achieved) and Area Under the Curve (the area under the concentration-time curve for drug levels), the 90% confidence intervals for both the amlodipine and celecoxib components of KIT-302 were documented to be between 80% and 125% of the values obtained with the off-the-shelf drugs, thus meeting the FDA's standard for establishing bioequivalence. A similar PK bioequivalence study for KIT-302, containing a lower dosage (2.5 mg) of amlodipine, was completed during the third quarter of 2016, and showed similar bioequivalence results to those found in the Final PK Study.

On June 28, 2016, we announced that Dexcel had successfully completed an initial stability study for KIT-302. On December 7, 2016, we announced that Dexcel completed a study of nine pivotal batches of KIT-302 demonstrating stability for 6 months, which is required to submit our NDA to the FDA.

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

Issuance of Patent by USPTO

On May 12, 2016, we announced that our patent application to approve a patent relating to a drug for treating hypertension has received a notice of allowance for ameliorating the elevation of blood pressure caused by a specific NSAID by the co-administration of a specific calcium channel blocker. It is possible to pursue claims to additional inventions based on the patent application by making patent filings prior to issuance of a patent on this patent application, and we have proceeded accordingly. On August 10, 2016, we announced that the United States Patent and Trademark Office (USPTO) issued patent #9,408,837 covering KIT-302. The patent, entitled "Ameliorating Drug-Induced Elevations In Blood Pressure By Adjunctive Use Of Antihypertensive Drugs," was issued on August 9, 2016 and will have a term that can extend to February 28, 2030. We are pursuing additional claims to inventions described in U.S. Patent #9,408,837.

July 2016 Follow-on Public Offering

On July 5, 2016, we completed a follow-on public offering of 2,378,823 Class A units, with each Class A unit consisting of one ADS and a public warrant, as well as 1,150,589 Class B units, with each Class B unit consisting of a non-listed, pre-funded warrant to purchase one ADS, or a pre-funded warrant, and a public warrant. Each Class A unit was sold at a negotiated price of \$3.40 per unit, including the ADS issuance fee of \$0.01 per ADS, and each Class B unit was sold at a negotiated price of \$3.40 per unit, including the pre-funded warrant exercise price of \$0.01 per full ADS and the ADS issuance fee of \$0.01 per ADS. The pre-funded warrants were exercisable at any time after the date of issuance upon payment of the exercise price and the ADS issuance fee, and all of these pre-funded warrants have been exercised to-date. The gross proceeds to us from this offering were approximately \$12,000,000, prior to deducting placement agent fees and other estimated offering expenses.

Renal Function Clinical Trial

Additional data from the Phase III clinical trial of KIT-302 also suggest beneficial effects on renal (kidney) function, as compared to negative effects on renal function caused by other NSAIDS. Greater reduction in plasma levels of creatinine was observed in patients in the KIT-302 arm (-3.22 umol/L) compared to creatinine reduction observed in patients in the amlodipine arm (-2.55 umol/L), suggesting better renal function. In addition, peripheral edema, a known side effect of calcium channel blockers such as amlodipine, was reported in 15.6% of patients receiving amlodipine alone, but in only 8.2% of patients receiving KIT-302, suggesting that KIT-302 may protect against the amlodipine side effect of causing fluid retention by the kidneys. It is recognized that such an effect could explain the synergistic blood pressure reducing effect of KIT-302 over therapy with amlodipine alone.

Although not intended as part of the information to be included in our new drug application that we expect to submit for the marketing clearance by the FDA of KIT-302 in early 2017, we have commenced conducting a clinical trial designed to validate and better quantify these potential beneficial renal effects. The trial analysis may further explain the synergistic antihypertensive effect, where the reduction in blood pressure demonstrated with KIT-302 was greater than that observed with amlodipine alone. Accordingly, we intend to conduct a double blind, placebo controlled, clinical trial intended to statistically demonstrate KIT-302's effects on renal and vascular function, while providing us with data with respect to KIT-302 in addition to the data of the Phase III clinical trial, by utilizing a primary efficacy end-point in the renal function clinical trial comparable to that of the Phase III clinical trial. The trial is expected to be performed in the U.K. in three groups of 15 to 45 patients (and a total of 105 patients), with each patient treated over a total period of two weeks. Group One is receiving a placebo, Group Two is being treated with a standard drug available in the market for treating hypertension (amlodipine besylate, one of the components of KIT-302), and Group Three is being treated with the two components of KIT-302 (celecoxib and amlodipine besylate). We expect to complete recruitment of the patients during the second calendar quarter of 2017 and to receive the interim results of the trial approximately eight weeks after completion of patient recruitment.

The renal function clinical trial for KIT-302 will be conducted in medical centers in the United Kingdom on the basis of the approval of the British Regulatory Authority (MHRA), as well as the approvals of the relevant U.K. ethics committees, which we have already received.

On September 7, 2016, we entered into an additional Work Order with Java Clinical Research Ltd., or Java, a contract research organization based in Dublin, Ireland, under our Master Research Services Agreement with Java, the term of which was extended by such Work Order. Pursuant to the Work Order Java will manage the renal function clinical trial for KIT-302, including preparation and filing of the requests to the ethics boards and the necessary regulatory bodies of the U.K., recruiting the trial participants, employment of the primary researchers, identification and evaluation of the medical centers and their subsequent management throughout the trial period and overall management of the trial process through its completion. We also have directly engaged with third party medical centers for the performance of our renal function clinical trial being managed by Java. The Master Research Services Agreement will remain in effect until Java has provided all services through the completion of our renal function clinical trial. The parties have customary termination rights and either party may terminate the Master Research Services Agreement (or any work thereunder) upon 60 days' notice. In addition, on July 26, 2016, we entered into a new services agreement with DABL Limited, or DABL, an Irish company based in Dublin, Ireland, in the ambulatory blood pressure monitoring technologies field, in connection with the renal function clinical trial. According to the agreement, DABL will provide protocol consultation services and coordinate the ambulatory blood pressure monitoring (ABPM) procedures and the analysis of the blood pressure tests during and after our renal function clinical trial. The services agreement will remain in effect until DABL has provided all services provided for in the agreement. However, we may terminate the agreement at any time upon 90 days' notice, and both parties have customary termination rights. We estimate that the total cost of the agreement with Java, as well the cost of all other service providers with respect to the renal function clinical trial, will amount to approximately \$1.8 million, assuming completion of the clinical trial as anticipated.

Corporate information

Kitov Pharma was incorporated under the laws of the State of Israel (under a previous name) on August 12, 1968 and its ordinary shares were originally listed for trading on the TASE in 1978. In November 2015, we completed an initial public offering of our ADSs and Series A warrants on The NASDAQ Capital Market. Our principal executive offices are located at One Azrieli Center, Round Tower, 23rd Floor, 132 Menachem Begin Road, Tel Aviv 6701101, Israel, and our telephone number is 972-3-933-3121. Our website is www.kitovpharma.com. The information contained therein or connected thereto shall not be deemed to be incorporated into this prospectus or the registration statement of which it forms a part.

RISK FACTORS

Investment in our securities involves a high degree of risk. Prior to making a decision about investing in our securities, you should carefully consider the risks described below and all other information contained in this prospectus and in any other filing we make with the SEC subsequent to the date of this prospectus, each of which is incorporated herein by reference, and in any supplement to this prospectus, before you decide to buy our securities. 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 our listed securities would likely decline and you might lose all or part of your investment. This prospectus and statements that we may make from time to time may contain forward-looking information. Please read carefully the section below entitled "Forward-Looking Statements." The information in this prospectus is complete and accurate as of the date of this prospectus, but the information may change thereafter.

Risks Related to Our Financial Condition and Capital Requirements

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

We are a clinical development stage biopharmaceutical company, and we are focused on the development of innovative pharmaceutical products. Our current therapeutic candidates are in the clinical development stage, and have not been approved for marketing nor are any being marketed or commercialized. Our therapeutic candidates may require additional clinical trials or other testing before we can obtain the regulatory approvals in order to initiate commercial sales. For professional considerations and in order to manage our financial and human resources, we are currently advancing the development of our primary therapeutic candidate, KIT-302. We have incurred losses from commencement of our pharmaceutical research and development activities through June 30, 2016 of approximately \$17.0 million as a result of research and development activities, clinical trial related activities, listing for trading and fund raising related activities, general administrative and other expenses. We may incur significant additional losses as we continue to focus our resources on advancing our therapeutic candidates, including those we may acquire. Our ability to generate revenue and achieve profitability depends mainly upon our ability, alone or with others, to successfully develop our therapeutic candidates and obtain the required regulatory approvals in various territories and then commercialize our therapeutic candidates. We may be unable to achieve any or all of these goals with regard to our therapeutic candidates. As a result, we may never be profitable or achieve significant or sustained revenues.

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

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

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

Our financial statements for the years ended December 31, 2014 and 2013 contained an explanatory paragraph in the footnotes as to our ability to continue as a going concern. In November 2015, we closed a public offering of our ADSs and Series A warrants for an aggregate of approximately \$13 million. Prior to this offering we funded our operations primarily through offerings of our securities on the TASE and private loans. In July 2016, we completed a follow-on public offering of ADSs, non-listed Series B pre-funded warrants, and Series A warrants, for an aggregate of approximately \$12,000,000. We believe our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements through at least the next twelve months. Our business presently generates no revenues, and we plan to continue expending substantial funds in research and development, including clinical trials. We plan to fund our future operations through commercialization and out-licensing of our therapeutic candidates and either debt or equity financing. However, we cannot be certain that we will be able to raise capital on commercially reasonable terms or at all, or that our actual cash requirements will not be greater than anticipated. We may have difficulty raising needed capital or securing a development or commercialization partner in the future as a result of, among other factors, our lack of revenues from commercialization of the therapeutic candidates, as well as the inherent business risks associated with our company and present and future market conditions. In addition, global and local economic and geopolitical conditions may make it more difficult for us to raise needed capital or secure a development or commercialization partner in the future and may impact our liquidity. If we are unable to obtain future financing, we may be forced to delay, reduce the scope of, or eliminate one or more of our research, development or commercialization programs related to our therapeutic candidates, any of which may have a material adverse effect on our business, financial condition and results of operations. Moreover, to the extent we are able to raise capital through the issuance of debt or equity securities, it could result in substantial dilution to existing shareholders.

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

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

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

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

Risks Related to Our Business and Regulatory Matters

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

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

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

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

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

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

- delays in securing clinical investigators or trial sites for the clinical trials;
- delays in receiving import or other government approvals to ensure appropriate drug supply;
- delays in obtaining institutional review board (human ethics committee) and other regulatory approvals to commence a clinical trial;
- negative or inconclusive results from clinical trials;
- the FDA or other foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical studies;
- an inability to monitor patients adequately during or after treatment;
- problems with investigator or patient compliance with the trial protocols;
- a therapeutic candidate may not prove safe or efficacious;
- there may be unexpected or even serious adverse events and side effects from the use of a therapeutic candidate;

- the results with respect to any therapeutic candidate may not confirm the positive results from earlier preclinical studies or clinical trials;
- the results may not meet the level of statistical significance required by the FDA or other foreign regulatory authorities;
- the results will justify only limited and/or restrictive uses, including the inclusion of warnings and contraindications, which could significantly limit the marketability and profitability of the therapeutic candidate;
- the clinical trials may be delayed or not completed due to the failure to recruit suitable candidates or if there is a lower rate of suitable candidates than anticipated or if there is a delay in recruiting suitable candidates; and
- changes to the current regulatory requirements related to clinical trials which can delay, hinder or lead to unexpected costs in connection with our receiving the applicable regulatory approvals.

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

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

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

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

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

- we may not be able to control the amount and timing of resources that our collaborators may devote to our therapeutic candidates;
- should a collaborator fail to comply with applicable laws, rules, or regulations when performing services for us, we could be held liable for such violations;
- our collaborators may experience financial difficulties or changes in business focus;

- our collaborators partners may fail to secure adequate commercial supplies of our therapeutic candidates upon marketing approval, if at all;
- our collaborators partners may have a shortage of qualified personnel;
- we may be required to relinquish important rights, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- under certain circumstances, a collaborator could move forward with a competing therapeutic candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which could delay the development and may increase the cost of developing our therapeutic candidates.

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

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

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

In addition, as part of our strategy for growth, we may consider the acquisition of therapeutic candidates or existing drug products, at various stages of development, which are not necessarily related to the simultaneous treatment of pain caused by osteoarthritis and hypertension. However, we may not be able to identify suitable acquisition candidates, complete acquisitions or integrate acquisitions successfully. In this regard, acquisitions involve numerous risks, including difficulties in the integration of the acquired therapeutic candidates and the diversion of management's attention from other business concerns. Although we will endeavor to evaluate the risks inherent in any particular transaction, there can be no assurance that we will properly ascertain all such risks. In addition, acquisitions could result in the incurrence of substantial additional indebtedness and other expenses or in potentially dilutive issuances of equity securities. There can be no assurance that difficulties encountered with acquisitions will not have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

While there may be several alternative suppliers of API in the market, we have not conducted extensive investigation into the quality or availability of their APIs. 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 suppliers or finding and qualifying new API suppliers can be costly and take a significant amount of time. Many APIs require significant lead time to manufacture. There can also be challenges in maintaining similar quality or technical standards from one manufacturing batch to the next.

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

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

To date, our therapeutic candidates have been manufactured in relatively small quantities by third-party manufacturers for formulation development, clinical trials, for purposes of submission to the FDA of our NDA for KIT-302, and for other therapeutic candidates which may be developed in the future for preclinical and clinical trials, as may be required. If the FDA or other regulatory agencies approve any of our therapeutic candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of our approved therapeutic candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any of our approved therapeutic candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If they are unable to successfully increase the manufacturing capacity for a therapeutic candidate, or we are unable to establish alternative manufacturing capabilities, the commercial launch of any approved therapeutic candidates may be delayed or there may be a shortage in supply.

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

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

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

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

- restrictions on such therapeutic candidate, manufacturer or manufacturing process;
- warning letters from the FDA or other foreign regulatory authorities;
- withdrawal of the therapeutic candidate from the market;
- suspension or withdrawal of regulatory approvals;

- refusal to approve pending applications or supplements to approved applications that we or our potential commercialization partners submit;
- voluntary or mandatory recall;
- fines;
- refusal to permit the import or export of our therapeutic candidates;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; or
- adverse publicity.

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

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

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

While we have negotiated a special protocol assessment, or SPA, agreement with the FDA relating to the Phase III clinical trial protocol for KIT-302, and have received minutes of a pre-NDA submission meeting with the FDA, this agreement and these minutes do not guarantee approval of KIT-302 or any other particular outcome from the final regulatory review of the study or the drug candidate.

We have reached an agreement with the FDA to conduct the Phase III clinical trial for KIT-302 pursuant to an SPA agreement. The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase III trials that are intended to form the primary basis for determining a therapeutic candidate's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial design and data analysis plans, within 45 days of receipt of the request. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the therapeutic candidate with respect to its effectiveness and safety against the indication studied. All agreements and disagreements between the FDA and the sponsor regarding an SPA agreement must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA. Nevertheless, an SPA agreement does not guarantee approval of a therapeutic candidate, and approval will require that the data will convince the FDA of the safety, efficacy and need for the therapeutic candidate. Even if the FDA agrees to the design, execution and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts. In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement. A revocation or alteration in our existing SPA agreement could significantly delay or prevent approval of our application. Our SPA agreement with the FDA does not ensure that KIT-302 will receive marketing approval or that the approval process will be faster than conventional regulatory procedures. Further, we cannot assure you that the reported results of our Phase III clinical trial of KIT-302, and the minutes of a pre-NDA submission meeting with the FDA which we received in May 2016, will result in any FDA approval for KIT-302. While we believe that our Phase III clinical trial has been completed in accordance with the SPA agreement, and that the data generated met the endpoints that have been agreed in the SPA agreement to represent adequate evidence of effectiveness, and while we anticipate that we will be able to satisfactorily provide the additional information requested by the FDA as part of the minutes we received following the pre-NDA submission meeting, if the FDA revokes or alters its agreement under the SPA agreement, or if the FDA interprets the data collected from the clinical trial differently than we do, or if the FDA is not satisfied with the additional information we submit to them, the FDA may not deem the data sufficient to support an application for regulatory approval, which could materially adversely affect our business, financial condition and results of operations.

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

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

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

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

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

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

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

Risks Related to Our Industry

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

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

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

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

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

The pharmaceutical and biotechnology industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address the indications for which we are currently developing therapeutic candidates or for which we may develop therapeutic candidates in the future. There are various other companies that currently market or are in the process of developing products that address all of the indications or diseases treated by our therapeutic candidates.

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

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

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

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

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

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

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

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

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

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

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

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

Several States and private entities initially mounted legal challenges to the healthcare reform legislation, and they continue to litigate various aspects of the legislation. On July 26, 2012, the United States Supreme Court generally upheld the healthcare reform legislation as constitutional. However, the Supreme Court held that the legislation improperly required the States to expand their Medicaid programs to cover more individuals. As a result, the States have a choice as to whether they will expand the numbers of individuals covered by their respective State Medicaid programs. Some States have determined that they will not expand their Medicaid programs and will develop other cost saving and coverage measures to provide care to currently uninsured residents. Many of these efforts to date have included the institution of Medicaid managed care programs. The manner in which these cost saving measures are implemented could have a materially adverse effect on our financial performance. Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Following the recent elections in the United States of America, the presumptive President-Elect, a Republican, has indicated that he, working together with Congress, the majority members of both houses of which will be from the Republican Party, will promote the repeal of all or part of Healthcare Reform Law. We cannot predict the impact on our business of future legal challenges to the healthcare reform legislation, as currently enacted, or other changes to the current laws and regulations which may be revised in the future.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under government healthcare programs such as the Medicare and Medicaid programs;
- the federal Anti-Inducement Law (also known as the Civil Monetary Penalties Law), which prohibits a person from offering or transferring remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program;
- the Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients for certain designated health services where that physician or its family member has a financial relationship with the entity providing the designated health service, unless an exception applies;

- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government healthcare programs that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

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

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

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property and Legal Proceedings

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Operations in Israel

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

We are incorporated under the laws of the State of Israel, our principal offices are located in central Israel and some of our officers, employees, consultants and directors are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors. Any hostilities involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could adversely affect our operations and results of operations and could make it more difficult for us to raise capital. In 2008, 2012, and again in the summer of 2014, Israel was engaged in an armed conflict with Hamas, a militia group and political party operating in the Gaza Strip, and during the summer of 2006, Israel was engaged in an armed conflict with Hezbollah, a Lebanese Islamist Shiite militia group and political party. These conflicts involved missile strikes against civilian targets in various parts of Israel, and negatively affected business conditions in Israel. Political uprisings and civil resistance demonstrations in various countries in the Middle East, including Egypt and Syria, have affected the political stability of those countries. It is not clear how this instability, will develop and how it will affect the political and security situation in the Middle East. This instability may lead to deterioration of the political relationships that exist between Israel and these countries, and have raised concerns regarding security in the region and the potential for armed conflict. The tension between Israel and Iran or extremist groups in the region, such as Hamas in Gaza and Hezbollah in Lebanon, may escalate in the future and turn violent, which could affect the Israeli economy generally and us in particular. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations. Parties with whom we may do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. The conflict situation in Israel could cause situations where medical product certifying or auditing bodies could not be able to visit manufacturing facilities of our subcontractors in Israel in order to review our certifications or clearances, thus possibly leading to temporary suspensions or even cancellations of our product clearances or certifications. The conflict situation in Israel could also result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

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

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

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

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

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for certain transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. These provisions of Israeli law may delay, prevent or make difficult an acquisition of us, which could prevent a change of control and therefore depress the price of our shares, See –the section titled “Merger” under the description of our Ordinary Shares for more information.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders, especially for those shareholders whose country of residence does not have a tax treaty with Israel which exempts such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of a number of conditions, including, in some cases, a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are subject to certain restrictions. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no disposition of the shares has occurred.

Our amended and restated articles of association also contain provisions that could delay or prevent changes in control or changes in our management. These provisions include matters in connection with the election and removal of directors, such as our staggered board of directors, the appointment by our board of directors of additional directors to fill vacancies on the board of directors, the size of the our board of directors, the terms of office of our directors and the special majority of our voting rights required to amend such provision in our amended and restated articles of association. See the sections titled “Board of Directors” and “Acquisitions under Israeli Law” for additional information.

In addition, we have 1,000,000,000 shares of non-voting senior preferred shares authorized, which can be issued by our 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 our shareholders, unless shareholder approval is otherwise required by applicable law, the rules of any exchange or other market on which our securities may then be listed or traded, our 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 our share capital.

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 or in Euros. We pay a portion of our expenses in U.S. dollars; however, a portion of our expenses, related to salaries of the employees in Israel and payment to part of the service providers in Israel, are paid in NIS and in other currencies. In addition, a portion of our financial assets is held in NIS. As a result, we are exposed to currency fluctuation risks. For example, if the NIS strengthens against the U.S. dollar, our reported expenses in U.S. dollars may be higher than anticipated. In addition, if the NIS weakens against the U.S. dollar, the U.S. dollar value of our financial assets held in NIS will decline.

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

We are incorporated in Israel. Most of our executive officers and directors reside outside of the U.S., and all of our assets and most of the assets of our executive officers and directors are located outside of the U.S. Therefore, a judgment obtained against us or such executive officers and our directors in the U.S., including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the U.S. and may not be enforced by an Israeli court. It may also be difficult for you to affect service of process on these persons in the U.S. or to assert U.S. securities law claims in original actions instituted in Israel. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not United States law is applicable to the claim. If United States law is found to be applicable, the content of applicable United States law must be proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against us in Israel, it may be impossible to collect any damages awarded by either a U.S. or foreign court.

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

We are incorporated under Israeli law. The obligations and responsibilities of the holders of our ordinary shares are governed by our amended and restated articles of association and Israeli law. These obligations and responsibilities differ in some respects from the obligations and responsibilities of shareholders in typical U.S.-based corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith toward the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at the general meeting of shareholders on matters such as amendments to a company’s articles of association, increases in a company’s authorized share capital, mergers and acquisitions and related party transactions requiring shareholder approval. In addition, a shareholder who knows that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company. There is limited case law available to assist us in understanding the implications of these provisions that govern shareholders’ actions. These provisions may be interpreted to impose additional obligations and responsibilities on holders of our ordinary shares and/or ADSs that are not typically imposed on shareholders of U.S. corporations.

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

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

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

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

As a result of the Motion or other claims which may be filed against our directors and officers, we may need to use a significant amount of our funds to satisfy our indemnification obligations, which could severely harm our business and financial condition and limit the funds available to shareholders who may choose to bring a claim against our company. See 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 Intellectual Property and Legal Proceedings".

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

Risks related to the offering

Our management team will have immediate and broad discretion over the use of the net proceeds from this offering and may not use them effectively.

Unless otherwise indicated in an accompanying prospectus supplement, we intend to use the net proceeds from the sale of securities to fund the possible acquisition of new therapeutic candidates and for general working capital purposes. See "Use of Proceeds." However, our management will have broad discretion in the application of the net proceeds. Our shareholders may not agree with the manner in which our management chooses to allocate the net proceeds from this offering. The failure by our management to apply these funds effectively could have a material adverse effect on our business, financial condition and results of operation. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income. The decisions made by our management may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

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

We will likely be classified as a Passive Foreign Investment Company, or PFIC, for U.S. federal income tax purposes in 2016 and may continue to be 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 will likely be classified as a PFIC in the current taxable year and in future years. If we are treated as a PFIC for any taxable year during which a U.S. investor held our ordinary shares or ADSs, certain adverse U.S. federal income tax consequences could apply to the U.S. investor.

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

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

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

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

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

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

As of December 11, 2016, we had an aggregate of 153,237,209 issued and outstanding ordinary shares (including 21 dormant ordinary shares held in treasury) (such number of ordinary shares would be represented by 7,661,860 of our ADSs), no non-voting senior preferred shares, 6,835,669 Series A warrants, representative's warrants to purchase 157,945 of our ADSs, which were granted to the underwriters as part of our initial U.S. offering in November 2015, placement agent's warrants to purchase 141,176 of our ADSs, which were granted to the placement agent as part of our follow-on U.S. offering in July 2016, and 11,583,883 non-tradable options to purchase 9,932,523 ordinary shares, (such number of non-tradable options and their underlying ordinary shares would be represented by 496,626 of our ADSs). Substantial sales of our ordinary shares or ADSs or other warrants or securities convertible into ordinary shares of 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 our ordinary shares or ADSs or other listed securities to decline. Moreover, the issuance of shares or ADSs underlying our options and warrants or any convertible securities we may issue will also have a dilutive effect on our shareholders, which could further reduce the price of our ordinary shares and ADSs and other listed securities on their respective exchanges.

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

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of those otherwise required under the NASDAQ Listing Rules for U.S domestic issuers. We will follow home country practice in Israel with regard to (1) director nomination procedures, as permitted by the Companies Law, under which either our board of directors, a group of directors, or shareholder(s) holding sufficient portion of our share capital selects director nominees, subject to the terms of our amended and restated articles of association. Directors are not selected, or recommended for board of director selection, as required by the NASDAQ Listing Rules, by independent directors constituting a majority of the board's independent directors or by a nominations committee comprised solely of independent directors, and (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 The NASDAQ may provide less protection than is accorded to investors under the NASDAQ Listing Rules applicable to domestic issuers.

In addition, as a foreign private issuer, we will be exempt from the rules and regulations under the U.S. Securities Exchange Act of 1934, as amended or the Exchange Act, related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

In addition, we will not be required under the Exchange Act, to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as domestic companies whose securities are registered under the Exchange Act. As our ordinary shares are traded on the Tel Aviv Stock Exchange (“TASE”), while our ADSs and Series A warrants are traded on The NASDAQ Capital Market, we currently also report to the Israel Securities Authority (“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. Furthermore, we have committed to the underwriters of our initial U.S public offering which was completed in November 2015 that for a period of three (3) years from November 25, 2015, we, at our expense, will announce its financial information for each of the first three fiscal quarters consistent with the practices of companies which are dual-listed on both the Tel Aviv Stock Exchange and a domestic U.S. securities exchange and report in accordance with the Dual-Listed Reporting Requirements; provided that the foregoing shall not apply in the event we enter into a merger transaction in which we are the non-surviving entity that would cause our ADSs and warrants to no longer be registered under the Exchange Act. The Representative of the underwriters of our initial U.S public offering which was completed in November 2015 previously waived any announcement by us with respect to the filing of financial information for the first quarter of 2016, and may issue such waivers to us in the future. It is noted that the Israel Securities Authority (“ISA”) has recently proposed draft legislation which would dispense with the requirement for the announcement of financial results for each of the first and third fiscal quarters of a calendar year. We would qualify for such dispensation based on our company size as set forth in the proposed draft legislation. In addition the SEC has recently announced that it is seeking comment for the dispensation of the requirement for the announcement of financial results for each of the first and third fiscal quarters for certain U.S. domestic issuers. Thus it remains uncertain as to how companies dual-listed on both the Tel Aviv Stock Exchange and a domestic U.S. securities exchange, and report in accordance with the in accordance with the Dual-Listed Reporting Requirements), will continue their practices with respect to the announcements of financial information for each of the first and third fiscal quarters, and it is possible that we may adopt practices for the announcement (if any) of financial information for each of the first and third fiscal quarters which are different than what we have provided in the past.

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

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

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

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

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

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

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

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

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

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

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

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

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

Our ADSs and Series A warrants have little prior trading history in the U.S., and present level of market activity may not be sustained, which may limit the ability of our investors to sell our ADSs in the U.S.

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

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

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

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

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

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

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

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

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

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

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements in this prospectus may include forward looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including “anticipates”, “believes”, “could”, “estimates”, “expects”, “intends”, “may”, “plans”, “potential”, “predicts”, “projects”, “should”, “will”, “would”, and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. In addition, certain sections of this prospectus contain information obtained from independent industry and other sources. You should not put undue reliance on any forward-looking statements. Unless we are required to do so under U.S. federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements.

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

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

You should review carefully the risks and uncertainties described under the heading “Risk Factors” in this prospectus for a discussion of these and other risks that relate to our business and investing in our securities. The forward-looking statements contained in this prospectus are expressly qualified in their entirety by this cautionary statement.

CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2016.

The amounts shown below are unaudited and represent management’s estimate. The information in this table should be read in conjunction with and is qualified by reference to the financial statements and notes thereto and other financial information incorporated by reference into this prospectus.

	As of June 30, 2016 (in thousand USD) Actual
Cash and cash equivalents and short-term deposits	8,433
Shareholders’ equity:	
Ordinary shares	
Share premium	23,052
Capital reserves	1,111
Accumulated deficit	(17,091)
Total shareholders’ equity	7,072
Total capitalization	7,072

PRICE RANGE OF OUR ORDINARY SHARES

Our ordinary shares were originally listed for trading on the TASE in 1978, and are currently traded under the symbol “KTOV”. The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our ordinary shares on the TASE in NIS and U.S. dollars. U.S. dollar per ordinary share amounts are calculated using the U.S. dollar representative rate of exchange on the date for which the high or low market price is applicable, as reported by the Bank of Israel.

	NIS		U.S. \$	
	Price per Ordinary Share*		Price per Ordinary Share*	
	High	Low	High	Low
Annual:				
2015	4.13	0.50	1.05	0.13
2014	18.06	1.34	5.16	0.34
2013	33.27	3.04	9.41	0.83
2012	9.31	3.29	2.43	0.83
2011	15.01	4.76	4.21	1.25
Quarterly:				
Third Quarter 2016	0.66	0.54	0.18	0.14
Second Quarter 2016	1.29	0.62	0.34	0.16
First Quarter 2016	0.92	0.46	0.24	0.12
Fourth Quarter 2015	2.07	0.50	0.54	0.13
Third Quarter 2015	1.82	1.19	0.48	0.31
Second Quarter 2015	1.84	1.38	0.47	0.35
First Quarter 2015	4.13	1.51	1.05	0.38
Fourth Quarter 2014	3.35	1.34	0.90	0.34
Third Quarter 2014	6.89	3.25	2.01	0.88
Second Quarter 2014	8.35	6.01	2.41	1.75
First Quarter 2014	18.06	8.10	5.16	2.33
Most Recent Six Months				
December 2016 (through December 11, 2016)	0.68	0.63	0.18	0.17
November 2016	0.69	0.61	0.18	0.16
October 2016	0.74	0.66	0.20	0.17
September 2016	0.66	0.56	0.18	0.15
August 2016	0.66	0.57	0.17	0.15
July 2016	0.63	0.54	0.16	0.14
June 2016	0.91	0.62	0.24	0.16

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

On December 11, 2016, the last reported sales price of our ordinary shares on the TASE was NIS 0.651 per share, or \$0.171 per share (based on the exchange rate reported by the Bank of Israel for such date). On December 9, 2016 the exchange rate of the NIS to the U.S. dollar was \$1.00 = NIS 3.818, as reported by the Bank of Israel.

PRICE RANGES OF OUR AMERICAN DEPOSITARY SHARES AND PUBLIC WARRANTS

Our ADSs and Series A warrants are currently traded on The NASDAQ Capital Market under the symbols “KTOV” and “KTOVW”, respectively. The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our ADSs on The NASDAQ Capital Market in U.S. dollars.

	U.S. \$	
	Price per ADS	
	High	Low
Annual:		
2015 (commencing November 20, 2015)	4.47	2.43
Quarterly:		
Third Quarter 2016	3.62	2.77
Second Quarter 2016	6.68	3.11
First Quarter 2016	4.60	2.33
Fourth Quarter 2015 (commencing November 20, 2015)	4.47	2.43
Most Recent Six Months		
December 2016 (through December 9, 2016)	3.51	3.23
November 2016	3.75	3.12
October 2016	3.54	2.46
September 2016	3.62	2.87
August 2016	3.40	2.96
July 2016	3.13	2.77
June 2016	4.84	3.11

On December 9, 2016, the last reported sales price of our ADSs on The NASDAQ Capital Market was \$3.44 per ADS.

The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our Series A warrants on The NASDAQ Capital Market in U.S. dollars.

	U.S. \$	
	Price per Series A Warrant	
	High	Low
Annual:		
2015 (commencing November 20, 2015)	0.75	0.49
Quarterly:		
Third Quarter 2016	1.10	0.73
Second Quarter 2016	2.50	0.76
First Quarter 2016	1.10	0.50
Fourth Quarter 2015 (commencing November 20, 2015)	0.75	0.49
Most Recent Six Months		
December 2016 (through December 9, 2016)	1.47	1.27
November 2016	1.68	1.30
October 2016	2.38	1.22
September 2016	1.10	0.73
August 2016	0.85	0.73
July 2016	0.81	0.75
June 2016	1.49	0.76

USE OF PROCEEDS

Unless otherwise indicated in an accompanying prospectus supplement, we intend to use the net proceeds from the sale of securities to fund possible acquisitions of new therapeutic candidates and for general working capital purposes.

DESCRIPTION OF ORDINARY SHARES

Authorized Share Capital. Our authorized share capital is 5,000,000,000 ordinary shares, with no par value, and 1,000,000,000 non-voting senior preferred shares, with no par value, divided into 5 classes of 200,000,000 preferred shares in each class. As of December 11, 2016, we had 153,237,209 ordinary shares outstanding (which would be represented by 7,661,860 of our ADSs) and no non-voting senior preferred shares outstanding, and as of June 30, 2016, we had 82,488,969 ordinary shares outstanding (which would be represented by 4,124,448 of our ADSs) and no non-voting senior preferred shares outstanding. The above amounts include 21 dormant ordinary shares held in treasury.

Ordinary Shares.

The following is a description of our ordinary shares.

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

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

Notices. Under the Companies Law, and regulations promulgated thereunder, and our amended and restated articles of association, we are required to publish notices on our website, at least 21 days' prior notice of a shareholders' meeting. However, under regulations promulgated under the Companies Law, we are required to publish notices on our website at least 35 calendar days prior any shareholders' meeting in which the agenda includes matters which may be voted on by voting instruments. Regulations under the Companies Law exempt companies whose shares are listed for trading both on a stock exchange in and outside of Israel, from some provisions of the Companies Law. These regulations exempt us from some of the requirements of the Israeli proxy regulations, under certain circumstances.

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

Election of Directors. Under our amended and restated articles of association, the number of directors on our Board will be no less than four and no more than nine (including any external directors, to the extent that we may be required to appoint external directors in accordance with the Companies Law and any Regulations enacted thereunder) ("Maximum Number"). The majority of the members of the Board shall be residents of Israel, unless our center of management shall have been transferred to another country in accordance with a resolution of our Board by a majority of three quarters (75%) of the participating director votes. The number of directors may be changed, at any time and from time to time, by our shareholders with a majority of (a) 75% of the voting rights participating and voting on the matter in the applicable general meeting of our shareholders and (b) more than 47.9% of all of the voting rights in the Company as of the record date established for the applicable general meeting of our shareholders ("Special Majority"). Our directors shall generally be nominated by our Board of Directors, and then appointed at our general meeting of shareholders with a regular majority. In accordance with our amended and restated articles of association, the directors elected to serve are divided into three classes, with each class comprising one-third of the members of our Board of Directors (the "Board") (who are not external directors, if any were appointed), (hereinafter the "first class"; the "second class"; and the "third class"). If the number of directors is not equally divisible by three, each of the first class and the second class will be comprised of a different number, the closest and lowest to one-third, while the third class will be comprised of the remaining directors (who are not external directors, if any were appointed). If the number of directors changes, the number of directors in each class will change in accordance with the aforesaid rule. In the annual general meeting of our shareholders that will take place each year, the shareholders shall be entitled to elect directors who shall be elected for a Three-Year Term to replace the class of directors whose term in office has expired as of such annual general meeting of our shareholders, and so on ad infinitum, so that the directors who shall be elected as stated above shall enter office at the end of the annual general meeting of our shareholders at which they were elected, unless a later date for commencement of the term was decided at the time of the appointment, and shall serve for Three-Year Terms (unless their appointment will be terminated in accordance with the provisions of our amended and restated articles of association), and so that each year, the terms in office of one of the classes of directors shall expire at the annual general meeting of our shareholders for such year. A "Three-Year Term" means a term of office of a director until the third annual general meeting of our shareholders which shall be held following the date of their election as director, provided that each director shall continue to serve in office until his or her successor is duly elected and qualified, or until his or her retirement, death, resignation or removal. Our Board may appoint a director at any time to fill any vacancies until the annual meeting of our shareholders set to take place at the end of the Three-Year Term for the class of directors to which such director is so appointed by the Board, provided that the total number of the members of the Board serving at such time will not exceed the Maximum Number. The shareholders may at all times, by a Special Majority vote of the shareholders, replace or dismiss a director (in the case of replacement, only if the appointed director is not a corporation). A director to be replaced shall be given a reasonable opportunity to address the shareholders at their meeting. The tenure of a director expires pursuant to the provisions of our amended and restated articles of association and the Companies Law, upon death or if s/he becomes incompetent, unless removed from office as described above.

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

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

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

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

Board of Directors

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

Under the Companies Law, except as provided below, companies incorporated under the laws of the State of Israel that are "public companies," including Israeli companies with shares listed on NASDAQ, are required to appoint at least two external directors who meet the qualification requirements set forth in the Companies Law. On July 13, 2016, our Board of Directors resolved to adopt the corporate governance exception set forth in Regulation 5D of the Israeli Companies Regulations (Relief for Public Companies with Shares Listed for Trading on a Stock Market Outside of Israel), 5760-2000. In accordance with such Regulation, a public company with securities listed on certain foreign exchanges, including NASDAQ, that satisfies the applicable foreign country laws and regulations that apply to companies organized in that country relating to the appointment of independent directors and composition of audit and compensation committees and have no controlling shareholder are exempt from the requirement to appoint external directors or comply with the audit committee and compensation committee composition requirements under the Companies Law. In accordance with our Board's resolution, for so long as the Company does not have a controlling shareholder as defined in Section 1 of the Companies Law, the Company intends to comply with the NASDAQ Listing Rules in connection with a majority of independent directors on the Board and in connection with the composition of each of the Audit Committee and the Compensation Committee, in lieu of such requirements set forth under the Companies Law. A majority of our Board members are independent as required by the NASDAQ Listing Rules. Furthermore, our Audit Committee consists of at least three independent directors, and our Compensation Committee consists of at least two independent directors. Should any person or entity become deemed to be a controlling shareholder as defined in Section 1 of the Companies Law, then in accordance with Section 248(a) of the Companies Law, we will be required to convene a special general meeting of the shareholders at the earliest possible date, the agenda of which shall include the appointment of at least two external directors. Following such appointment, all of the external directors shall be appointed to each of our Audit Committee and Compensation Committee, and at least one external director shall be appointed to each committee of the Board of Directors authorized to exercise any of the powers of the board of directors.

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

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

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

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

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

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

Under the Companies Regulations (Relief from Related Party Transactions), 5760-2000, promulgated under the Companies Law, as amended, certain extraordinary transactions between a public company and its controlling shareholder(s) do not require shareholder approval. Such extraordinary transactions must be approved by both the board of directors and the audit committee and (i) must involve the extension of an existing transaction that was duly approved and does not involve any significant change in the terms of the existing transaction or the change is solely for the benefit of the company; (ii) is solely for the benefit of the company; (iii) is with the controlling shareholder or another person in which the controlling shareholder has an interest and the transaction is in accordance with the terms of a framework agreement that was duly approved; (iv) is with the controlling shareholder or another person in which the controlling shareholder has an interest, the purpose of which is a transaction of theirs with a third party or a joint proposal to enter into a transaction with a third party, and the terms of the transaction that apply to the controlling shareholder are not significantly different from the terms that apply to the controlling shareholder or an entity controlled by him or her (while taking into account the extent of their respective involvement in the transaction); (v) is among companies controlled by the controlling shareholder, or between the public company and the controlling shareholder or another person in which the controlling shareholder has a personal interest, and the transaction is on market terms, within the ordinary course of business and does not harm the company; or (vi) on the date of approval of the extraordinary transaction by the board of directors and audit committee, the shareholders who do not have personal interest in the approval of the said transactions do not hold more than 2% of the voting rights in the company. In addition, under such regulations, directors' compensation and employment arrangements in a public company do not require the approval of the shareholders if both the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and the board of directors agree that such arrangements are solely for the benefit of the company. Employment and compensation arrangements for an office holder that is a controlling shareholder of a public company, or the provision of directors and officers insurance for the chief executive officer, do not require shareholder approval if certain criteria are met. The Board, following the prior determination of the Audit Committee or Compensation Committee, as applicable, may also determine that the compensation being offered to certain office holders (including directors) is an engagement which, pursuant to the leniencies set forth in the Relief Regulations, can be entered into by a company immediately, with the approval by the shareholders being deferred to the next shareholder meeting to be called by the Company, is such compensation is consistent with compensation policy of the company which was approved by the shareholders of the company in accordance with the Companies Law, and are no more beneficial to the recipient as such similar compensation previously granted to other holders of the same office.

Acquisitions under Israeli Law

Full Tender Offer

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

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

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

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

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

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

Special Tender Offer

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

Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company.

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

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

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

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

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

Under the Companies Regulations (Relief for Public Companies whose Shares are Traded on Exchanges Outside of Israel), 5760-2000 (the “Foreign Listing Relief Regulations”), the above requirements for a special tender offer do not apply in instances whereby according to the laws of the foreign jurisdiction there are limitations regarding the acquisition of a controlling interest in the company of any specified portion or the acquisition of a controlling interest of any specified portion necessitates an offer by the potential acquirer of a controlling interest to acquire shares from amongst the publicly traded shares. The Israeli Securities Authority is of the view that US securities laws and exchange regulations of various exchanges do not purport to limit the acquisition of controlling interests in a company, do not require the potential acquirer of a controlling interest to make an offer to acquire shares from the public, and as such Israeli companies that are publicly traded in the United States of America cannot benefit from the special tender offer waiver pursuant to the Foreign Listing Relief Regulations and are thus subject to the general provisions of the Companies Law which require a special tender offer as outlined above.

Merger

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

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

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares voting at the shareholders’ meeting (excluding abstentions) that are held by parties other than the other party to the merger, any person who holds 25% or more of the means of control of the other party to the merger or any one on their behalf including their relatives or corporations controlled by any of them, vote against the merger.

In addition, if the non-surviving entity of the merger has more than one class of shares, the merger must be approved by each class of shareholders, and such separate class voting may also include any classes of otherwise non-voting shares.

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

Under the Companies Law, each merging company must send a copy of the proposed merger plan to its secured creditors. Unsecured creditors are entitled to receive notice of the merger, as provided by the regulations promulgated under the Companies Law. Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the target company. The court may also give instructions in order to secure the rights of creditors.

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

Private Placements

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

Exchange Controls

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

Access to corporate records

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

Modification of class rights

Under the Companies Law and our amended and restated articles of association, the rights attached to any class of share, such as voting, liquidation and dividend rights, may be amended by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting, or otherwise in accordance with the rights attached to such class of shares, as set forth in our amended and restated articles of association. The enlargement of an existing class of shares or the issuance of additional shares thereof, shall not be deemed to modify the rights attached to the previously issued shares of such class or of any other class, unless otherwise provided by the terms of the shares.

Establishment

We were incorporated under the laws of the State of Israel. We are registered with the Israeli Registrar of Companies in Jerusalem, Israel.

Listing

Our ordinary shares are traded on the TASE under the symbol “KTOV.”

Share History

The following is a summary of the history of our share capital for the last three years.

Ordinary Share Issuances

On January 3, 2014, we issued a holder of options, 18,047 ordinary shares upon the exercise of options.

On March 3, 2014, we issued 2,211,450 ordinary shares, in exchange for NIS 17.25 million (approximately \$4.9 million based on the representative rate of exchange on the date of closing, March 3, 2014) in a public offering on the Tel Aviv Stock Exchange pursuant to a prospectus we filed with the Israel Securities Authority. As part of the offering, we committed to our shareholders that we would initiate a rights offering to all existing shareholders. The specific terms of the rights offering were not described in the prospectus.

On April 1, 2014, we issued in Israel 157,783 ordinary shares to Dexcel for services provided pursuant to the Development Services Agreement with Dexcel.

On May 28, 2014, we published a prospectus for a rights offering under which each shareholder received, at no cost, one Series 1 TASE traded warrant for each ten ordinary shares held by such shareholder. No consideration was received by us in connection with the issuance of the warrants. The aggregate number of Series 1 TASE traded warrants issued was 5,717,074 exercisable into 439,757 ordinary shares. During June 2015 we issued, in aggregate, 352 of our ordinary shares upon exercises of 4,571 Series 1 TASE traded warrants, and the remainder of the Series 1 Traded warrants expired unexercised on June 30, 2015.

On September 3, 2014 we issued 1,548,015 ordinary shares, and 25,156,250 Series 2 TASE traded warrants exercisable into 1,935,019 ordinary shares in exchange for NIS 8.05 million (approximately \$2.2 million based on the representative rate of exchange on the date of closing, September 3, 2014) in a public offering on the Tel Aviv Stock Exchange, and on March 31, 2015 we issued an additional 24,913,200 Series 2 TASE traded warrants exercisable into 1,916,323 ordinary shares under the same terms and conditions. The Series 2 TASE traded warrants were exercisable any time until September 2, 2015 at an exercise price of NIS 5.20 (approximately \$1.38). On August 30, 2015, following approval of the extension by special meetings of our shareholders and our holders of our Series 2 TASE traded warrants on August 16, 2015, the Tel Aviv District courts approved, under Section 350 of the Israeli Companies Law, the extension of the exercise period of the Series 2 TASE traded warrants until March 1, 2016. During September 2015 we issued, in aggregate, 1,231 of our ordinary shares upon exercises of 16,000 Series 2 TASE traded warrants, and the remainder of the Series 2 TASE traded warrants expired unexercised on March 1, 2016.

On March 31, 2015 we issued 6,388,000 ordinary shares and 3,194,000 Series 3 TASE traded warrants exercisable into 3,194,000 ordinary shares, as well as the additional 24,913,200 Series 2 TASE traded warrants exercisable into 1,916,323 ordinary shares as noted above, all in exchange for NIS 8.304 million (approximately \$2.1 million based on the representative rate of exchange on the date of closing, March 31, 2015) in a public offering on the Tel Aviv Stock Exchange. No Series 3 TASE traded warrants were exercised and they expired on April 30, 2015.

In May 2015, we issued in Israel 597,511 ordinary shares to Dexcel for services provided pursuant to the Development Services Agreement with Dexcel.

On November 25, 2015, we completed an underwritten public offering of 3,158,900 ADSs, each representing 20 of our ordinary shares, and public warrants to purchase up to 3,158,900 ADSs. The ADSs and public warrants were issued in a fixed combination of one ADS and one warrant to purchase one ADS for a combined price to the public of \$4.13. In addition, the underwriters of the offering partially exercised their option to purchase an additional 220,074 warrants to purchase 220,074 ADSs. At closing of the offering we issued 63,178,000 of our ordinary shares, represented by 3,158,900 of our ADSs. The public warrants had an initial per ADS exercise price of \$4.13, were exercisable immediately, and have a term of five years from the date of issuance. The gross proceeds to us from this offering were approximately \$13 million, prior to deducting underwriting discounts, commissions and other offering expenses. Between December 2015 and May 2016, we issued in, aggregate, 1,454,340 of our ordinary shares, represented by 72,717 ADSs which were issued upon exercises of 72,717 public warrants. The public warrants were subject to “weighted average” ratchet anti-dilution provisions as set forth in the Warrant Agent Agreement, providing that until November 25, 2016, upon issuances of our ADSs or an equivalent number of ordinary shares (or securities convertible or exercisable into ADSs or an equivalent number of ordinary shares), subject to specified exceptions, at a price less than the exercise price then in effect, the exercise price would be reduced based on the “weighted average” formula set forth in the Warrant Agent Agreement. The “weighted average” ratchet provision of the public warrants was triggered by our July 5, 2016 follow-on public offering (described below), and upon closing of the follow-on public offering on July 5, 2016, the exercise price of all the public warrants was reduced in accordance with its terms to \$3.78.

On December 24, 2015 we issued in Israel 1,379,060 of our ordinary shares to the former shareholders of Kitov Pharmaceuticals Ltd. as a result of the attainment of milestones as set forth in the 2013 Share Transfer Agreement, and the termination of the non-listed share purchase rights reflecting such milestone shares. For more information on this agreement see “Certain Relationships and Related Party Transactions – Share Transfer Agreement with Kitov Pharmaceuticals” in our 2015 Annual Report on Form 20-F. One of the recipients, Dr. J. Paul Waymack, the chairman of our board of directors, who is the beneficial holder of 1,103,248 shares issued to a trustee in Israel, is a U.S. resident.

On each of January 20, 2016 and on March 7, 2016, we issued 160,000 of our ordinary shares represented by 8,000 of our ADSs issued on such dates to a vendor of ours located in the U.S. in consideration for services provided to us, and on May 2, 2016, we issued 189,100 of our ordinary shares, represented by 9,455 ADSs issued to a vendor of ours located in the U.S. in consideration for services provided to us.

In June 2016, we issued in Israel 3,009,888 ordinary shares to Dexcel for services provided pursuant to the Development Services Agreement with Dexcel.

On July 5, 2016, we completed a follow-on public offering of 2,378,823 Class A units, with each Class A unit consisting of one ADS and a public warrant, as well as 1,150,589 Class B units, with each Class B unit consisting of a non-listed, pre-funded warrant to purchase one ADS, or a pre-funded warrant, and a public warrant. At closing of the offering we issued 47,576,460 of our ordinary shares, represented by 2,378,823 of our ADSs. Each Class A unit was sold at a negotiated price of \$3.40 per unit, including the ADS issuance fee of \$0.01 per ADS, and each Class B unit was sold at a negotiated price of \$3.40 per unit, including the pre-funded warrant exercise price of \$0.01 per full ADS and the ADS issuance fee of \$0.01 per ADS. The pre-funded warrants were exercisable at any time after the date of issuance upon payment of the exercise price and the ADS issuance fee. The gross proceeds to us from this offering were approximately \$12,000,000, prior to deducting placement agent fees and other estimated offering expenses. Between July and September 2016 we issued, in aggregate, 23,011,780 of our ordinary shares represented by 1,150,589 ADSs which were issued upon exercises of all 1,150,589 of the pre-funded warrants.

As of December 11, 2016, we had an aggregate of 153,237,209 issued and outstanding ordinary shares (including 21 dormant ordinary shares held in treasury) (such number of ordinary shares would be represented by 7,661,860 of our ADSs), no non-voting senior preferred shares issued and outstanding, 6,835,669 Series A warrants, representative's warrants to purchase 157,945 of our ADSs, which were granted to the underwriters as part of our initial U.S. offering in November 2015, placement agent's warrants to purchase 141,176 of our ADSs, which were granted to the placement agent as part of our follow-on U.S. offering in July 2016, and 11,583,883 non-tradable options to purchase 9,932,523 ordinary shares (such number of non-tradable options and their underlying ordinary shares would be represented by 496,626 of our ADSs).

Authorized Share Capital

On November 20, 2014, our shareholders approved an increase in our authorized share capital from 38,461,538 ordinary shares with no par value, to 500,000,000 ordinary shares with no par value.

On November 30, 2014 we effected a consolidation of our share capital at a ratio of 1:13, so that: (A) each 13 ordinary shares of Kitov Pharma was consolidated into one ordinary share of Kitov Pharma; and (B) each option (tradable and non-tradable) outstanding immediately prior to the Consolidation was adjusted by multiplying the number of ordinary shares into which such option was exercisable by 1/13 (rounded to 0.07692).

On December 5, 2016, our shareholders approved the proposals to increase our authorized ordinary share capital to 5,000,000,000 ordinary shares, with no par value, and to add to our authorized share capital 1,000,000,000 non-voting senior preferred shares, with no par value, divided into 5 classes of 200,000,000 preferred shares in each class.

Our present authorized share capital is 5,000,000,000 ordinary shares, with no par value, and 1,000,000,000 non-voting senior preferred shares, with no par value, divided into 5 classes of 200,000,000 preferred shares in each class.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

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

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

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

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

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR. Directions on how to obtain copies of those documents are provided under the heading "Where You Can Find Additional Information".

Dividends and Other Distributions

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

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

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

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

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

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

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

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act of 1933, as amended, or the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. *This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.*

Deposit, Withdrawal and Cancellation

How are ADSs issued?

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

How can ADS holders withdraw the deposited securities?

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

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

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

Voting Rights

How do you vote?

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

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

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

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

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

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

Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:

\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)

\$.05 (or less) per ADS

A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs

\$.05 (or less) per ADS per calendar year

Registration or transfer fees

Expenses of the depositary

Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes

Any charges incurred by the depositary or its agents for servicing the deposited securities

For:

- Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
- Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
- Any cash distribution to ADS holders

- Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to ADS holders

- Depositary services

- Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
- Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement)
- converting foreign currency to U.S. dollars
- As necessary

- As necessary

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

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

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

Payment of Taxes

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

Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender of those ADSs or cancel those ADSs upon notice to the ADS holders.

Amendment and Termination

How may the deposit agreement be amended?

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

How may the deposit agreement be terminated?

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

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

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

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

Limitations on Obligations and Liability

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

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

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

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

Requirements for Depositary Actions

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

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

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

Right to Receive the Shares Underlying your ADSs

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

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

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

Pre-release of ADSs

The deposit agreement permits the depositary to deliver ADSs before deposit of the underlying shares. This is called a pre-release of the ADSs. The depositary may also deliver shares upon cancellation of pre-released ADSs (even if the ADSs are canceled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying shares are delivered to the depositary. The depositary may receive ADSs instead of shares to close out a pre-release. The depositary may pre-release ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made represents to the depositary in writing that it or its customer owns the shares or ADSs to be deposited; (2) the pre-release is fully collateralized with cash or other collateral that the depositary considers appropriate; and (3) the depositary must be able to close out the pre-release on not more than five business days' notice. In addition, the number of ADSs that may be outstanding at any time as a result of pre-release will not normally exceed 30% of the total number of ordinary shares deposited under the deposit agreement, although the depositary may disregard the limit from time to time if it thinks it is appropriate to do so. The depositary has full discretion as to how and to what extent it may disregard the limit for the amount of ADSs that may be outstanding at any time as a result of the pre-release.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder communications; inspection of register of holders of ADSs

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depositary will send you copies of those communications or otherwise make those communications available to you if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

Transfer agent and registrar

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

Listing

Our ADSs are listed on The NASDAQ Capital Market under the symbol "KTOV."

DESCRIPTION OF PREFERRED SHARES

Pursuant to Israel's securities laws, a company whose ordinary shares are registered for trade on the TASE may not have more than one class of shares for a period of one year following initial registration of the company on the TASE. After a period of one year, it is permitted to issue preferred shares if the preference of those shares is limited to a preference in the distribution of dividends and these preferred shares have no voting rights, and if such issuance is otherwise in accordance with any then applicable TASE regulations or directives with respect to the issuance of preferred shares by a company whose ordinary shares are listed on the TASE.

We presently do not have any issued and outstanding preferred shares. On December 5, 2016, our shareholders approved the amendment to our amended and restated articles of association, as well as to our memorandum of association, for the addition to the Company's registered share capital of 1,000,000,000 non-voting senior preferred shares, with no par value, divided into 5 classes of 200,000,000 preferred shares in each class (the "Preferred Shares").

Pursuant to our amended and restated articles of association, our board of directors is authorized to fix, by resolution of the board of directors, (i) the number of issued Preferred Shares (subject to the maximum number of Preferred Shares authorized in such class), (ii) the designation of such class of Preferred Shares, and (iii) the conversion, redemption, optional and other special rights, qualifications, limitations or restrictions, if any, of the shares of such class of Preferred Shares. Consequently, the issuance of Preferred Shares would be available for issuance without further actions by the Company's shareholders, unless shareholder approval is required by Israeli law, the rules of any exchange or other market on which the Company's securities may then be listed or traded, the Company's Articles of Association then in effect, or any other applicable rules and regulations. For so long as we are also listed on the TASE, the issuance of any Preferred Shares will also be subject to the requirements of any TASE regulations or directives governing the issuance of preferred shares by companies whose ordinary shares are listed on the TASE. The TASE has not yet issued any directives in connection with the issuance of preferred shares by a company whose ordinary shares are listed on TASE, other than a recently issued temporary directive which is currently scheduled to expire in November 2017.

Subject to the actual terms of issuance determined by our Board of Directors for any Preferred Shares when issued, our Preferred Shares may be convertible into our ordinary shares or another series of Preferred Shares. Each such series of Preferred Shares shall have such number of shares, designations, preferences, voting powers, qualifications, and special or relative rights or privileges as shall be determined by the board of directors, which may include, among others, dividend rights, voting rights, liquidation preferences, conversion rights and preemptive rights, rights, qualifications, limitations and/or restrictions determined by our board of directors in accordance with our articles of association in effect at the time of any such issuance, including, but not limited to, some or all of the following: (i) the number of Preferred Shares constituting that series and the distinctive designation of that series, which number may be increased or decreased (but not below the number of Preferred Shares then outstanding) from time to time by action of the board of directors; (ii) the dividend rate and the manner and frequency of payment of dividends on the Preferred Shares of that series, whether dividends will be cumulative, and, if so, from which date; (iii) subject to applicable law, whether that series will have voting rights, in addition to any voting rights provided by law, and, if so, the terms of such voting rights; (iv) the terms and conditions of any conversion privilege of the series, including provision for adjustment of the conversion rate in such events as the board of directors may determine; (v) whether or not the shares of that series will be redeemable, and, if so, the terms and conditions of such redemption; (vi) whether that series will have a sinking fund for the redemption or purchase of Preferred Shares of that series, and, if so, the terms and amount of such sinking fund; (vii) whether or not the Preferred Shares of the series will have priority over or be on a parity with or be junior to the Preferred Shares of any other series or class in any respect; (viii) the rights of the Preferred Shares of that series in the event of voluntary or involuntary liquidation, dissolution or winding up of the corporation, and the relative rights or priority, if any, of payment of Preferred Shares of that series; and any other relative rights, preferences and limitations of that series.

Issuance of Preferred Shares by our board of directors may result in such shares having dividend or liquidation preferences senior to the rights of the holders of our ordinary shares and, Preferred Shares which are convertible into our ordinary shares could potentially dilute the voting rights of the holders of our ordinary shares.

Once designated by our board of directors, and offered hereby, each series of Preferred Shares may have specific financial and other terms that will be described in a prospectus supplement. The description of the Preferred Shares that is set forth in any prospectus supplement is not complete without reference to the documents that govern the Preferred Shares.

All Preferred Shares offered hereby will, when issued, be fully paid and nonassessable, including Preferred Shares issued upon the exercise of Preferred Share warrants or subscription rights, if any.

Each Preferred Share shall be entitled to receive upon distribution, and in preference to our ordinary shares, (i) dividends in excess of the general dividends issued to all shareholders including holders of Ordinary Shares, and/or (ii) amounts paid in a distribution of our surplus assets on winding up, in an amount equal to the original issue price for such Preferred Shares as set forth in the Company's share registrar (adjusted for share combinations or subdivisions or other recapitalizations of the Company's shares), and less the amount of any dividend previously paid in preference, all pro rata to the number of the Company's Preferred Shares of each specific class of Preferred Shares issued and outstanding at such time, without having regard to any premium paid or discount thereon, and all subject to the provisions hereof.

Furthermore, and after payment of the Preferred Shares' dividend preferences or liquidation preferences as aforesaid, each Preferred Share in the Company's capital shall be entitled to receive upon distribution, (i) a general dividend issued to all Shareholders, (ii) bonus shares, and (iii) amounts paid in a distribution of the Company's surplus assets on winding up, all pro rata to the number of the Company's Shares (Ordinary Shares and Preferred Shares) issued and outstanding at such time, without having regard to any premium paid thereon or discount, and all subject to the provisions hereof.

All Preferred Shares shall be non-voting shares and shall not vest the holder thereof with any right to participate in the Company's general meetings, to receive notice thereof and/or to vote thereat. Without limitation to the above, the Preferred Shares shall not confer upon the holders thereof any voting rights or any right to appoint directors or any other right with respect to general meetings, including without limitation, attending, voting at or requesting to convene, such general meetings or proposing matters for the agenda of such general meetings, except as expressly set forth below or as otherwise specifically provided by Israeli law.

So long as any Preferred Shares are outstanding, the provisions of the section below titled "Modification of class rights", and the provisions of this section shall apply, such that the adoption of a resolution, by a regular majority in voting power of the Preferred Shares who are present, entitled to vote thereon (if any) and voting thereon, voting together as a single class, given in person or by proxy or by an authorized proxy holder, at a meeting of holders of Preferred Shares shall be necessary for effecting or validating:

(i) Authorization of Senior Shares. Any amendment or alteration of the Memorandum of Association or Articles of Association of the Company so as to authorize or create, or increase the authorized amount of, any class or series of shares to be so authorized, created or increased after the initial issuance of any class of Preferred Shares, the terms of which expressly provide that such class or series will rank senior to the outstanding class or classes of Preferred Shares as to dividend rights and distribution rights upon the liquidation, winding up or dissolution of the Company (collectively, "Senior Shares");

(ii) Amendment of the Preferred Shares. Any amendment, alteration or repeal of any provision of the Articles of Association so as to adversely affect the special rights, preferences, privileges or voting powers of the Preferred Shares.

(iii) Share Exchanges, Reclassifications, Mergers and Consolidations. Any consummation of a binding share exchange or reclassification involving the Preferred Shares, or of a merger or consolidation of the Company with or into another entity, unless in each case (x) the Preferred Shares remain outstanding or, in the case of any such merger or consolidation with respect to which the Company is not the surviving or resulting entity (or the Preferred Shares are otherwise exchanged or reclassified), are converted or reclassified into or exchanged for preferred shares of the surviving or resulting entity or its ultimate parent, and (y) such Preferred Shares that remain outstanding or such preferred shares, as the case may be, have rights, preferences, privileges and voting powers of the surviving or resulting entity or its ultimate parent that, taken as a whole, are not materially less favorable to the holders thereof than the rights, preferences, privileges and voting powers, taken as a whole, of the Preferred Shares immediately prior to the consummation of such transaction;

provided, however, that (A) for all purposes of this section, (1) any increase in the amount of the Company's authorized Ordinary Shares or Preferred Shares or the issuance of any additional Ordinary Shares or Preferred Shares or (2) the authorization or creation of any class or series of shares established after the initial issuance of any class of Preferred Shares, the terms of which do not expressly provide that such class or series ranks senior to or on a parity with the previously issued and outstanding Preferred Shares as to dividend rights and distribution rights upon any liquidation, winding up or dissolution of the Company (collectively, "Junior Shares"); or the authorization or creation of any class or series of shares established after the initial issuance of any class of Preferred Shares the terms of which expressly provide that such class or series will rank on a parity with the previously issued and outstanding Preferred Shares as to dividend rights and distribution rights upon any liquidation, winding up or dissolution of the Company (collectively, "Parity Shares"); and, any increase in the amount of authorized but unissued shares of such class or series of Parity Shares or Junior Shares or the issuance of additional shares of such class or series of Parity Shares or Junior Shares, will be deemed not to adversely affect (or to otherwise cause to be materially less favorable) the rights, preferences, privileges or voting powers of the previously issued and outstanding Preferred Shares and shall not require the consent or the adoption of a resolution by the holders of the previously issued and outstanding Preferred Shares; (B) in the event of a binding share exchange or reclassification involving the Preferred Shares, or of a merger or consolidation of the Company with or into another entity, as described above in which the provisions of sub-section (b)(iii)(x) and (y) above are complied with, the consent or the adoption of a resolution by the holders of the previously issued Preferred Shares shall not be required in order to effect, validate or approve such share exchange, reclassification, merger or consolidation; and (C) to the extent that, notwithstanding the provisions of immediately preceding clauses (A) and (B), the consent or approval of the holders of Preferred Shares, voting together as a single class, is nonetheless required by applicable law or the Articles of Association in such circumstances, or such consent or approval is otherwise required by applicable law or the Articles of Association with respect to any matter that is not set forth in the provisions of items (i)-(iii) of this section above, such approval or consent may be given by the adoption of a resolution, by a simple majority of the voting power of the Preferred Shares who are present, entitled to vote thereon (if any) and voting thereon, voting together as a single class, given in person or by proxy or by an authorized person, at a meeting of holders of Preferred Shares and the legal quorum for any such meeting shall be as set forth above with respect to meeting of holders of our Ordinary Shares.

The rules and procedures for calling and conducting any meeting of the holders of Preferred Shares (including, without limitation, the fixing of a record date in connection therewith), the solicitation and use of proxies at such a meeting, the obtaining of written consents and any other procedural aspect or matter with regard to such a meeting or such consents shall be governed by any rules the Board of Directors, in its discretion, may adopt from time to time, which rules and procedures shall conform to the requirements of our amended and restated articles of association (including the provisions set forth above), applicable law and, if applicable, the rules of any national securities exchange or other trading facility on which the Preferred Shares are listed or traded at the time.

Although our board of directors has no intention at the present time of doing so, it could authorize the issuance of a series of Preferred Shares that could, depending on the terms of such series, impede the completion of a merger, tender offer, change of control or other takeover attempt.

DESCRIPTION OF WARRANTS

We may issue warrants to purchase ADSs and/or ordinary shares and/or Preferred Shares and/or debt securities. Warrants may be issued independently or together with any other securities and may be attached to, or separate from, such securities. Each series of warrants will be issued under a separate warrant agreement to be entered into between us and a warrant agent and/or the warrant holder. Any warrant agent will act solely as our agent and will not assume any obligation or relationship of agency for or with holders or beneficial owners of warrants. The terms of any warrants to be issued and a description of the material provisions of the applicable warrant agreement will be set forth in the applicable prospectus supplement.

The applicable prospectus supplement will describe the following terms of any warrants in respect of which this prospectus is being delivered:

- the title of such warrants;
- the aggregate number of such warrants;
- the price or prices at which such warrants will be issued and exercised;
- the currency or currencies in which the price of such warrants will be payable;
- the securities purchasable upon exercise of such warrants;
- the date on which the right to exercise such warrants shall commence and the date on which such right shall expire;
- if applicable, the minimum or maximum amount of such warrants which may be exercised at any one time;
- if applicable, the designation and terms of the securities with which such warrants are issued and the number of such warrants issued with each such security;
- if applicable, the date on and after which such warrants and the related securities will be separately transferable;
- if applicable, any provisions for cashless exercise of the warrants;
- if applicable; any exercise limitations with respect to the ownership limitations by the holder exercising the warrant;
- information with respect to book-entry procedures, if any;
- any material Israeli and United States federal income tax consequences;
- the anti-dilution provisions of the warrants, if any; and
- any other terms of such warrants, including terms, procedures and limitations relating to the exchange and exercise of such warrants.

Series A Warrants

We may also expand the existing Series A warrants series currently listed on The NASDAQ Capital Market under the symbol “KTOVW,” and issue additional Series A warrants.

The following summary of certain terms and provisions of the outstanding Series A warrants is not complete and is subject to, and qualified in its entirety by the provisions of the Warrant Agent Agreement and form of Warrant Certificate, which is filed as an exhibit to the registration statement filed with the SEC on Form F-1 (Registration No. 333-207117) on November 18, 2015, as amended by the Letter Amendment to Warrant Agent Agreement which is filed as an exhibit to our Report on Form 6-K submitted to the SEC on June 29, 2016, as subsequently amended and supplemented. Prospective investors should carefully review the terms and provisions set forth in the Warrant Agent Agreement and form of Warrant Certificate, as amended. Series A warrants are administered by the Bank of New York Mellon, as warrant agent.

Exercisability. The Series A warrants are exercisable immediately upon issuance and at any time up to November 25, 2020. The Series A warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of ADSs purchased upon such exercise (except in the case of a cashless exercise as discussed below), together with the ADS issuance fee of \$0.05 per ADS and other applicable charges and taxes. Unless otherwise specified in the Series A warrant, the holder will not have the right to exercise the Series A warrants, in whole or in part, if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of our ordinary shares outstanding immediately after giving effect to the exercise, as such percentage is determined in accordance with the terms of the Series A warrants.

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

Exercise Price. The initial exercise price per ADS purchasable upon exercise of the Series A warrants is equal to \$3.78 per full ADS (which may be adjusted as set forth below). In addition to the exercise price per ADS, the \$0.05 issuance fee per ADS and other applicable charges and taxes are due and payable upon exercise.

Adjustment Provisions. The exercise price and the number of ADSs issuable upon exercise are subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock subdivisions and combinations, reclassifications or similar events affecting our ADSs or ordinary shares.

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

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

Fundamental Transaction. If, at any time while the Series A warrants are outstanding, (1) we consolidate or merge with or into another person, (2) we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets, (3) any purchase offer, tender offer or exchange offer (whether by us or another person) is completed pursuant to which holders of our ordinary shares are permitted to sell, tender or exchange their ordinary shares for other securities, cash or property and has been accepted by the holders of 50% or more of our outstanding shares of ordinary shares, (4) we effect any reclassification or recapitalization of our ADSs or ordinary shares or any compulsory share exchange pursuant to which our ordinary shares are converted into or exchanged for other securities, cash or property, or (5) we consummate a stock or share purchase agreement or other business combination with another person whereby such other person acquires more than 50% of our outstanding ordinary shares, each, a “Fundamental Transaction”, then upon any subsequent exercise of the Series A warrants, the holders thereof will have the right to receive the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of ADSs then issuable upon exercise of the Series A warrant, and any additional consideration payable as part of the Fundamental Transaction.

Rights as a Shareholder. Except as otherwise provided in the Warrant Agent Agreement or by virtue of such holder’s ownership of ADSs or ordinary shares, the holder of Series A warrants does not have rights or privileges of a holder of ADSs or ordinary shares, including any voting rights, until the holder exercises the Series A warrants.

Outstanding Series A warrants. As of December 11, 2016, there were 6,835,669 Series A warrants issued to public investors in our initial public offering in November 2015 and our follow-on public offering in July 2016, pursuant to prospectuses dated November 23, 2015 and June 30, 2016.

Representative's Warrants

We issued to the representative of the underwriters in our November 2015 initial public offering 157,945 representative's warrants to purchase up to 157,945 ADSs. The ADSs issuable upon exercise of these representative's warrants are identical to those offered to investors in our initial public offering in the U.S., except that such representative's warrants are in certificate form and have an exercise price equal to \$4.956. We have registered the representative’s warrants and the ADSs issuable upon exercise of the representative's warrants. The representative’s warrants are exercisable for cash or on a cashless basis at per share exercise price equal to \$4.956 and expire on the fifth anniversary of the issuance date. In addition, the representative’s warrants provide for registration rights upon request, in certain cases, at our expense. The exercise price and number of ADSs issuable upon exercise of the representative's warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary cash dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of ADSs at a price below the warrant exercise price.

Placement Agent's Warrants

On July 5, 2016, we issued to the placement agent for our July 2016 follow-on public offering 141,176 warrants to purchase 141,176 ADSs, or the "placement agent's warrants". The ADSs issuable upon exercise of the placement agent's warrants are identical to the ADSs issuable upon exercise of the public warrants. The placement agent's warrants are exercisable for cash or on a cashless basis at a per ADS exercise price equal to \$4.08 and expire on June 28, 2021. The placement agent's warrants and the ADSs underlying the placement agent's warrants have been deemed compensation by FINRA and are, therefore, subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The placement agent (or permitted assignees under the Rule) will not sell, transfer, assign, pledge or hypothecate the placement agent's warrants or the securities underlying the placement agent's warrants, nor will it engage in any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of these warrants or the underlying securities for a period of 180 days after the effective date. The exercise price and number of ADSs issuable upon exercise of the placement agent's warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary cash dividend or our recapitalization, reorganization, merger or consolidation.

The description in the applicable prospectus supplement of any warrants we offer, including, without limitation, any additional Series A warrants, will not necessarily be complete and will be qualified in its entirety by reference to the applicable warrant agreement, which will be filed with the SEC if we offer warrants, or to the Warrant Agent Agreement, as amended, and form of Warrant Certificate, as subsequently amended and supplemented, if we offer Series A warrants without amending its terms. For more information on how you can obtain copies of the applicable warrant agreement if we offer warrants, see "Where You Can Find More Information" beginning on page 74 and "Incorporation of Information by Reference" beginning on page 76. We urge you to read any applicable prospectus supplement and the applicable warrant agreement, or the Warrant Agent Agreement, as amended, and form of Warrant Certificate, as subsequently amended and supplemented, if we offer Series A warrants without amending its terms, in their entirety.

OVERALLOTMENT PURCHASE RIGHTS

We may issue over-allotment purchase rights to purchase ADSs and/or ordinary shares and/or Preferred Shares and/or warrants and/or subscription rights and/or units and/or debt securities. Over-allotment purchase rights may be issued independently or together with any other securities and may be attached to, or separate from, such securities. Any over-allotment purchase rights will be issued under a form of over-allotment purchase right and/or over-allotment purchase agreement to be filed with the SEC. The terms of any over-allotment purchase rights to be issued and a description of the material provisions of the applicable form of over-allotment purchase right will be set forth in the applicable prospectus supplement.

The applicable prospectus supplement relating to any over-allotment purchase rights we offer, if any, will, to the extent applicable, include specific terms relating to the offering, including some or all of the following:

- the form of such over-allotment purchase rights;
- the aggregate number of such over-allotment purchase rights;
- the price or prices at which such over-allotment purchase rights will be issued and exercised;
- the currency or currencies in which the price of such over-allotment purchase rights will be payable;
- the securities purchasable upon exercise of such over-allotment purchase rights;
- the date on which the right to exercise such over-allotment purchase rights shall commence and the date on which such right shall expire;
- if applicable, the minimum or maximum amount of such over-allotment purchase rights which may be exercised at any one time;
- if applicable, the designation and terms of the securities with which such over-allotment purchase rights are issued and the number of such over-allotment purchase rights issued with each such security;
- if applicable, the date on and after which such over-allotment purchase rights and the related securities will be separately transferable;
- if applicable, any provisions for cashless exercise of the over-allotment purchase rights;

- if applicable; any exercise limitations with respect to the ownership limitations by the holder exercising the overallotment purchase rights;
- information with respect to book-entry procedures, if any;
- the anti-dilution provisions of the overallotment purchase rights, if any; and
- any other terms of such warrants, including terms, procedures and limitations relating to the exchange and exercise of such warrants.

The description in the applicable prospectus supplement of any overallotment purchase rights we offer will not necessarily be complete and will be qualified in its entirety by reference to the applicable form of overallotment purchase right, which will be filed with the SEC if we offer overallotment purchase rights. For more information on how you can obtain copies of the applicable form of overallotment purchase right if we offer overallotment purchase rights, see “Where You Can Find More Information” beginning on page 74 and “Incorporation of Information by Reference” beginning on page 76. We urge you to read the applicable form of overallotment purchase right and any applicable prospectus supplement in their entirety.

DESCRIPTION OF SUBSCRIPTION RIGHTS

We may issue subscription rights to purchase our ordinary shares, and/or Preferred Shares, and/or our ADSs and/or debt securities. These subscription rights may be issued independently or together with any other security offered hereby and may or may not be transferable by the shareholder receiving the subscription rights in such offering. In connection with any offering of subscription rights, we may enter into a standby arrangement with one or more underwriters or other purchasers pursuant to which the underwriters or other purchasers may be required to purchase any securities remaining unsubscribed for after such offering.

The prospectus supplement relating to any subscription rights we offer, if any, will, to the extent applicable, include specific terms relating to the offering, including some or all of the following:

- the price, if any, for the subscription rights;
- the exercise price payable for each ordinary share, and/or preferred share, and/or ADS and/or debt security upon the exercise of the subscription rights;
- the number of subscription rights to be issued to each shareholder;
- the number and terms of the ordinary shares, and/or Preferred Shares, and/or ADSs and/or debt securities which may be purchased per each subscription right;
- the extent to which the subscription rights are transferable;
- any other terms of the subscription rights, including the terms, procedures and limitations relating to the exchange and exercise of the subscription rights;
- the date on which the right to exercise the subscription rights shall commence, and the date on which the subscription rights shall expire;
- the extent to which the subscription rights may include an over-subscription privilege with respect to unsubscribed securities; and
- if applicable, the material terms of any standby underwriting or purchase arrangement which may be entered into by us in connection with the offering of subscription rights.

The description in the applicable prospectus supplement of any subscription rights we offer will not necessarily be complete and will be qualified in its entirety by reference to the applicable subscription right agreement, which will be filed with the SEC if we offer subscription rights. For more information on how you can obtain copies of the applicable subscription right agreement if we offer subscription rights, see “Where You Can Find More Information” beginning on page 74 and “Incorporation of Information by Reference” beginning on page 76. We urge you to read the applicable subscription right agreement and any applicable prospectus supplement in their entirety.

DESCRIPTION OF UNITS

We may issue units comprised of one or more of the other securities that may be offered under this prospectus, in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately at any time, or at any time before a specified date.

The prospectus supplement relating to any units we offer, if any, will, to the extent applicable, include specific terms relating to the offering, including some or all of the following:

- the material terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any material provisions relating to the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units; and
- any material provisions of the governing unit agreement that differ from those described above.

The description in the applicable prospectus supplement of any units we offer will not necessarily be complete and will be qualified in its entirety by reference to the applicable unit agreement, which will be filed with the SEC if we offer units. For more information on how you can obtain copies of the applicable unit agreement if we offer units, see “Where You Can Find More Information” beginning on page 74 and “Incorporation of Information by Reference” beginning on page 76. We urge you to read the applicable unit agreement and any applicable prospectus supplement in their entirety.

DESCRIPTION OF CAPITAL NOTES

We may from time to time offer and sell under this prospectus capital notes, referred to herein as equity equivalent capital notes. When we offer to sell a particular series of capital notes, we will describe the specific terms of the series in a prospectus supplement. We will also indicate in the prospectus supplement whether the general terms and provisions described in this prospectus apply to a particular series of capital notes.

The capital notes are instruments of equity and not debt. Unless otherwise specified in a prospectus supplement, (i) the face amounts of the capital notes will not bear interest nor will they be linked to any index, (ii) the face amounts of the capital notes will only payable by us out of distributions made upon the winding-up, liquidation or dissolution of our company on a pari passu and pro rata basis with the holders of our ordinary shares and (iii) we will have no right to prepay or redeem the equity equivalent capital notes. In addition, the holder may at any time, convert the face amount of the equity equivalent capital notes, in whole or in part, without payment of any additional consideration, into ADSs or ordinary shares, as set forth in the equity equivalent capital note, at a conversion price agreed with the holder. Unless otherwise specified in a prospectus supplement, the equity equivalent capital notes shall have no maturity date and the right to convert into ADSs or ordinary shares shall not expire.

The terms of any particular series of equity equivalent capital notes will be set forth in the purchase agreement with the purchasers and the governing capital note certificate, each of which will be incorporated by reference as an exhibit to the registration statement of which this prospectus forms a part. The foregoing summary of the equity equivalent capital notes is not complete. We encourage you to read the purchase agreement and capital note certificate, because they, and not this summary, will govern your rights as a holder of equity equivalent capital notes.

DESCRIPTION OF DEBT SECURITIES

The following summary of the terms of the debt securities describes general terms that apply to the debt securities. The debt securities offered pursuant to this prospectus will be unsecured obligations and will be either senior debt or subordinated debt. The debt securities may be convertible into shares of our ordinary shares, ADSs or Preferred Shares. In addition, one or more of our subsidiaries may be guarantors of our debt securities. The particular terms of any debt securities will be described more specifically in each prospectus supplement relating to those debt securities. Where any provision in an accompanying prospectus supplement is inconsistent with any provision in this summary, the prospectus supplement will control.

Senior debt securities and subordinated debt securities will be issued under a debt indenture summarized below. Where we make no distinction in our summary between senior debt securities and subordinated debt securities, the applicable information refers to any debt securities. Since this is only a summary, it does not contain all of the information that may be important to you. A form of indenture relating to the debt securities is an exhibit to the registration statement of which this prospectus is a part. The executed indenture will be incorporated by reference from a report on Form 6-K. We encourage you to read those documents.

General

The indenture does not limit the aggregate principal amount of debt securities we may issue and provides that we may issue debt securities thereunder from time to time in one or more series. The indenture does not limit the amount of other indebtedness or debt securities which we or our subsidiaries may issue. Under the indenture, the terms of the debt securities of any series may differ and we, without the consent of the holders of the debt securities of any series, may reopen a previous series of debt securities and issue additional debt securities of the series or establish additional terms of the series.

Unless otherwise provided in a prospectus supplement, the senior debt securities will be our unsecured obligations and will rank equally with all of our other unsecured and senior indebtedness, and the subordinated debt securities will be unsecured obligations of ours and, as set forth below under “—Subordinated Debt Securities,” will be subordinated in right of payment to all of our senior indebtedness.

If any of our assets are held in subsidiaries established in connection with financing transactions, our rights and the rights of our creditors (including the holders of debt securities) and shareholders to participate in any distribution of assets of any subsidiary upon the subsidiary’s liquidation or reorganization or otherwise would be subject to the prior claims of the subsidiary’s creditors, except to the extent that we may be a creditor with recognized claims against the subsidiary.

You should refer to the prospectus supplement that accompanies this prospectus for a description of the specific series of debt securities we are offering by that prospectus supplement. The terms may include:

- the title and specific designation of the debt securities, including whether they are senior debt securities or subordinated debt securities;
- any limit on the aggregate principal amount of the debt securities or the series of which they are a part;
- whether the debt securities are to be issuable as registered securities, as bearer securities or alternatively as bearer securities and registered securities, and if as bearer securities, whether interest on any portion of a bearer security in global form will be paid to any clearing organizations;
- the date or dates on which we must pay principal;
- the rate or rates at which the debt securities will bear interest or the manner in which interest will be determined, if any interest is payable;
- the date or dates from which any interest will accrue, the date or dates on which we must pay interest and the record date for determining who is entitled to any interest payment;
- the place or places where we must pay the debt securities and where any debt securities issued in registered form may be sent for transfer, conversion or exchange;
- the terms and conditions on which we may, or may be required to, redeem the debt securities;
- the terms and conditions of any sinking fund;
- if other than denominations of \$1,000, the denominations in which we may issue the debt securities;

- the terms and conditions upon which debt securities may be convertible into ordinary shares, ADSs or Preferred Shares, including the conversion price, the conversion period and other conversion provisions;
- the amount we will pay if the maturity of the debt securities is accelerated;
- whether we will issue the debt securities in the form of one or more global securities and, if so, the identity of the depositary for the global security or securities;
- any addition to or changes in the events of default or covenants that apply to the debt securities;
- whether the debt securities will be defeasible;
- whether one or more of our subsidiaries will provide guarantees of the debt securities, and the terms of any subordination of such guarantee; and
- any other terms of the debt securities and any other deletions from or modifications or additions to the debt indenture in respect of the debt securities, including those relating to the subordination of any debt securities.

Unless the applicable prospectus supplement specifies otherwise, the debt securities will not be listed on any securities exchange.

Unless the applicable prospectus supplement specifies otherwise, we will issue the debt securities in fully registered form without coupons. If we issue debt securities of any series in bearer form, the applicable prospectus supplement will describe the special restrictions and considerations, including special offering restrictions and special income tax considerations, applicable to those debt securities and to payment on and transfer and exchange of those debt securities. Debt securities issued in bearer form will be transferable by delivery.

Unless otherwise stated in the prospectus supplement, we will, subject to certain conditions, pay principal, premium, interest and additional amounts, if any, on the debt securities at the office or agency we maintain for that purpose (initially the corporate trust office of the trustee). We may, subject to certain conditions, pay interest on debt securities issued in registered form by check mailed to the address of the persons entitled to the payments or we may pay by transfer to their U.S. or other bank accounts. Interest on debt securities issued in registered form will be payable on any interest payment date to the registered owners of the debt securities at the close of business on the regular record date for the interest payment. We will name in the prospectus supplement all paying agents we initially designate for the debt securities. We may designate additional paying agents, rescind the designation of any paying agent or approve a change in the office through which any paying agent acts, but we must maintain a paying agent in each place where payments on the debt securities are payable.

Unless otherwise stated in the prospectus supplement, the debt securities may be presented for transfer (duly endorsed or accompanied by a written instrument of transfer, if we or the security registrar so requires) or exchanged for other debt securities of the same series (containing identical terms and provisions, in any authorized denominations, and in the same aggregate principal amount) at the office or agency we maintain for that purpose (initially the corporate trust office of the trustee). There will be no service charge for any transfer or exchange, but we may require payment sufficient to cover any tax or other governmental charge or expenses payable in connection with the transfer or exchange. We will not be required to:

- issue, register the transfer of, or exchange, debt securities during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption of any such debt securities and ending at the close of business on the day of such mailing; or
- register the transfer of or exchange any debt security selected for redemption in whole or in part, except the unredeemed portion of any debt security being redeemed in part.

We shall appoint the trustee as security registrar. Any transfer agent (in addition to the security registrar) we initially designate for any debt securities will be named in the related prospectus supplement. We may designate additional transfer agents, rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, but we must maintain a transfer agent in each place where any payments on the debt securities are payable.

Unless otherwise stated in the prospectus supplement, we will issue the debt securities only in fully registered form, without coupons, in minimum denominations of \$1,000 and integral multiples of \$1,000. The debt securities may be represented in whole or in part by one or more global debt securities. Each global security will be registered in the name of a depository or its nominee and the global security will bear a legend regarding the restrictions on exchanges and registration of transfer. Interests in a global security will be shown on records maintained by the depository and its participants, and transfers of those interests will be made as described below. Provisions relating to the use of global securities are more fully described below in the section entitled “Use of Global Securities.”

We may issue the debt securities as original issue discount securities (bearing no interest or bearing interest at a rate which at the time of issuance is below market rates) to be sold at a substantial discount below their principal amount. We will describe certain special Israeli and U.S. federal income tax and other considerations applicable to any debt securities that are issued as original issue discount securities in the applicable prospectus supplement.

We will comply with Section 14(e) under the Exchange Act, and any other tender offer rules under the Exchange Act that may then be applicable, in connection with any obligation to purchase debt securities at the option of the holders. Any such obligation applicable to a series of debt securities will be described in the related prospectus supplement.

Unless otherwise described in a prospectus supplement relating to any debt securities, the indenture does not limit our ability to incur debt or give holders of debt securities protection in the event of a sudden and significant decline in our credit quality or a takeover, recapitalization or highly leveraged or similar transaction involving us. Accordingly, we could in the future enter into transactions that could increase the amount of indebtedness outstanding at that time or otherwise affect our capital structure or credit quality. You should refer to the prospectus supplement relating to a particular series of debt securities for information regarding any changes in the events of default described below or covenants contained in the debt indenture, including any addition of a covenant or other provisions providing event risk or similar protection.

Conversion Rights

The applicable prospectus supplement may set forth the terms on which the debt securities of any series are convertible into ordinary shares, ADSs or Preferred Shares. Those terms will address whether conversion is mandatory, at the option of the holder or at our option. The terms may also provide that the number of ordinary shares or ADSs to be received by the holders of the debt securities will be calculated according to the market price of our ADSs as of a time stated in the prospectus supplement or otherwise.

Subordinated Debt Securities

Unless otherwise provided in the applicable prospectus supplement, the following provisions will apply for subordinated debt securities.

Before we pay the principal of, premium, if any and interest on, the subordinated debt securities, we must be current and not in default on payment in full of all of our senior indebtedness. Senior indebtedness includes all of our indebtedness as described below, except for:

- obligations issued or assumed as the deferred purchase price of property;
- conditional sale obligations;
- obligations arising under any title retention agreements;
- indebtedness relating to the applicable subordinated debt securities;
- indebtedness owed to any of our subsidiaries; and
- indebtedness that, by its terms, is subordinate in right of payment to or equal with the applicable subordinated debt securities.

Generally, indebtedness means:

- the principal of, premium, if any, and interest on indebtedness for money borrowed;
- the principal of, premium, if any, and interest on indebtedness evidenced by notes, debentures, bonds or other similar instruments;
- capitalized lease obligations;
- obligations issued or assumed as the deferred purchase price of property, all conditional sale obligations and all obligations arising under any title retention agreements;
- obligations for the reimbursement of any obligor on any letter of credit, banker's acceptance or similar credit transaction (other than obligations with respect to certain letters of credit securing obligations entered into in the ordinary course of business);
- obligations of the type referred to in the bullet points above assumed for another party and dividends of another party for the payment of which, in either case, one is responsible or liable as obligor, guarantor or otherwise; and
- obligations assumed of the types referred to in the bullet points above for another party secured by any lien on any of one's property or assets.

Indebtedness does not include amounts owed pursuant to trade accounts arising in the ordinary course of business.

Generally, we may not pay the principal of, premium, if any, or interest on the subordinated debt securities if, at the time of payment (or immediately after giving effect to such payment):

- there exists under any senior indebtedness, or any agreement under which any senior indebtedness is issued, any default, which default results in the full amount of the senior indebtedness being declared due and payable; or
- the trustee has received written notice from a holder of senior indebtedness stating that there exists under the senior indebtedness, or any agreement under which the senior indebtedness is issued, a default, which default permits the holders of the senior indebtedness to declare the full amount of the senior indebtedness due and payable,

unless, among other things, in either case:

- the default has been cured or waived; or
- full payment of amounts then due for principal and interest and of all other obligations then due on all senior indebtedness has been made or duly provided for under the terms of any instrument governing senior indebtedness.

Limited subordination periods apply in the event of non-payment defaults relating to senior indebtedness in situations where there has not been an acceleration of senior indebtedness.

A failure to make any payment on the subordinated debt securities as a result of the foregoing provisions will not affect our obligations to the holders of the subordinated debt securities to pay the principal of, premium, if any, and interest on the subordinated debt securities as and when such payment obligations become due.

The holders of senior indebtedness will be entitled to receive payment in full of all amounts due or to become due on senior indebtedness, or provisions will be made for such payment, before the holders of the subordinated debt securities are entitled to receive any payment or distribution of any kind relating to the subordinated debt securities or on account of any purchase or other acquisition of the subordinated debt securities by us or any of our subsidiaries, in the event of:

- insolvency or bankruptcy case or proceeding, or any receivership, liquidation, reorganization or other similar case, relating to us or our assets;
- any liquidation, dissolution or other winding up of Kitov Pharma whether voluntary or involuntary and whether or not involving insolvency or bankruptcy; or
- any assignment for the benefit of our creditors or any other marshaling of our assets and liabilities.

In addition, the rights of the holders of the subordinated debt securities will be subrogated to the rights of the holders of senior indebtedness to receive payments and distributions of cash, property and securities applicable to the senior indebtedness until the principal of, premium, if any, and interest on the subordinated debt securities are paid in full.

Because of these subordination provisions, our creditors who hold senior indebtedness or other unsubordinated indebtedness may recover a greater percentage of the debt owed to them than the holders of the subordinated debt securities.

The debt indenture will not limit the aggregate amount of senior indebtedness that we may issue. If this prospectus is being delivered in connection with the offering of a series of subordinated debt securities, the accompanying prospectus supplement or the information incorporated in this prospectus by reference will set forth the approximate amount of senior debt outstanding as of a recent date.

Consolidation, Merger and Sale of Assets

We may not consolidate with or merge into any other person or convey or transfer or lease our properties and assets substantially as an entirety to any person unless:

- if we consolidate with or merge into another corporation or convey or transfer our properties and assets substantially as an entirety to any person, the successor is organized under the laws of the United States, or any state, and assumes our obligations under the debt securities;
- immediately after the transaction, no event of default occurs and continues; and
- we meet certain other conditions specified in the indenture.

Modification and Waiver

We and the trustee may modify and amend the debt indenture without the consent of the holders of the outstanding debt securities of each affected series, in order to, among other things:

- evidence the succession of another corporation to us and the assumption of all of our obligations under the debt securities, any related coupons and our covenants by a successor;
- add to our covenants for the benefit of holders of debt securities or surrender any of our rights or powers;

- add additional events of default for any series;
- add, change or eliminate any provision affecting debt securities that are not yet issued;
- secure certain debt securities;
- establish the form or terms of debt securities not yet issued;
- make provisions with respect to conversion or exchange rights of holders of debt securities;
- evidence and provide for successor trustees;
- permit payment in respect of debt securities in bearer form in the United States, if allowed without penalty under applicable laws and regulations; or
- correct or supplement any inconsistent provisions, cure any ambiguity or mistake, or add any other provisions, on the condition that this action does not adversely affect the interests of any holder of debt securities of any series issued under the indenture in any material respect.

In addition, we and the trustee may modify and amend the debt indenture with the consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each affected series. However, without the consent of each holder, we cannot modify or amend the debt indenture in a way that would:

- change the stated maturity of the principal of, or any premium or installment of interest on, any debt security;
- reduce the principal or interest on any debt security;
- change the place of payment of principal or interest on any debt security;
- impair the right to sue to enforce any payment on any debt security after it is due; or
- reduce the percentage in principal amount of outstanding debt securities necessary to modify or amend the debt indenture, to waive compliance with certain provisions of the debt indenture or to waive certain defaults.

The holders of at least a majority in aggregate principal amount of outstanding debt securities may waive our compliance with certain restrictive covenants of the debt indenture. The holders of at least a majority in principal amount of the outstanding debt securities of any series may waive any past default under the debt indenture with respect to outstanding debt securities of that series, which will be binding on all holders of debt securities of that series, except a default in the payment of principal or interest on any debt security of that series or in respect of a provision of the debt indenture that cannot be modified or amended without each holder's consent.

Events of Default

Each of the following will be an event of default:

- default for 30 days in the payment of any interest;
- default in the payment of principal;
- default in the deposit of any sinking fund payment;
- default in the performance of any other covenant in the debt indenture for 60 days after written notice; and
- certain events in bankruptcy, insolvency or reorganization.

We are required to furnish the trustee annually a statement as to our fulfillment of our obligations under the debt indenture. The trustee may withhold notice of any default to the holders of debt securities of any series (except for a default on principal or interest payments on debt securities of that series) if it considers it in the interest of the holders to do so.

If an event of default occurs and continues, either the trustee or the holders of not less than 25% in principal amount of the outstanding debt securities of the series in default may declare the principal amount immediately due and payable by written notice to us (and to the trustee if given by the holders). Upon any such declaration, the principal amount will become immediately due and payable. However, the holders of a majority in principal amount of the outstanding debt securities of that series may, under certain circumstances, rescind and annul the acceleration.

Except for certain duties in case of an event of default, the trustee is not required to exercise any of its rights or powers at the request or direction of any of the holders, unless the holders offer the trustee reasonable security or indemnity. If the holders provide this security or indemnity, the holders of a majority in principal amount of the outstanding debt securities of a series may direct the time, method and place of conducting any proceeding for any remedy available to the trustee, or exercising any trust or powers conferred on the trustee with respect to the debt securities of that series.

No holder of a debt security may bring any lawsuit or other proceeding with respect to the indenture or for any remedy under the indenture, unless:

- the holder first gives the trustee written notice of a continuing event of default;
- the holders of at least 25% in principal amount of the outstanding debt securities of the series in default give the trustee a written request to bring the proceeding and offer the trustee reasonable security or indemnity; and
- the trustee fails to institute the proceeding within 60 days of the written request and has not received from holders of a majority in principal amount of the outstanding debt securities of the series in default a direction inconsistent with that request.

However, the holder of any debt security has the absolute right to receive payment of the principal of and any interest on the debt security on or after the stated due dates and to take any action to enforce any such payment.

Discharge, Defeasance and Covenant Defeasance

We may discharge certain obligations to holders of any series of debt securities that have not already been delivered to the trustee for cancellation and that either have become due and payable or will become due and payable within one year (or scheduled for redemption within one year) by depositing with the trustee, in trust, funds in U.S. dollars an amount sufficient to pay the principal and any premium, interest and additional amounts on such debt securities to the date of deposit (if the debt securities have become due and payable) or to the maturity date, as the case may be.

Unless a prospectus supplement states that the following provisions do not apply to the debt securities of that series, we may elect either:

- to defease and be discharged from any and all obligations with respect to such debt securities (except for, among other things, the obligation to pay additional amounts, if any, upon the occurrence of certain events of taxation, assessment or governmental charge with respect to payments on the debt securities and other obligations to provide for the conversion rights of the holders of such debt securities, to register the transfer or exchange of such debt securities, to replace temporary or mutilated, destroyed, lost or stolen debt securities, to maintain an office or agency with respect to such debt securities and to hold moneys for payment in trust), such an action a “defeasance,” or
- to be released from our obligations under the indenture with respect to the debt securities as may be further described in any prospectus supplement, and our failure to comply with these obligations will not constitute an event of default with respect to such debt securities, such an action a “covenant defeasance”.

Defeasance or covenant defeasance is conditioned on our irrevocable deposit with the trustee, in trust, of an amount in cash or government securities, or both, sufficient to pay the principal of, any premium and interest on, and any additional amounts with respect to, the debt securities on the scheduled due dates. Additional conditions to defeasance or covenant defeasance require that:

- the applicable defeasance or covenant defeasance does not result in a breach or violation of, or constitute a default under, the debt indenture or any other material agreement or instrument to which we are a party or by which we are bound,
- no event of default has occurred and continues on the date the trust is established and, with respect to defeasance only, at any time during the period ending on the 123rd day after that date, and
- we have delivered to the trustee an opinion of counsel to the effect that the holders of such debt securities will not recognize income, gain or loss for U.S. federal income tax purposes as a result of the defeasance or covenant defeasance and will be subject to U.S. federal income tax for the same amounts, in the same manner and at the same times as would have been the case if the defeasance or covenant defeasance had not occurred. This opinion, in the case of defeasance, must refer to and be based upon a letter ruling we have received from the Internal Revenue Service, a Revenue Ruling published by the Internal Revenue Service, or a change in applicable U.S. federal income tax law occurring after the date of the debt indenture.

If we accomplish covenant defeasance on debt securities of certain holders, those holders can still look to us for repayment of their debt securities in the event of any shortfall in the trust deposit. If one of the remaining events of default occurred, such as our bankruptcy, and the debt securities became immediately due and payable, there may be a shortfall. Depending on the event causing the default, such holders may not be able to obtain payment of the shortfall.

In the case of subordinated debt securities, the subordination provisions described under “—Subordinated Debt Securities” above are made subject to the provisions for defeasance and covenant defeasance. In other words, if we accomplish defeasance or covenant defeasance on any subordinated debt securities, such securities would cease to be so subordinated.

Guarantee

One or more subsidiary guarantors may fully and unconditionally guarantee on an unsecured basis the full and prompt payment of the principal of and any premium and interest on the debt securities when and as the payment becomes due and payable, whether at maturity or otherwise. The guarantee provides that in the event of a default in the payment of principal of or any premium or interest on a debt security, the holder of that debt security may institute legal proceedings directly against the applicable subsidiary guarantor to enforce the guarantee without first proceeding against Kitov Pharma. If senior debt securities are so guaranteed, the guarantee will rank equally with all of the subsidiary guarantor’s other unsecured and unsubordinated debt from time to time outstanding and senior to any subordinated debt of the subsidiary guarantor. If subordinated debt securities are so guaranteed, the guarantee will be subordinated to all of the subsidiary guarantor’s other unsecured and unsubordinated debt from time to time outstanding.

The obligations of any subsidiary guarantor under the guarantee will be limited to the maximum amount that will not result in the obligations of the subsidiary guarantor under the guarantee constituting a fraudulent conveyance or fraudulent transfer under federal or state law, after giving effect to any other contingent and fixed liabilities of the subsidiary guarantor.

No guarantor shall consolidate with or merge into any other person or sell, convey or transfer all or substantially all its properties and assets to any person, unless:

(1) in case such guarantor shall consolidate with or merge into another person or sell, convey, transfer or lease all or substantially all its properties and assets to any person, the person formed by such transaction shall be a corporation, partnership or trust, shall be organized and validly existing under the laws of the State of Israel and/or the United States, any state thereof or the District of Columbia and shall expressly assume the performance or observance of every covenant of the indenture and any guarantees on the part of such guarantor to be performed or observed;

(2) immediately after giving effect to such transaction no event of default, and no event which, after notice or lapse of time or both, would become an event of default, shall have happened and be continuing; and

(3) the transaction meets certain other criteria described in the indenture.

The guarantee may be released under certain circumstances. If Kitov Pharma exercises its legal or covenant defeasance option with respect to debt securities of a particular series as described above in “—Discharge, Defeasance and Covenant Defeasance,” then any subsidiary guarantor will be released with respect to that series. Further, if no default has occurred and is continuing under the indentures, and to the extent not otherwise prohibited by the indentures, any subsidiary guarantor will be unconditionally released and discharged from the guarantee:

- automatically upon any sale, exchange or transfer, whether by way of merger or otherwise, to any person that is not an affiliate of Kitov Pharma, of all of Kitov Pharma’ equity interests in the subsidiary guarantor;
- automatically upon the merger of the subsidiary guarantor into Kitov Pharma or the liquidation and dissolution of the subsidiary guarantor; or
- following delivery of a written notice by Kitov Pharma to the trustee, upon the release of all guarantees by the subsidiary guarantor of any debt of Kitov Pharma’ for borrowed money, except for any series of debt securities.

Governing Law

Unless otherwise specified in a prospectus supplement, the debt indentures and the debt securities will be governed by and interpreted under the laws of the State of Israel, without regard to conflict of law principles that would result in the application of any law other than the laws of the State of Israel.

USE OF GLOBAL SECURITIES

The debt securities of any series may be issued in whole or in part in the form of one or more global debt securities that will be deposited with a depositary or its nominee identified in the series prospectus supplement.

The specific terms of the depositary arrangement covering debt securities will be described in the prospectus supplement relating to that series. We anticipate that the following provisions or similar provisions will apply to depositary arrangements relating to debt securities, although to the extent the terms of any arrangement differs from those described in this section, the terms of the arrangement shall supersede those in this section as ultimately described in the applicable indenture and related documents.

Upon the issuance of a global security, the depositary for the global security or its nominee will credit, to accounts in its book-entry registration and transfer system, the principal amounts of the debt securities represented by the global security. These accounts will be designated by the underwriters or agents with respect to such debt securities or by us if such debt securities are offered and sold directly by us. Only institutions that have accounts with the depositary or its nominee, and persons who hold beneficial interests through those participants, may own beneficial interests in a global security. Ownership of beneficial interests in a global security will be shown only on, and the transfer of those ownership interests will be effected only through, records maintained by the depositary, its nominee or any such participants. The laws of some states require that certain purchasers of securities take physical delivery of such securities in definitive form. These laws may prevent you from transferring your beneficial interest in a global security.

As long as the depositary or its nominee is the registered owner of a global security, the depositary or nominee will be considered the sole owner or holder of the debt securities represented by the global security. Except as described below, owners of beneficial interests in a global security will not be entitled to have debt securities registered in their names and will not be entitled to receive physical delivery of the debt securities in definitive form.

We will make all payments of principal of, any premium and interest on, and any additional amounts with respect to, debt securities issued as global securities to the depositary or its nominee. Neither we nor the trustee, any paying agent or the security registrar assumes any responsibility or liability for any aspect of the depositary's or any participant's records relating to, or for payments made on account of, beneficial interests in a global security.

We expect that the depositary for a series of debt securities or its nominee, upon receipt of any payment with respect to such debt securities, will credit immediately participants' accounts with payments in amounts proportionate to their respective beneficial interest in the principal amount of the global security for such debt securities as shown on the records of such depositary or its nominee. We also expect that payments by participants to owners of beneficial interests in such global security held through such participants will be governed by standing instructions and customary practices, as is now the case with securities held for the accounts of customers registered in "street name," and will be the responsibility of such participants.

The applicable indenture provides that if:

- the depositary notifies us that it is unwilling or unable to continue as depositary for a series of debt securities, or if the depositary is no longer legally qualified to serve in that capacity, and we have not appointed a successor depositary within 90 days of written notice;
- we determine that a series of debt securities will no longer be represented by global securities and we execute and deliver an order to that effect to the trustee; or
- an event of default with respect to a series of debt securities occurs and continues;

the global securities for that series will be exchanged for registered debt securities in definitive form. The definitive debt securities will be registered in the name or names the depositary instructs the trustee. We expect that these instructions may be based upon directions the depositary receives from participants with respect to ownership of beneficial interests in global securities.

TAXATION

The material Israeli and U.S. federal income tax consequences relating to the purchase, ownership and disposition of any of the securities offered by this prospectus will be set forth in the prospectus supplement offering those securities.

PLAN OF DISTRIBUTION

The securities being offered by this prospectus may be sold:

- through agents;
- to or through one or more underwriters on a firm commitment or agency basis;
- through put or call option transactions relating to the securities;
- to or through dealers, who may act as agents or principals, including a block trade (which may involve crosses) in which a broker or dealer so engaged will attempt to sell as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- through privately negotiated transactions;

- purchases by a broker or dealer as principal and resale by such broker or dealer for its own account pursuant to this prospectus;
- directly to purchasers, including our affiliates, through a specific bidding or auction process, on a negotiated basis or otherwise; to or through one or more underwriters on a firm commitment or best efforts basis;
- exchange distributions and/or secondary distributions;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- in “at-the-market” offerings, within the meaning of Rule 415(a)(4) of the Securities Act to or through a market maker or into an existing trading market, on an exchange or otherwise;
- transactions not involving market makers or established trading markets, including direct sales or privately negotiated transactions;
- transactions in options, swaps or other derivatives that may or may not be listed on an exchange or
- in any combination of these methods of sale.
- through any other method permitted pursuant to applicable law; or
- through a combination of any such methods of sale.

At any time a particular offer of the securities covered by this prospectus is made, a revised prospectus or prospectus supplement, if required, will be distributed which will set forth the aggregate amount of securities covered by this prospectus being offered and the terms of the offering, including the name or names of any underwriters, dealers, brokers or agents, any discounts, commissions, concessions and other items constituting compensation from us and any discounts, commissions or concessions allowed or re-allowed or paid to dealers. Such prospectus supplement, and, if necessary, a post-effective amendment to the registration statement of which this prospectus is a part, will be filed with the SEC to reflect the disclosure of additional information with respect to the distribution of the securities covered by this prospectus. In order to comply with the securities laws of certain states, if applicable, the securities sold under this prospectus may only be sold through registered or licensed broker-dealers. In addition, in some states the securities may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from registration or qualification requirements is available and is complied with.

The distribution of securities may be effected from time to time in one or more transactions, including block transactions and transactions on The NASDAQ Capital Market or any other organized market where the securities may be traded. The securities may be sold at a fixed price or prices, which may be changed, or at market prices prevailing at the time of sale, at prices relating to the prevailing market prices or at negotiated prices. The consideration may be cash or another form negotiated by the parties. Agents, underwriters or broker-dealers may be paid compensation for offering and selling the securities. That compensation may be in the form of discounts, concessions or commissions to be received from us or from the purchasers of the securities. Any dealers and agents participating in the distribution of the securities may be deemed to be underwriters, and compensation received by them on resale of the securities may be deemed to be underwriting discounts. If any such dealers or agents were deemed to be underwriters, they may be subject to statutory liabilities under the Securities Act.

Agents may from time to time solicit offers to purchase the securities. If required, we will name in the applicable prospectus supplement any agent involved in the offer or sale of the securities and set forth any compensation payable to the agent. Unless otherwise indicated in the prospectus supplement, any agent will be acting on a best efforts basis for the period of its appointment. Any agent selling the securities covered by this prospectus may be deemed to be an underwriter, as that term is defined in the Securities Act, of the securities.

To the extent that we make sales to or through one or more underwriters or agents in at-the-market offerings, we will do so pursuant to the terms of a distribution agreement between us and the underwriters or agents. If we engage in at-the-market sales pursuant to a distribution agreement, we will sell any of our listed securities to or through one or more underwriters or agents, which may act on an agency basis or on a principal basis. During the term of any such agreement, we may sell any of our listed securities on a daily basis in exchange transactions or otherwise as we agree with the underwriters or agents. The distribution agreement will provide that any of our listed securities which are sold will be sold at prices related to the then prevailing market prices for our listed securities. Therefore, exact figures regarding proceeds that will be raised or commissions to be paid cannot be determined at this time and will be described in a prospectus supplement. Pursuant to the terms of the distribution agreement, we also may agree to sell, and the relevant underwriters or agents may agree to solicit offers to purchase, blocks of our listed securities. The terms of each such distribution agreement will be set forth in more detail in a prospectus supplement to this prospectus.

If underwriters are used in a sale, securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale, or under delayed delivery contracts or other contractual commitments. Securities may be offered to the public either through underwriting syndicates represented by one or more managing underwriters or directly by one or more firms acting as underwriters. If an underwriter or underwriters are used in the sale of securities, an underwriting agreement will be executed with the underwriter or underwriters, as well as any other underwriter or underwriters, with respect to a particular underwritten offering of securities, and will set forth the terms of the transactions, including compensation of the underwriters and dealers and the public offering price, if applicable. The prospectus and prospectus supplement will be used by the underwriters to resell the securities.

If a dealer is used in the sale of the securities, we or an underwriter will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. To the extent required, we will set forth in the prospectus supplement the name of the dealer and the terms of the transactions.

We may directly solicit offers to purchase the securities and may make sales of securities directly to institutional investors or others. These persons may be deemed to be underwriters within the meaning of the Securities Act with respect to any resale of the securities. To the extent required, the prospectus supplement will describe the terms of any such sales, including the terms of any bidding or auction process, if used.

Agents, underwriters and dealers may be entitled under agreements which may be entered into with us to indemnification by us against specified liabilities, including liabilities incurred under the Securities Act, or to contribution by us to payments they may be required to make in respect of such liabilities. If required, the prospectus supplement will describe the terms and conditions of the indemnification or contribution. Some of the agents, underwriters or dealers, or their affiliates may be customers of, engage in transactions with or perform services for us or our subsidiaries.

Any person participating in the distribution of securities registered under the registration statement that includes this prospectus will be subject to applicable provisions of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the applicable SEC rules and regulations, including, among others, Regulation M, which may limit the timing of purchases and sales of any of our securities by that person. Furthermore, Regulation M may restrict the ability of any person engaged in the distribution of our securities to engage in market-making activities with respect to our securities. These restrictions may affect the marketability of our securities and the ability of any person or entity to engage in market-making activities with respect to our securities.

Certain persons participating in an offering may engage in over-allotment, stabilizing transactions, short-covering transactions, penalty bids and other transactions that stabilize, maintain or otherwise affect the price of the offered securities. These activities may maintain the price of the offered securities at levels above those that might otherwise prevail in the open market, including by entering stabilizing bids, effecting syndicate covering transactions or imposing penalty bids, each of which is described below:

- A stabilizing bid means the placing of any bid, or the effecting of any purchase, for the purpose of pegging, fixing or maintaining the price of a security.
- A syndicate covering transaction means the placing of any bid on behalf of the underwriting syndicate or the effecting of any purchase to reduce a short position created in connection with the offering.
- A penalty bid means an arrangement that permits the managing underwriter to reclaim a selling concession from a syndicate member in connection with the offering when offered securities originally sold by the syndicate member are purchased in syndicate covering transactions.

These transactions may be effected on an exchange or automated quotation system, if the securities are listed on that exchange or admitted for trading on that automated quotation system, or in the over-the-counter market or otherwise.

If so indicated in the applicable prospectus supplement, we will authorize agents, underwriters or dealers to solicit offers from certain types of institutions to purchase offered securities from us at the public offering price set forth in such prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. Such contracts will be subject only to those conditions set forth in the prospectus supplement and the prospectus supplement will set forth the commission payable for solicitation of such contracts.

In addition, ordinary shares, Preferred Shares, or ADSs may be issued upon conversion of or in exchange for debt securities or other securities.

Any underwriters to whom offered securities are sold for public offering and sale may make a market in such offered securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice. The offered securities may or may not be listed on a national securities exchange. No assurance can be given that there will be a market for the offered securities.

Any securities that qualify for sale pursuant to Rule 144 or Regulation S under the Securities Act, may be sold under Rule 144 or Regulation S rather than pursuant to this prospectus.

To the extent that we make sales to or through one or more underwriters or agents in at-the-market offerings, we will do so pursuant to the terms of a distribution agreement between us and the underwriters or agents. If we engage in at-the-market sales pursuant to a distribution agreement, we will sell our ordinary shares, Preferred Shares, or ADSs to or through one or more underwriters or agents, which may act on an agency basis or on a principal basis. During the term of any such agreement, we may sell ordinary shares, Preferred Shares, or ADSs on a daily basis in exchange transactions or otherwise as we agree with the underwriters or agents. The distribution agreement will provide that any ordinary shares, Preferred Shares, or ADSs sold will be sold at prices related to the then prevailing market prices for our ordinary shares, Preferred Shares, or ADSs. Therefore, exact figures regarding proceeds that will be raised or commissions to be paid cannot be determined at this time and will be described in a prospectus supplement. Pursuant to the terms of the distribution agreement, we also may agree to sell, and the relevant underwriters or agents may agree to solicit offers to purchase, blocks of our ordinary shares, Preferred Shares, ADSs or warrants. The terms of each such distribution agreement will be set forth in more detail in a prospectus supplement to this prospectus.

In connection with offerings made through underwriters or agents, we may enter into agreements with such underwriters or agents pursuant to which we receive our outstanding securities in consideration for the securities being offered to the public for cash. In connection with these arrangements, the underwriters or agents may also sell securities covered by this prospectus to hedge their positions in these outstanding securities, including in short sale transactions. If so, the underwriters or agents may use the securities received from us under these arrangements to close out any related open borrowings of securities.

We may enter into derivative transactions with third parties or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, such third parties (or affiliates of such third parties) may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, such third parties (or affiliates of such third parties) may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of shares, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of shares. The third parties (or affiliates of such third parties) in such sale transactions will be underwriters and will be identified in the applicable prospectus supplement (or a post-effective amendment).

We may loan or pledge securities to a financial institution or other third party that in turn may sell the securities using this prospectus. Such financial institution or third party may transfer its short position to investors in our securities or in connection with a simultaneous offering of other securities offered by this prospectus or in connection with a simultaneous offering of other securities offered by this prospectus.

LEGAL MATTERS

Certain legal matters with respect to Israeli law and with respect to the validity of the offered securities under Israeli law will be passed upon for us by Gross, Kleinhendler, Hodak, Halevy, Greenberg & Co., Tel Aviv, Israel. Certain legal matters with respect to U.S. federal securities law will be passed upon for us by Haynes and Boone LLP, New York, New York.

EXPERTS

The consolidated financial statements of Kitov Pharma Ltd. as of December 31, 2015 and 2014 and for each of the years in the three-year period ended December 31, 2015, have been incorporated by reference herein in reliance upon the report of Somekh Chaikin, a Member Firm of KPMG International, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

LEGAL PROCEEDINGS

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

Under applicable Israeli law, a motion to approve a lawsuit as a class action initially needs to be approved as such by the court. Only after such approval is granted by the court, will the court proceed to the second stage of hearing the underlying claims of the class action lawsuit. We announced that we reject the claims asserted in the Motion. We have delivered our response to the court in accordance with applicable law, and a preliminary hearing was held by the court on September 12, 2016. At such hearing the court determined that certain claims of the petitioners in connection with alleged personal interests by affiliates of the Company in connection with the public offering of our initial public offering of our securities in the U.S. during November 2015 are not part of the grounds for the Motion and no remedies shall be sought by the petitioners in connection therewith. The court set a schedule for the submission by the petitioners of a motion for discovery, and any responses to such motion, which have already been submitted by the parties to the Motion. An additional preliminary hearing was scheduled by the court for February 7, 2017. On November 8, 2016, a shareholder, submitted a request to the court in connection with the Motion to be excluded from the Purported Class and claiming to have independent causes of action and claims of approximately NIS 1 million (the “Petition to Exclude”). We responded to the court as required, and, amongst other arguments, we noted that pursuant to the Class Action Lawsuits Law 5766-2006 and the Regulations enacted thereunder, at the current stage of the court proceedings with respect to the Motion, such shareholder cannot petition to be excluded from the Purported Class. The court ordered the shareholder to respond to our response and he has done so. The shareholder has not submitted any independent lawsuit against us, and we are of the view that such shareholder’s claims are identical to the asserted claims for damages in the Motion.

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

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

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form F-3 under the Securities Act relating to the offering of our securities offered hereby. This prospectus does not contain all of the information contained in the registration statement. The rules and regulations of the SEC allow us to omit certain information from this prospectus that is included in the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we filed any of these documents as an exhibit to the registration statement, you may read the document itself for a complete description of its terms.

We are required to file reports and other information with the SEC under the Exchange Act, and the regulations thereunder applicable to foreign private issuers. We also furnish to the SEC under cover of Form 6-K material information required to be made public in Israel, filed with and made public by any stock exchange or distributed by us to our shareholders. You may read and copy the registration statement, including the related exhibits and schedules, and any document we file with the SEC without charge at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains an Internet site that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are also available to the public through this web site at <http://www.sec.gov>.

In addition, since our ordinary shares are traded on the TASE, in the past we filed Hebrew language periodic and immediate reports with, and furnished information to, the TASE and the Israel Securities Authority, or the ISA, as required under Chapter F of the Israel Securities Law, 1968. In accordance with Section 35XXXIII of the Israel Securities Law, and pursuant to the prior approvals of our securities holders to change to reporting in accordance with the U.S. securities laws and regulations, and in accordance with the exemption from reporting under Chapter F of the Law which was received by us from ISA pursuant to Section 35XXXII(1A) of the Law, as of December 31, 2015, we commenced reporting to ISA and the TASE in accordance with 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. Our major shareholders are required to make applicable ownership disclosures in accordance with U.S. securities laws and reporting requirements. We generally initially file or furnish our reports, as applicable, to the SEC. We then submit copies of the SEC filings and submissions to ISA and TASE, including any filings made by our major shareholders with respect to their holdings in the Company, in accordance with the Dual-Listed Reporting Requirements. Such copies can be retrieved electronically through the websites for listed company reports of ISA (www.magna.isa.gov.il) and TASE (maya.tase.co.il).

As a foreign private issuer, we will be exempt from the rules under the Exchange Act relating to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. As permitted under the Companies Law, and the Notice Regulations which were enacted pursuant to such law, and as set forth in our amended and restated articles of association, we are not required to physically deliver a notice of a shareholders meeting, a proxy statement or a voting slip. We prepare notices of general meetings of our shareholders, as well as the accompanying proxy statements, voting slips and voting instruction forms, (collectively, the "Proxy Materials") in accordance with applicable laws, rules and regulations and disclosure requirements in the State of Israel, as such are applicable to a company whose shares are traded on both the TASE and the NASDAQ, and which reports to the SEC as a foreign private issuer and to ISA and the TASE in accordance with the Dual-Listed Reporting Requirements. Our Proxy Materials may not necessarily be mailed to our beneficial shareholders in Israel, nor to our beneficial ADS holders in the U.S. We will furnish to the SEC on Form 6-K the forms of our Proxy Materials, and they will be made available to the public on the SEC's website at www.sec.gov. We will also submit the Proxy Materials to ISA and TASE and they will be made available to the public on their respective websites for listed company reports: www.magna.isa.gov.il and www.maya.tase.co.il. We will also include the Proxy Materials on our corporate website, to the extent required under the Companies Law and the applicable regulations enacted thereunder governing publication of notices of general meetings of our shareholders and the distribution of the Proxy Materials. The circulation of by us of any Proxy Materials should not be taken as an admission that we are subject to the proxy rules under the Exchange Act.

In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we intend to file with the SEC, within 120 days after the end of 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. Furthermore, we have committed to the underwriters of our initial U.S public offering which was completed in November 2015 that for a period of three (3) years from November 25, 2015, the Company, at its expense, will announce its financial information for each of the first three fiscal quarters consistent with the practices of companies which are dual-listed on both the TASE and a domestic U.S. securities exchange and report in accordance with the Dual-Listed Reporting Requirements; provided that the foregoing shall not apply in the event the Company enters into a merger transaction in which the Company is the non-surviving entity that would cause our ADSs and warrants to no longer be registered under the Exchange Act. We will furnish this periodic information with the SEC under cover of Form 6-K. The Representative of the underwriters of our initial U.S public offering which was completed in November 2015 previously waived any announcement by us with respect to the filing of financial information for the first quarter of 2016, and may issue such waivers to us in the future. It is noted that ISA has recently proposed draft legislation which would dispense with the requirement for the announcement of financial results for each of the first and third fiscal quarters of a calendar year. We would qualify for such dispensation based on our company size as set forth in the proposed draft legislation. In addition the SEC has recently announced that it is seeking comment for the dispensation of the requirement for the announcement of financial results for each of the first and third fiscal quarters for certain U.S. domestic issuers. Thus it remains uncertain as to how companies dual-listed on both the TASE and a domestic U.S. securities exchange, and report in accordance with the Dual-Listed Reporting Requirements, will continue their practices with respect to the announcements of financial information for each of the first and third fiscal quarters, and it is possible that we may adopt practices for the announcement (if any) of financial information for each of the first and third fiscal quarters which are different than what we have provided in the past.

We maintain a corporate website at www.kitovpharma.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference. We will post on our website any materials required to be posted on such website under applicable corporate or securities laws and regulations, including posting any notices of general meetings of our shareholders.

INCORPORATION BY REFERENCE

The SEC allows us to incorporate by reference the information we file with or furnish to the SEC, which means that we can disclose important information to you by referring you to another document filed or furnished separately with the SEC. The information incorporated by reference is considered to be part of this prospectus. Any information that we file or furnish later with the SEC and that is deemed incorporated by reference will also be considered to be part of this prospectus and will automatically update and supersede the information in this prospectus. In all cases, you should rely on the later information over different information included in this prospectus. This prospectus incorporates by reference the documents listed below, and any future Annual Reports on Form 20-F that we file with the SEC and certain Reports on Form 6-K that we furnish to the SEC (but only to that extent that such Form 6-K states that it is incorporated by reference herein), in each case, between the date of the initial registration statement and the effectiveness of the registration statement and following the effectiveness of the registration statement until the offering of the securities under the registration statement is terminated:

- The description of our ordinary shares, no par value per share, and the American Depositary Shares representing the ordinary shares, contained in Item 1 of the Registration Statement on Form 8-A (File No. 001-37643) filed with the Commission on November 18, 2015;
- our Annual Report on Form 20-F for the fiscal year ended on December 31, 2015, filed with the SEC on March 18, 2016; and
- our reports on Form 6-K furnished to the SEC on May 20, 2016, May 24, 2016, May 26, 2016, June 27, 2016 (2 reports), June 29, 2016, July 5, 2016, July 13, 2016, August 17, 2016 (limited to the text which is found under the headings entitled “Financial Results for Six Months Ended June 30, 2016” and “Balance Sheet Highlights”, respectively, in Exhibit 99.1 attached thereto; and, the entire Exhibit 99.2 attached thereto), September 27, 2016 (film number 161903448 only), October 3, 2016, October 27, 2016, November 2, 2016, December 6, 2016, and December 7, 2016.

We will provide, free of charge, to each person, including any beneficial owner, to whom this prospectus is delivered, a copy of any or all information that has been incorporated by reference into this prospectus, but which has not been delivered with the prospectus, upon written or oral request to us at the following address:

Kitov Pharma Ltd.
One Azrieli Center, Round Tower, 23rd Floor
132 Menachem Begin Rd.
Tel Aviv 6701101, Israel
Tel: +972-3-9333121
Attention: Chief Financial Officer

You should rely only on the information contained or incorporated by reference in this prospectus or a prospectus supplement. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus and any accompanying prospectus supplement, as well as the information we previously filed with the SEC and incorporated by reference, is accurate only as of the dates on the front cover of those documents, or such earlier date, that is indicated in such documents. Our business, financial condition, results of operations and prospects may have changed since those dates.

ENFORCEABILITY OF CIVIL LIABILITIES

We are incorporated under the laws of the State of Israel. Service of process upon us and upon our directors and officers and the Israeli experts named in this prospectus, substantially all of whom reside outside the United States, may be difficult to obtain within the United States. Furthermore, because substantially all of our assets and substantially all of our directors and officers are located outside the United States, any judgment obtained in the United States against us or any of our directors and officers may not be collectible within the United States.

It may be difficult to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws because Israel is not the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable then it must be proved as a fact which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law.

Subject to specified time limitations and legal procedures, Israeli courts may enforce a United States judgment in a civil matter which, subject to certain exceptions, is non-appealable, including judgments based upon the civil liability provisions of the Securities Act and the Exchange Act and including a monetary or compensatory judgment in a non-civil matter, provided that:

- the judgments are obtained after due process before a court of competent jurisdiction, according to the laws of the state in which the judgment is given and the rules of private international law currently prevailing in Israel;
- the prevailing law of the foreign state in which the judgments were rendered allows the enforcement of judgments of Israeli courts (however, the Israeli courts may waive this requirement following a request by the attorney general);
- adequate service of process has been effected and the defendant has had a reasonable opportunity to be heard and to present his or her evidence;
- the judgments are not contrary to public policy, and the enforcement of the civil liabilities set forth in the judgment does not impair the security or sovereignty of the State of Israel;
- the judgments were not obtained by fraud and do not conflict with any other valid judgment in the same matter between the same parties;
- an action between the same parties in the same matter is not pending in any Israeli court at the time the lawsuit is instituted in the foreign court; and
- the obligations under the judgment are enforceable according to the laws of the State of Israel and according to the law of the foreign state in which the relief was granted.

We have irrevocably appointed Puglisi & Associates, 850 Library Avenue, Suite 204, Newark, DE 19715 Tel: +1 (302) 738-6680 as our agent to receive service of process in any action against us in any United States federal or state court arising out of this offering or any purchase or sale of securities in connection with this offering.

If a foreign judgment is enforced by an Israeli court, it generally will be payable in Israeli currency, which can then be converted into non-Israeli currency and transferred out of Israel. The usual practice in an action before an Israeli court to recover an amount in a non-Israeli currency is for the Israeli court to issue a judgment for the equivalent amount in Israeli currency at the rate of exchange in force on the date of the judgment, but the judgment debtor may make payment in foreign currency. Pending collection, the amount of the judgment of an Israeli court stated in Israeli currency ordinarily will be linked to the Israeli consumer price index plus interest at the annual statutory rate set by Israeli regulations prevailing at the time. Judgment creditors must bear the risk of unfavorable exchange rates.

OFFERING EXPENSES

We are paying all of the expenses of the registration of our securities under the Securities Act, including, to the extent applicable, registration and filing fees, printing and duplication expenses, administrative expenses, accounting fees and the legal fees of our counsel. The following is a statement of estimated expenses at the present time in connection with the distribution of the securities registered hereby. All amounts shown are estimates except the SEC registration fee. The estimates do not include expenses related to offerings of particular securities. Each prospectus supplement describing an offering of securities will reflect the estimated expenses related to the offering of securities under that prospectus supplement.

SEC registration fees	\$ 23,180
Legal fees and expenses	\$ 20,000
Accountants fees and expenses	\$ 10,000
Miscellaneous	\$ 40,000
Total	<u>\$ 93,180</u>

3,428,572 American Depositary Shares Representing 3,428,572 Ordinary Shares

Kitov Pharma Ltd.

PROSPECTUS SUPPLEMENT

H.C. Wainwright & Co.

January 16, 2019
