

XTL BIOPHARMACEUTICALS LTD  
Form 6-K  
October 26, 2012

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**Form 6-K**

**Report of Foreign Private Issuer**

**Pursuant to Rule 13a-16 or 15d-16  
of the Securities Exchange Act of 1934**

For the month of October, 2012

Commission File Number: **000-51310**

XTL Biopharmaceuticals Ltd.  
(Translation of registrant's name  
into English)

**85 Medinat Hayehudim St., Herzliya  
Pituach, PO Box 4033,**

Herzliya 46140, Israel  
(Address of principal executive offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F

Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes

No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-  
N/A

**Incorporation by Reference: This Form 6-K of XTL Biopharmaceuticals Ltd. dated October 25, 2012 is hereby incorporated by reference into the registration statements on Form F-3 (File No. 333-141529, File No. 333-147024 and File No. 333-153055) filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on March 23, 2007, October 30, 2007 and August 15, 2008, respectively, and the registration statements on Form S-8 (File No. 333-148085, File No. 333-148754 and File No. 333-154795) filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on December 14, 2007, January 18, 2008, and October 28, 2008, respectively.**

**XTL Biopharmaceuticals Ltd. (the “Company”) Convenes an Extraordinary Special Meeting**

Attached hereto is an English translation (from Hebrew) of a notice for convening an Extraordinary General Meeting, as submitted on the Tel Aviv Stock Exchange (TASE).

In order to vote, ADR holders should contact Ms. Agness Moskowitch, BNY Mellon Depository Receipts at Tel (212) 815 8223.

The following documents are included:

- A. Notice of Extraordinary General Meeting Regarding Extraordinary Private Placement.
- B. Kitov Pharmaceuticals Ltd. Company Outline.
- C. Kitov Pharmaceuticals Ltd. Valuation Study.

XTL BIOPHARMACEUTICALS LTD.

("The Company")

October 24, 2012

To The Securities Authority To The Tel Aviv Stock Exchange Ltd. ("TASE")  
Through the Magna Through the Magna  
www.isa.co.il www.tase.co.il

**An immediate report with respect to convening an extraordinary general meeting of Company Shareholders in accordance with the Israeli Securities Regulations (Periodic and Immediate Reports) 1970, and the Israeli Securities Regulations (Private Offering of Securities in a Listed Company) 2000.**

## **Introduction**

Pursuant to the immediate reports published by the Company on April 15, 2012, on June 19, 2012 and on September 10, 2012 and in accordance with the Israeli Securities Regulations (Private Offering of Securities in a Listed Company) 2000, ("**Private Offering Regulations**"), Regulation 36 to the Israeli Securities Regulations (Periodic and Immediate Reports) 1970 ("**Periodic and Immediate Reports Regulations**"), and in accordance with the resolution of the Company's Board of Directors of October 21, 2012, the Company hereby announces the convening of an extraordinary general meeting of the Company's Shareholders ("**the General Meeting**" or "**Meeting**"), which will convene on Wednesday, November 28, 2012, at 9:00 AM, at the law offices Kantor & Co., 12 Abba Hillel Silver Rd., 8<sup>th</sup> Floor, Ramat-Gan, Israel and with the resolutions detailed in this report on its agenda as follows:

### 1. Condensed Description of the Transaction and its Main Terms

On October 21, 2012 The Company's Board of Directors approved convening a Meeting of Company Shareholders object of this report for the purpose of approving the Company's engagement in a Purchase Agreement with Kitov Pharmaceuticals Ltd. (hereinafter: "**Kitov**") according to which a new private company will be merged, wholly owned 100% by the Company which will be established only for the purpose of the merger (hereinafter: "**NewCo**"), by way of a reverse triangular merger with Kitov following which NewCo will cease to exist (hereinafter: "**the Purchase Agreement**"). As a result of completing the Purchase Agreement, Kitov will become a private company wholly owned (100%) by the Company and Kitov shareholders and additional service providers of Kitov (hereinafter: "**the Offerees**") will receive shares and warrants for Company shares as well as various milestone payments throughout the development process of Kitov products, and all as detailed below:



On the date of completion of the Purchase Agreement, the Company will pay the Offerees an amount of USD 140 thousand in cash and issue: (1) 8,709,052 ordinary shares of the Company to Kitov shareholders (hereinafter: "**Completion Shares**"); and (2) 218,728 unregistered warrants to Kitov Service Providers for the purchase of 218,728 Company shares (hereinafter; "**Service Providers Warrants**"). In addition to the securities aforementioned, the Company will issue the Offerees 612,800 warrants for the purchase of 612,800 Company shares (hereinafter: "**The Additional Warrants**").

1.1. The Additional Warrants will be exercisable in return for an exercise consideration equivalent to NIS 0.01 per Additional Warrant<sup>1</sup>, at the earlier of either the passing of 18 months from the Completion Date or after the Company has completed raising cumulative capital in the amount of USD 4 million. Alternatively, the Additional Warrants will be annulled immediately upon the Offerees receipt of USD 160 thousand from the Company. All the aforesaid securities issued to the Offerees at the date of completion of the Purchase Agreement constitute 3.59% of the Company's fully diluted issued and outstanding share capital. For additional details regarding the securities issued by the Company according to the Purchase Agreement see paragraph 4 to the Transaction Report.

Pursuant to the completion of the Purchase Agreement and subject to the fulfillment of the milestones contingent to the progress of development of Kitov drugs, as stated the Purchase Agreement, the Company will pay the Offerees up to seven (7) additional payments that are likely to jointly amount to a total of USD 61 million (hereinafter: "**Milestone Payment**").

1.2. The Company has the sole discretion at any time to convert any of the milestone payments, by means of an issuance of up to 91,828,110 Company shares (assuming that all milestones have been completed), which will constitute up to approximately 25.70% of the Company's issued and outstanding share capital (fully diluted) immediately upon completing the Purchase Agreement (or approximately 28.37% of the Company's fully diluted issued and outstanding share capital including the securities issued according to paragraph 1.1 above). Milestones Payments will be paid as long as the said milestones are fulfilled during the course of 5 years from the Completion Date.

The securities issued according to the Purchase Agreement are brought for approval by the Company by means of an issuance of Company shares through an extraordinary Private Placement in accordance with the Israeli Securities Regulations (Private Offering of Securities in a Listed Company, 2000) (hereinafter: "**the Regulations**").

It should be noted that in light of the fact that the transaction, object of this report, does not comply with the definition 'Business Combination', the accounting treatment of the transaction as aforesaid is as purchase of intellectual property against the issuance of shares/warrants so that following the completion of the transaction the intellectual property will be recorded in the Company books in accordance with the value set in the valuation report conducted by an external valuator and enclosed as **Appendix C** to the Transaction Report.

For details about Kitov see a description of Kitov attached to the Transaction Report as **Appendix A**.

<sup>1</sup> After the planned 1:10 share consolidation, the exercise price of 61,280 Additional Warrants will be NIS 0.1 per each Additional Warrant. It should be noted that the difference between the exercise price of the Additional Warrants and the nominal value of the Company shares will be covered at the date of exercising the Special Warrants, should and to the extent that they will be exercised, by transferring in the Company's financial statements the total sum of the difference from the premium on shares clause to the share capital clause.

## 2. Description of the topics on the agenda

The Purchase Agreement, including the extraordinary private placement in respect thereof, is presented for approval as a whole, together with all the engagements and resolution required for its fulfillment, as detailed below:

- 2.1. Approve the Company's engagement in a Purchase Agreement including an extraordinary Private Offering in respect thereof, which includes the Completion Shares, Additional Warrants, Service Providers Warrants, and payment of milestones or alternatively, at the Company's sole discretion, allocation of shares in accordance with the milestones stipulated in the Purchase Agreement,.
- 2.2. Approve to consolidate the Company's capital at a ratio of 10:1 in a manner that every 10 Company shares of NIS 0.1 par value each will be consolidated as one share of NIS 1.0 par value each.
- 2.3. Approve the appointments, in accordance with the Company's Articles of Association, of Messers Dr. Paul Waymack and Mr. Simcha Rock as Directors in the Company until next year's annual general meeting. The vote regarding each of the directors as aforesaid will be done separately. Declarations of candidates for appointment as directors are enclosed as Appendix B to the report.
- 2.4. Approve the Company's engagement in a service agreement with Dr. Paul Waymack with regard to his position as Chairman of the Company's Board of Directors and as executive in charge of the clinical and regulatory development of all the Company's products in return for a monthly management fee of USD 9,166 plus VAT, as applicable. For details regarding the service provider agreement see paragraph 15.4 of the Transaction Report.

It is clarified hereto that the approval of the Audit Committee and the Company's Board of Directors is given to the Company's engagement in the Purchase Agreement and for executing transactions and engagements entailed in this transaction, as a whole, including the appointments and agreements detailed in paragraphs 2.1 – 2.4 above.

**It is hereby clarified that all the resolutions on the meeting's agenda are interconnected resolutions, namely that the rejection of one of the resolutions may be deemed as a rejection of the other resolutions even though another resolution has been accepted and approved by the extraordinary general meeting of the Company's shareholders.**

## 3. The private placement Offerees and the status as interested party

According to the Purchase Agreement object of this Transaction Report, the Offerees in the Private Placement are Kitov shareholders and Additional Service Providers of Kitov. The names of the Offerees alongside mention of their



holdings in Kitov at the time of this report and their holdings in the Company close to the transaction Completion Date are detailed hereunder:

Offeree's name	Holding in Kitov		Holding in the Company after the completion date of the Purchase Agreement <sup>2</sup>					
	Nr. of shares	% Holding	Shares	Warrants	% Holding	% Holdings fully diluted		
JPW PCH LLC <sup>3</sup>	8,000,000	80 %	7,119,907	488,708	2.99 %	2.86 %		
Moshe Laster	2,000,000	20 %	1,589,145	109,078	0.67 %	0.64 %		
Simcha Rock	-	-	-	23,851	-	0.01 %		
Clal Underwriting	-	-	-	71,554	-	0.03 %		
Ronen Kantor <sup>4</sup>	-	-	3,792,908	174,486	1.59 %	1.49 %		
Charity Fund <sup>5</sup>	-	-	-	23,851	-	0.01 %		
Total	10,000,000	100 %	12,501,960	891,528	5.25 %	5.04 %		

assuming that any or all of the milestones will be fulfilled and the Company will choose, ensuing the payment of the milestone to issue to the Offerees Company shares, to the best of the Company's knowledge, JPW PCH LLC (hereinafter: "**JPW**"), will become an interested party in the Company and this in light of the fact that following the issuances ensuing the payment of the milestones aforementioned, it will hold shares constituting over 5% of the Company's issued and outstanding capital.

#### 4. The terms, number and percentage the offered securities constitute in the Company's share capital after the issuance

In consideration for the assignment of Kitov's share capital in full in a manner that Kitov will become a company fully owned (100%) by the Company, the Company will allocate to the Offerees, at the date of completion of the Purchase Agreement, 8,709,052 ordinary shares of NIS 0.1 par value each of the Company, at a price per share of NIS 1.641<sup>6</sup> ("**the Price Per Share in a Private Placement** ") and also will allocate to Kitov's service providers 218,728 warrants, unregistered, for the purchase of 218,728 Company shares ("**Services Providers Warrants**"). In addition to the aforementioned securities, the Company will allocate 612,800 warrants for the purchase of 612,800 Company shares to Kitov shareholders and Kitov service providers (hereinafter: "**The Additional** 4.1. **Warrants**"). The Additional Warrant will be exercisable against an exercise price equivalent to NIS 0.01 for each Additional Warrant<sup>7</sup> (hereinafter: "**Additional Warrants Exercise Price**"), at the earlier of either the passing of 18 months from the Completion Date or after the Company has completed raising cumulative capital in the amount of USD 4 million. Alternatively, the Additional Warrants will be cancelled immediately upon the Offerees receipt of USD 160 thousand from the Company or the passing of five (5) years, i.e. until October 23, 2017 ("**The Latest Date for Exercising the Additional Warrants**"). All the aforesaid securities issued to the Offerees at the date of completion of the Purchase Agreement constitute approximately 3.59% of the Company's fully diluted issued and outstanding share capital.

<sup>2</sup> The data presented is as at the date of completion of the Agreement and prior to the fulfillment of any of the milestones. Additionally, it should be noted that the figures detailed in this table are prior to executing the share consolidation of Company capital at a 10:1 ratio

<sup>3</sup> A Company incorporated in the United States controlled by Messers Dr. Peter Hoyle and Dr. Paul Waymack

<sup>4</sup> It should be noted that Mr. Ronen Kantor holds prior to the private placement object of this Report 3,792,908 Company ordinary shares of NIS 0.1 par value each of the Company and 60,000 warrants exercisable into 60,000 Company ordinary shares of NIS 0.1 par value each.

<sup>5</sup> Kitov shareholders decided to donate 0.25% of Kitov to the Pelech charity.

<sup>6</sup> It should be noted that the price of the share in the private placement according to this report is determined through negotiations between the Company and the Offerees based, *inter alia*, on the share's average trading price on the Tel-Aviv Stock Exchange during the 21 days prior to the date of approval by the Company's Board of Directors and also, in consideration of the fact that the securities offered according to this report are "restricted" both by voluntary restriction and according to the Purchase Agreement and also pursuant to provisions of paragraph 15c of the Israeli Securities Law 1968, and the Israeli Securities Regulations (details pertaining paragraphs 15a and 15c of the Law), 2000. The price per share in the private placement according to the Tel Aviv Stock Exchange was calculated by way of dividing the relative part in Kitov's valuation (out of a total valuation of Kitov (approximately USD 40.2 million) USD 36 million, which are related to future consideration upon milestone payments were discounted of the total valuation of Kitov according to the valuation for this calculation) according to the valuation in a total of issued securities that are issued in the Completion Date.

<sup>7</sup> After the planned 1:10 share consolidation, the exercise price of 61,280 Additional Warrants will be NIS 0.1 per each Additional Warrant. It should be noted that the disparity between the exercise price of the Additional Warrants and the nominal value of the Company shares will be covered at the date of exercising the Special Warrants, should and to the extent that they will be exercised, by transferring in the Company's financial statements the total sum of the disparity from the premium on shares clause to the share capital clause.

4.2. The Service Providers' Warrant will be exercisable on any trading day starting at the date of their issuance and for a period of five (5) years, i.e., until October 23, 2017 ("**The Latest Date for Exercising Service Providers Warrants**") at an exercise price equivalent to the nominal value of a Company share ("**Exercise Price of Service Providers Warrants**").

4.3. Service Providers Warrants or and Additional Warrants not exercised until the expiry of latest exercising date will be annulled and will not provide the Offerees any right or claim whatsoever.

4.4. For details pertaining to the rights deriving from the shares and the shares that will derive from exercising the Service Providers Warrants and the Additional Warrants including how they will be listed and adjusted, see paragraph 12 hereunder.

4.5. For details pertaining to the percentage which the securities constitute in the voting rights and the Company's issued and outstanding share capital after the issuance and assuming that the Offerees will convert and exercise their issued securities according to this report, see paragraph 3 above.

#### 5. Consideration for the offered securities

In accordance with the provisions of the Purchase Agreement, in consideration for the issuance of 8,709,052 ordinary shares of NIS 0.1 par value each. of the Company, the issuance of the Service Providers Warrants and Additional Warrants (as defined above) to the Offerees, the Offerees will assign to NewCo all of Kitov shares which they hold and constitute 100% of Kitov's issued capital so that upon completion of the transaction, object of this report, the Offerees will hold approximately 3.66% of the Company's issued and outstanding share capital and approximately 3.59% on a fully diluted basis and the Company will hold (through NewCo) 100% of Kitov's issued and outstanding share capital ("**The Consideration**").

It should be noted that in accordance with the provisions of the Purchase Agreement, the Company has an undertaking to pay throughout the process of development of Kitov products various milestone, in cash, payments that can jointly amount to a total of approximately USD 61 million. Alternatively, the Company is entitled to pay any of the milestone payments, or all of them, by issuing up to 91,828,110 shares, all at the Company's sole discretion and subject to the fulfillment of the milestones as detailed in paragraph 12.8 hereunder.

6. The price of the Company shares in the extraordinary private placement and their quoted market price on the stock exchange

The price per share at the Private Placement in accordance with this report as aforesaid in paragraph 4.1 above was determined through negotiations between the Company and the Offerees bases, *inter alia*, on the share's average trading price on the Tel-Aviv Stock Exchange during the 21 days prior to the date of approval by the Company's Board of Directors and also, in consideration of the fact that the offered securities according to this report are "restricted" both by voluntary restriction according to Purchase Agreement and also in accordance with the provisions of paragraph 15c of the Israeli Securities Law 1968, and the Israeli Securities Regulations (details pertaining paragraphs 15a and 15c of the Law), 2000. The price per share on the stock exchange on the day before to the date of this report is NIS 1.296. The price per share in the Private Placement is higher than the share price on the stock exchange on the day before the date of this report by approximately 26.6%.

7. Names of directors who have personal interest in the private placement and the nature of the personal interest

To the best of the Company's knowledge none of the directors serving on the Company's Board of Directors have personal interest in the private Offering object of this report.

8. Announcement of convening an extraordinary general meeting of the Company's shareholders

In accordance with the Israeli Companies Law, 1999 ("**the Companies Law**"), an announcement is hereby provided of the convening of an extraordinary general meeting of the Company's shareholders to be held on Wednesday, November 28, 2012 at 09:00 a.m. at the law offices of Kantor & Co. on 12 Abba Hillel Silver, 8th floor, Ramat-Gan, Israel with on its agenda a Purchase Agreement including an extraordinary Private Placement in respect thereof, as detailed above presented for approval, as a whole, together with all the resolutions and engagements required for its completion, as follows:

- 8.1. Approve the Company's engagement in a Purchase Agreement including an extraordinary Private Placement in respect thereof, which includes the Completion Shares, Additional Warrants, Service Providers' Warrants, payment of the milestones or alternatively, at the Company's sole discretion, allocation of shares in accordance with the milestones stipulated in the Purchase Agreement.
- 8.2. Approve to consolidate the Company's capital at a ratio of 10:1 in a manner that every 10 Company shares of NIS 0.1 par value each will be consolidated as one share of NIS 1.0 par value each.
- 8.3. Approve the appointments, in accordance with the Company's Articles of Association, of Messers Dr. Paul Waymack and Mr. Simcha Rock as Directors in the Company until next year's annual general meeting. The vote regarding each of the directors as aforesaid will be done separately. Declarations of candidates for appointment as directors are enclosed as Appendix B to the report.
- 8.4. Approve the Company's engagement in a service agreement with Dr. Paul Waymack with regard to his position as Chairman of the Company's Board of Directors and as manager in charge of the clinical and regulatory development of all the Company's products in return for a monthly management fee of USD 9,166 plus VAT, as applicable. For details regarding the service provider agreement see paragraph 15.4 of the Transaction Report.

**It is hereby clarified that all the resolutions on the meeting's agenda are interconnected resolutions, namely that the rejection of one of the resolutions may be deemed as a rejection of the other resolutions even though another resolution has been accepted and approved by the extraordinary general meeting of the Company's shareholders.**

8.5. Meeting venue and date

- 8.5.1. The extraordinary general meeting will convene on Wednesday, November 28, 2012 at 09:00 AM at the law offices of Kantor & Co. on 12 Abba Hillel Silver, 8th floor, Ramat-Gan, Israel. A deferred meeting, if necessary, will convene on Wednesday, December 5, 2012 at the same place and time.

- 8.5.2. In the extraordinary general meeting, a legal quorum will constitute the presence of at least two (2) shareholders, represented by themselves or by their proxies, who hold or represent together at least 33.33% of the voting rights in the Company. If at the elapse of thirty minutes from the meeting's scheduled date, the legal quorum is not achieved, the meeting will be automatically deferred to the same day of the following week, at the same time and place as scheduled for the original meeting; or to a different time or place as decided by the board of directors in an announcement to the shareholders. If in such deferred meeting no legal quorum is obtained within thirty minutes from the scheduled date, two shareholders that are present by themselves or by a proxy will form a legal quorum and the meeting will be entitled to discuss the issues on the agenda.

8.5.3.

The date for establishing the shareholders' right to vote in the general meeting, as stipulated in Section 182 to the Israeli Companies Law, is Monday, October 29, 2012 ("**the meeting participation record date**").

8.5.4. Any existing shareholder of the Company on the record date, whether or not the shares are registered in its name or are held by it through a member of the Stock Exchange, is entitled to participate in the meeting by itself or via a proxy. In accordance with the Israeli Companies Regulations (Proof of Share Ownership for Voting in General Meetings), 2000, a Company shareholder whose shares are held by a member of the Stock Exchange will be able to participate in said meeting by itself or via a proxy provided that an original proof of Company share ownership on the meeting participation record date is delivered to the Company before the meeting (to be obtained by that member of the Stock Exchange). Any documents appointing proxies ("**the letters of appointment**") as well as the original authorizations under which the letters of appointment (if any) were signed must be deposited with the Company's registered headquarters up to 48 hours prior to the date of the meeting.

8.5.5. A written format of the voting paper and statements of position, if any, can be found at the Israel Securities Authority's site at [www.magna.isa.gov.il](http://www.magna.isa.gov.il) and at the TASE's site at [www.tase.co.il](http://www.tase.co.il). In addition, a shareholder may apply to the Company directly for receiving the written format of the voting paper and statements of position, if any. A member of the Stock Exchange will send, at no consideration, via e-mail, a link to the written format of the voting paper and statements of position, if any, to each shareholder that is not registered with the Company's shareholders' registrar and whose shares are listed with that member of the Stock Exchange, if the shareholder has notified the member of the Stock Exchange of its wish and provided that the notice was made with respect to a certain securities account and prior to the record date. Any shareholder whose shares are listed with a member of the Stock Exchange is entitled to receive proof of ownership from the relevant member of the Stock Exchange at the member of the Stock Exchange's branch or by mail to their address in return for payment of delivery fees only, if so requested, and this application will be granted in advance to the relevant securities account. Pursuant to the Israeli Companies Regulations (Voting Paper and Statements of Position), 2005, that shareholder will vote on the second part of the voting paper and specify the manner of voting and deliver it to the Company or mail it via registered mail whereby the proof of ownership must reach the Company's headquarters no later than 72 hours prior to the meeting date.

8.5.6. The Company does not allow voting via the internet.

8.5.7. One or more shareholders that hold at least five percent or more of total voting rights and also hold such rate of total voting rights that are not held by the controlling shareholder in the Company, as defined in Section 286 to the Israeli Companies Law, are entitled to review the voting papers as detailed in Regulation 10 to the Israeli Companies Regulations (Voting Paper and Statements of Position), 2005.

8.5.8. The last date for producing statements of position is within ten days after the meeting participation record date ("**the last statement of position date of delivery**"), namely: Thursday, November 8, 2012 and the last date for producing the board of directors' response to the statements of position is five days after the last statement of position date of delivery, namely Tuesday, November 13, 2012.



8.6. The required decision passing majority

- 8.6.1. The majority required for passing of the decision mentioned in paragraphs 8.1 – 8.4 above is an ordinary majority of the voting participants.

9. Review of Documents

The documents pertaining to this report may be reviewed at the law offices of Kantor & Co. on 12 Abba Hillel Silver, 8<sup>th</sup> floor, Ramat-Gan, Israel during standard work hours and after advance coordination by telephone: +(972)-3-6133371.

XTL BIOPHARMACEUTICALS LTD.

("The Company")

October 24, 2012

To The Securities Authority To The Tel Aviv Stock Exchange Ltd. ("TASE")  
Through the Magna Through the Magna  
www.isa.co.il www.tase.co.il

**An immediate report regarding an extraordinary private placement pursuant to the Securities Regulations (Private Offering of Securities in a Listed Company) 2000, and pursuant to Regulation 36 of the Israeli Securities Regulations (Periodic and Immediate Reports) 1970 and with respect to convening an extraordinary general meeting that will have on its agenda, inter alia, approval of an extraordinary private offering, in accordance with the purchase agreement signed between the Company and Kitov Pharmaceuticals Ltd.**

## 10. Introduction

On September 9, 2012 the Company's board of directors approved the Company's engagement in a Purchase Agreement with Kitov Pharmaceuticals Ltd. (hereinafter: "**Kitov**") according to which a new private company will merge, wholly owned 100% by the Company which will be established only for the purpose of the merger (hereinafter: "**NewCo**"), by way of a reverse triangular merger with Kitov following which NewCo will cease to exist (hereinafter: "**the Purchase Agreement**"). As a result of completing the Purchase Agreement, Kitov will become a private company wholly owned (100%) by the Company and Kitov shareholders and additional service providers of Kitov (hereinafter: "**the Offerees** ") will receive shares and warrants for Company shares as well as payments of various milestones throughout the development process of Kitov products, all as detailed below:

On the date of completion of the Purchase Agreement, the Company will issue: (1) 8,709,052 ordinary shares of the Company to Kitov shareholders (hereinafter: "**Completion Shares**"); and (2) 218,728 unregistered warrants for the purchase of 218,728 Company shares to Kitov Service Providers (hereinafter; "**Service Providers Warrants**"). In addition to the securities aforementioned, the Company will issue to the Offerees 612,800 warrants for the purchase of 612,800 Company shares (hereinafter: "**The Additional Warrants**"). The Additional Warrants will be exercisable in return for an exercise consideration equivalent to NIS 0.01 per 10.1. Additional Warrant<sup>8</sup>, at the earlier of either the passing of 18 months from the completion date or after the Company has completed raising cumulative capital in the amount of USD 4 million. Alternatively, the Additional Warrants will be annulled immediately upon the Offerees receipt of USD 160 thousand from the Company. All the aforesaid securities issued to the Offerees at the date of completion of the Purchase Agreement constitute 3.59% of the Company's fully diluted issued and outstanding share capital. For additional details regarding the securities issued by the Company according to the Purchase Agreement see paragraph 4 to the Transaction Report.

<sup>8</sup> After the planned 1:10 share consolidation, the exercise price of 61,280 Additional Warrants will be NIS 0.1 per each Additional Warrant. It should be noted that the difference between the exercise price of the Additional Warrants and the nominal value of the Company shares will be covered at the date of exercising the Special Warrants, should and to the extent that they will be exercised, by transferring in the Company's financial statements the total sum of the disparity from the premium on shares clause to the share capital clause.

Pursuant to the completion of the Purchase Agreement and subject to the fulfillment of the milestones contingent to the progress of the development of Kitov products, as stated in the Purchase Agreement, the Company will pay the Offerees up to seven (7) additional payments that are likely to jointly amount to a total of approximately USD 61 million (hereinafter: "**Milestone Payment**"). The Company has the sole discretion at any time to convert any of the milestone payments, by means of an issuance of up to 91,828,110 Company 10.2. shares (assuming that all milestones have been completed), which will constitute up to approximately 25.70% of the Company's issued and outstanding share capital (fully diluted) immediately upon completing the Purchase Agreement (or approximately 28.37% of the Company's fully diluted issued and outstanding share capital including the securities issued according to paragraph 10.1 above). Milestones Payments will be paid as long as the said milestones are fulfilled during the course of 5 years from the date of completion of the Purchase Agreement.

The securities issued according to the Purchase Agreement are presented for approval by the Company by means of an issuance of Company shares through an extraordinary private placement in accordance with the Israeli Securities Regulations (Private Offering of Securities in a Listed Company, 2000) (hereinafter: "**the Regulations**").

For details about Kitov see a description of Kitov attached to this Transaction Report as **Appendix A**.

The valuation of Kitov which was prepared by an external valuator is enclosed to the Transaction Report as **Appendix C**.

10.3. Execution of the Purchase Agreement as aforesaid and issuance of securities in respect thereof is conditioned, *inter alia*, by the approval of the Company's general meeting of shareholders for executing the extraordinary private placement aforesaid and any resolutions required by the Purchase Agreement as detailed above, receipt of a valuation report of Kitov as well as receipt of the pre-ruling approval from the Israeli Tax Authority as detailed below, and this no later than November 23, 2012 (hereinafter: "**the Record Date**"). For additional details regarding the prerequisites for executing the Purchase Agreement see paragraph 14.1.2 hereunder.

## 11. Details of the Offerees

The Offerees are Kitov shareholders and additional service providers of Kitov. For details regarding the Offerees who will hold the status of interested parties in the Company pursuant to the completion of the transaction object of the report see paragraph 3 of this report.

**12. The terms, number and percentage the offered securities will constitute of the Company's share capital after the issuance**

In consideration for the transfer of Kitov's share capital in full in a manner that Kitov will become a company fully owned (100%) by the Company, the Company will allocate to the Offerees, at the Completion Date of the Purchase Agreement 8,709,052 ordinary shares of NIS 0.1 par value each of the Company, at a price per share of NIS 1.641<sup>9</sup> ("**the Price Per Share in the Private Placement** ") and also will allocate to Kitov's service providers 218,728 warrants, unregistered, for the purchase of 218,728 Company shares ("**Services Providers Warrants**"). In addition to the aforementioned securities, the Company will allocate to Kitov shareholders and Kitov service providers 612,800 warrants for the purchase of 612,800 Company shares (hereinafter: "**The** 12.1. **Additional Warrants**"). The Additional Warrant will be exercisable against an exercise price equivalent to NIS 0.01 for each Additional Warrant<sup>10</sup> (hereinafter: "**Additional Warrants Exercise Price**"), at the earlier of either the passing of 18 months from the completion date or after the Company has completed raising cumulative capital in the amount of USD 4 million (the Additional Warrants not exercised within the 5 years since their issue will expire). Alternatively, the Additional Warrants will be annulled immediately upon the Offerees receipt of USD 160 thousands from the Company. All the aforesaid securities issued to the Offerees at the Completion Date of the Purchase Agreement constitute approximately 3.59% of the Company's fully diluted issued and outstanding share capital.

The Service Providers' Warrant will be exercisable on any trading day starting at the date of their issuance and for a period of five (5) years, i.e., until October 23, 2017 ("**The Latest Date for Exercising Service Providers** 12.2. **Warrants**") at an exercise price equivalent to the nominal value of a Company share ("**Exercise Price of Service Providers Warrants**").

12.3. A Service Providers Warrant or and Additional Warrant not exercised until the expiry of latest exercising date will be annulled and will not provide the Offerees any right or claim whatsoever.

The shares and also the shares deriving from the exercise of the Service Providers Warrants or from the exercise of the Additional Warrants (hereinafter jointly: "The Warrants" and "The Exercise Shares") will provide the right to receive invitations, to participate and vote at Company meetings. All Company shares, including the 12.4. aforesaid Exercise Shares, have equal rights between them with regard to the capital amounts paid or credited as paid on their nominal value, with any regard to dividend, and any other distribution and to the participation in distribution of excess Company assets at winding-up.

<sup>9</sup> It should be noted that the price of the share in the private placement according to this report is determined through negotiations between the Company and the Offerees based, *inter alia*, on the share's average trading price on the Tel-Aviv Stock Exchange during the 21 days prior to the date of approval by the Company's Board of Directors and

also, in consideration of the fact that the securities offered according to this report are "restricted" both by voluntary restriction and according to the Purchase Agreement and also pursuant to provisions of paragraph 15c of the Israeli Securities Law 1968, and the Israeli Securities Regulations (details pertaining paragraphs 15a and 15c of the Law), 2000. The price per share in the private placement according to the Tel Aviv Stock Exchange was calculated by way of dividing the relative part in Kitov's valuation (out of a total valuation of Kitov (approximately USD 40.2 million) USD 36 million, which are related to future consideration upon milestone payments were discounted of the total valuation of Kitov according to the valuation for this calculation) according to the valuation in a total of issued securities that are issued in the Completion Date.

<sup>10</sup> After the planned 1:10 share consolidation, the exercise price of 61,280 Additional Warrants will be NIS 0.1 per each Additional Warrant. It should be noted that the difference between the exercise price of the Additional Warrants and the nominal value of the Company shares will be covered at the date of exercising the Special Warrants, should and to the extent that they will be exercised, by transferring in the Company's financial statements the total sum of the disparity from the premium on shares clause to the share capital clause.

- 12.5. The Shares and also the Exercise Shares will be listed in the Company's name on those lists through which the Company shares will be listed at that time.

- 12.6. Pursuant to the Regulations of the Tel-Aviv stock Exchange due to the transition to clearing on day T+1 for convertible unregistered shares and securities, the conversion of warrants will not be executed on the record date for distribution of the bonus shares, placement by means of rights, distribution of dividend, consolidation of capital, splitting of capital or reduction of capital (each of the above mentions referenced hereinafter as: "**Company Event**"). Additionally, if the X day of a Company Event occurs prior to the record date of the Company Event, then no conversion will be executed on the X day as aforesaid.

- 12.7. Pursuant to the issuance of securities to the Offerees in accordance with the aforesaid in this report, the exercise price and number of warrants not yet exercised will be adjusted in the instances detailed hereunder:

#### 12.7.1. Distribution of bonus shares

Should the Company distribute bonus shares from the date of this allocation report until the end of the exercise period of the warrants the rights of the holders of warrants from the relevant series will be preserved in the manner detailed below:

- a. Immediately after the record date for determining the right to participate in the said distribution the number of exercise shares to which the holder of the warrants will be entitled to upon their exercise will grow, by means of adding the number of shares that the said holder was entitled to then as bonus shares, should he have exercised the said warrants immediately prior to the aforesaid record date.

b. According to the aforementioned, holder of a warrant will not have the right to partial allocation of the bonus shares, however all the fractional bonus shares that will be formed at the time of the allocation and will accumulate to complete shares will be sold on TASE, through a trustee appointed for this purpose by the Company, within thirty (30) days from the date for the aforesaid allocation, and the net consideration (after deduction of the sale expenses and compulsory payment of levies), will be distributed between those entitled to them within fifteen (15) days from the date of sale. No single check for an amount less than NIS 50 will be sent to an entitled person, whereas such sums will be available for collection at the Company offices on regular working days and during regular working hours. An entitled person, as aforesaid who did not arrive at the Company offices to receive this sum as mentioned within twelve (12) months from the date of sale, will forfeit his entitlement to the sum.

c. Subject to the Regulations and Provisions of the Stock Exchange the method of adjustment detailed above is not subject to change.

#### 12.7.2. Rights Issuance

Should the Company offer its shareholders securities of any kind whatsoever by way of an issuance of rights, from the date of this allocation report and until the end of the Warrants Exercise Period, the number of exercise shares for exercising the warrants from the relevant series, that have not yet been exercised into the Company's regular shares at the date set for entitlement to the rights offered at the rights issue, will be adjusted in accordance with the bonus component of the rights as expressed in the ratio between the share value on the stock exchange on the said record date to the base "ex rights" price. Subject to the Israeli Regulations and Provisions of the stock exchange, the adjustment method detailed above is not subject to change.

#### 12.7.3. Distribution of Dividend

Should the Company distribute dividend in accordance with its definition in the Israeli Companies Law ("**The Distribution**"), for which the record date stipulating the right of distribution will occur prior to the end of the Warrants Exercise Period, starting on the first trading day the Company shares will be traded on after the record date for distribution, the exercise price of the aforesaid warrants will be adjusted by multiplying it with the ratio between the Company share price on the stock exchange, adjusted to the distribution of dividend, as will be determined by the stock exchange ("Ex-Dividend Rate") and the closing price determined by the stock exchange for Company shares on the aforesaid record date.

Pursuant to the completion of the Purchase Agreement and subject to the fulfillment of the milestones contingent to the progress of development of Kitov drugs, as stipulated in the Purchase Agreement, the Company will pay the Offerees the Milestone Payment. The Company has the sole discretion at any time to  
12.8. convert any of its milestone payments, by means of an allocation of 91,828,110 shares of the Company (assuming that all the milestone has been fulfilled), that will constitute approximately 25.70% of the Company (fully diluted) issued and outstanding share capital immediately upon completion of the Purchase Agreement and all of these at the Company's sole discretion as detailed in the table below<sup>11</sup>:

<sup>11</sup> Terms that are not defined in this table will have their meaning recorded alongside them in the Kitov description attached as **Appendix A** to this transaction report.





Milestone	Essence of Milestone	Payment in cash USD	Payment in shares	Upon the fulfillment of milestone 2A		Upon the fulfillment of milestone 2B	
				% of company equity	<b>% of company equity</b> (fully diluted)	% of company equity	<b>% of company equity</b> (fully diluted)
Milestone 1	<p>Receipt of the FDA approval for an SPA for KIT-302. The Company, NewCo or Kitov will submit an SPA as an amendment to the IND of KIT-302 within 90 days from the Completion Date.</p> <p>Upon Successful completion by the Company or Kitov of the phase III clinical trial that will meet the results set in the trial protocol approved by the FDA, as a result of which the company will be able to publish an updating press release stating that the Phase III clinical trials has been successfully completed..</p> <p>Regardless of the aforementioned, the Company and Kitov have agreed that a successful completion of Phase III clinical trial will prevail also should the trial results support an NDA with regard to all the dosing strengths of the antihypertensive component in the drug. Additionally, is was decided that should the Company choose to start development of the KIT-301 drug instead of KIT-302, all the aforesaid conditions pertaining to KIT-302 will prevail on KIT-301 respectively.</p>	4,924,500	10,733,156	3.25 %	3.00 %	3.33 %	3.07 %
Milestone 1A	<p>and Kitov have agreed that a successful completion of Phase III clinical trial will prevail also should the trial results support an NDA with regard to all the dosing strengths of the antihypertensive component in the drug. Additionally, is was decided that should the Company choose to start development of the KIT-301 drug instead of KIT-302, all the aforesaid conditions pertaining to KIT-302 will prevail on KIT-301 respectively.</p>	6,567,000	14,310,874	4.34 %	4.01 %	4.43 %	4.09 %

Milestone 1B	Upon the passing of six (6) months from the date of submitting the NDA to FDA with regard to KIT-302 or KIT-301, and without additional studies having been required by the FDA.	3,283,000	7,155,437	2.17%	2.00%	2.22%	2.04%
Milestone 2A*	Upon the successful completion of the partnership/marketing transaction of KIT-301 or KIT-302 with either: (1) A transaction of more than \$30 million down payment plus not less than 12% royalties or; (2) A transaction of more than \$25 million down payment plus not less than 15% royalties or royalties of not less than 20% with a big pharma company. <sup>12</sup> . It should be noted that if the forgoing transactions are completed with multiple entities, the sum total of the largest five (5) transactions will be used to determine if this milestone has been reached.	23,293,033	26,236,603	7.95%	7.34%	—	—
Milestone 2B*	Upon the successful completion of the partnership/marketing transaction of KIT-301 or KIT-302 <b>with more than \$15 million</b> down payment plus not less than 10% royalties. It should be noted that if the forgoing transactions are completed with multiple entities, the sum total of the five (5) largest transactions will be used to determine if this milestone has been reached.	13,338,958	19,081,166	—	—	5.91%	5.45%
Milestone 3	Upon the successful regulatory approval from the FDA for marketing KIT-301 or KIT-302 in the US.	15,982,294	21,466,312	6.51%	6.01%	6.65%	6.13%
Milestone 4A	Upon the approval of Kitov's patents affording protection in relation to the marketing or sales of KIT-302 or KIT-301.	4,000,000	7,155,437	2.17%	2.00%	2.22%	2.04%

<sup>12</sup> For the purpose of milestones, a large pharmaceutical company is a company with market value of over USD 2 billion.

Milestone 4B	Upon approval of an exclusive marketing period of KIT-301 or KIT-302 for a period of at least 5 years on average for the territories Germany, France and the UK.	2,666,666	4,770,291	1.45 %	1.34 %	1.48 %	1.36 %
Total upon fulfillment of milestone 2A		60,716,492	91,828,110	27.84 %	25.70 %	—	—
Total upon fulfillment of milestone 2B		50,762,418	84,672,673	—	—	26.24 %	24.18 %

Milestone 2A and 2B are alternate, and the fulfillment of one of these milestones cancels the possibility that the other of the two milestones will be fulfilled. It should be noted that it is possible that any of these milestones will be fulfilled.

### 13. The economic value of the offered securities

The economic value of each warrant of the Additional Warrants is NIS 1.287. The above mentioned economic value was calculated according to the Black–Scholes model, in accordance with the calculation formula of the Tel Aviv Stock Exchange guidelines and in consideration that the closing price of the Company's ordinary shares on the stock exchange on October 23, 2012, was NIS 1.296 while the weekly standard deviation was 10.47% (constituting an annual standard deviation of 75.50%) and a 2% annual capitalization rate for the warrants, and also assuming that the Additional Warrants will be exercised on the last date of exercise.

The economic value of each Service Providers Warrant is NIS 1.287. The above mentioned economic value was calculated according to the Black – Scholes model, in accordance with the calculation formula of the stock exchange guidelines and in consideration that the closing rate of the Company's ordinary shares on the stock exchange on October 23, 2012, was NIS 1.296 while the weekly standard deviation was 10.47% (constituting an annual standard deviation of 75.50%) and a 2% annual capitalization rate for the warrants, and also assuming that the Additional Warrants will be exercised on the last date of exercise.

### 14. The overall transaction within which the Private Placement is executed

#### 14.1. Purchase Agreement

On September 9, 2012 the Company engaged in a Purchase Transaction with Kitov according to which the designated company NewCo will be merged through a reverse triangular merger following which NewCo will cease to exist. As a result of completing the merger Kitov will become a private company wholly owned by the Company and the Offerees will receive the merger consideration in shares and warrants for Company shares and also various milestone payments throughout the development process of Kitov products, in cash, or in Company shares and all by means of an issuance of securities of the Company by an extraordinary private placement pursuant to the Israeli Securities Regulations (Private Offering of Securities in a Listed Company, 2000) (hereinafter: "**The Regulations**").

Pursuant to the completion of the first stage of the Purchase Agreement (namely, the first payment executed on the date of completion of the Purchase Agreement without the milestone payment hereinafter: "**The Closing Date**") as aforesaid, Kitov shareholders will hold 8,709,052 shares of the Company which constitute approximately 3.66% of the Company's issued and outstanding share capital and 597,786 Additional Warrants (as defined above) and additional service providers will hold 218,728 Service Providers Warrants (as defined above) converted to Company shares and also 15,014 Additional Warrants. The amount of securities issued to the Offerees at the Closing Date constitutes 3.59% of the Company's fully diluted issued and outstanding share capital.

Assuming that all of the various milestones throughout the development process of Kitov products will be fulfilled, the Company will pay Kitov an cumulative sum of up to USD 60,716,492 or alternatively, at the Company's sole discretion, in 30 days from the date of the fulfillment of a milestone, issue ensuing the aforesaid payment 91,828,110 ordinary shares of NIS 0.1 par value each of the Company which at the date of this report and after their allocation constitute 27.84% of the Company's issued and outstanding share capital and approximately 25.70% on a fully diluted basis, (or approximately 30.48% of the Company's issued and outstanding share capital and approximately 28.37% of the Company's fully diluted issued and outstanding share capital, including the securities issued at the Closing Date). For details regarding the milestones see paragraph 12.8 above.

14.1.2. **Prerequisites** – The purchase agreement stipulates that its execution is conditioned, inter alia, by the fulfillment of the prerequisites detailed hereunder:

a. Publication of an extraordinary private placement report with regard to the issuance of securities issued on the date of completion of the agreement and the shares that may be issued, at the Company's discretion, subject to fulfilling the milestones defined in the Purchase Agreement;

b. Approve the Purchase Agreement by the general meeting of the Company and the resolutions in respect thereof including approval to consolidate the Company's capital at a ratio of 10:1, the appointment of Messers Dr. Paul Waymack and Mr. Simcha Rock as directors in the Company and also approval of the Company's engagement in a service agreement with Dr. Paul Waymack with regard to his position as Chairman of the Company's Board of Directors and as an executive in charge of the clinical and regulatory development of all the Company's products in return for a monthly management fee of USD 9,166 plus VAT, as applicable;

c. Pre-Ruling approval from the Israeli Tax Authority in accordance with paragraph 104h of the Israeli Income Tax Ordinance that the sale of Kitov shares and the issuance of the Company's securities to holders of Kitov securities will not constitute a tax event on the day of completion of the transaction;

d. Receipt of a valuation from an independent third-party that will support the consideration determined in the aforesaid agreement and which will determine Kitov's value which will not drop from USD 40 million;

e. TASE approval to list the issued shares to the Oferees;

f. Any other approval required to lawfully execute the shares exchange agreement;

**Undertaking to execute the development program** – within the framework of the Purchase Agreement the Company undertook to execute a development program for one of the drugs under development by Kitov. As part of the aforesaid undertaking, the Company will invest the amount of USD 1.5 million to finance the completion of the Phase III clinical trials, the execution thereof will begin on the latest of the following: (i) three months after the completion of the agreement, or (ii) six months from the date of signing the Purchase Agreement, whereas the duration of the trial as mentioned, is expected to last over a period of 18 months from its start. Should the Company not fulfill its undertaking to execute the development program aforementioned, 14.1.3. except for certain instances in which a substantial change for the worst had occurred in the designated area for which the Kitov drug is targeted, the relevant restriction will expire regarding 50% of the Company shares issued to Kitov shareholders in accordance with the Purchase Agreement and the restriction will prevail only subject to the provisions of the law. For details regarding the relevant restrictions which the Offerees undertook according to the provisions of the Purchase Agreement see paragraph 21 below. To remove any doubt it is hereby clarified that in accordance with Kitov's estimates as presented in the Purchase Agreement, an overall investment of USD 9 million will be required to complete the development of Kitov drugs and up to the receipt of the approval to market it.

**Representations** - Within the framework of the Purchase Agreement the Company received from Kitov representations regarding its activities and, *inter alia*, with regard to its incorporation, shareholders, lack of rights of third parties in Kitov shares, financial statements, financial liabilities, legal proceeds, officers, employees and consultants, liens, guarantees, insurance, intellectual property, licenses and permits and also a declaration that it is authorized and entitled to enter the transaction. Additionally, within the framework of the 14.1.4. Purchase Agreement the Company submitted notices with regard to it being a public company, publication of its periodical report for 2011, absence of any event influentially material to the results of the Company's activities, legal proceedings, receipt of all the approvals required to execute the merger, absence of contradiction between the provisions of the Purchase Agreement and Agreements to which the Company is party, etc.

**Indemnification** - The parties to the Purchase Agreement have mutually undertaken that the representations 14.1.5. submitted within the framework of the Purchase Agreement or any other agreement, including certificate, document or agreement attached to the Purchase Agreement by any of the parties will be correct and exact as at the date of completion of the Purchase Agreement.

Starting at the Closing Date and for a period of 18 months, each of Kitov shareholders, relative to his holdings of Kitov shares undertakes, to protect and indemnify the Company, and its senior officers, directors, employees, shareholders, agents and representatives, against all damages, losses, costs and expenses (including reasonable legal fees) which will derive from third party claims, based on a breach of the representations included in the Purchase Agreement including documents attached therein ("**Indemnification Claims**"). Regardless of the aforementioned the above undertaking to indemnify will not apply to any indemnification claim based on consequential damage.

The undertaking to indemnify Kitov shareholders will be restricted only to the number of Company securities they received until the date of the Indemnification Claim, provided that the false representation or breach of issued the Purchase Agreement will not be deemed fraudulent.

**Prevention or restriction to execute actions in the securities issued to the Offerees** – According to the 14.1.6. provisions of this Purchase Agreement the Offerees have undertaken a voluntary lock-up period, for details pertaining to the restriction provisions prevailing on the Oferees see paragraph 21 to the transaction report.

#### 15.A description of the topics on the meeting agenda

The Purchase Agreement including the extraordinary private placement thereof, as detailed above is presented for approval, to remove all doubt, as a whole, together with all the engagements and resolutions required for its completion, as detailed hereunder:

##### 15.1. Purchase Agreement

Approve the Company's engagement in a Purchase agreement and the extraordinary private placement thereof, which includes the Completion Shares, Additional Warrants, Service Providers Warrants, milestone payments or alternatively issuance of shares in accordance with the milestones determined in the Purchase Agreement, at the Company's sole discretion.

##### 15.2. Capital Consolidation

Approve to consolidate the Company's capital at a ratio of 10:1 in a manner that every 10 shares of NIS 0.1 par value each of the Company will be consolidated into one share of NIS 1.0 par value each.

##### 15.3. Appointment of Directors



Approve the appointments in accordance with the Company's Articles of Association, of Messers Dr. Paul Waymack and Mr. Simcha Rock as directors in the Company until next year's annual general meeting and approve the conditions of their fees. The vote regarding each of the directors as aforesaid will be done separately. Declarations of candidates for appointment as directors are enclosed as Appendix B to the report.

#### 15.4. Engagement in a Service Providers Agreement

Approve the Company's engagement in a service provider agreement with Dr. Paul Waymack with regard to his position as Chairman of the Company's Board of Directors and as an executive responsible for the clinical and regulatory development of all the Company's products and this in accordance with the principal conditions presented hereunder:

**Scope of services** – Dr. Paul Waymack will invest 65% of his working time, at the least, in order to fulfill his position as Chairman of the Company's Board of Directors and also as an executive responsible for the clinical and regulatory development of all the company products. Dr. Paul Waymack will execute all the requirements of his aforesaid positions including, without limitation, participate in the Company's board meetings and be the leading authority for all the regulatory and clinical trial procedures of the Company Products.

**Compensation** – For Dr. Paul Waymack's services as director, chairman of the board of directors and executive responsible for the clinical and regulatory development of all the Company products, the Company will pay Dr. Paul Waymack a monthly management fee of USD 9,166 ("**Basic Management Fee**"). The Basic Management Fees will be paid to Mr. Waymack once per quarter, except for the payment detailed in paragraph C below it is hereby clarified that the Basic Management Fees include all the provisions for social payment lawfully required. The Basic Management Fees will be paid against receipt of an invoice.

**Annual bonus** – In addition to payment of the aforesaid Basic Management Fees, and subject to receipt of approval from the Company's Board of Directors and subject to any provisions of the law, the Company will pay Dr. Waymack an annual bonus of USD 30,000 ("**The Annual Bonus**"). The Annual Bonus will be paid, if paid, until March 1, of each year and will be executed in four equal quarterly payments.

**Taxes** – Dr. Paul Waymack will be exclusively responsible for payment of all taxes required on the Basic Management Fee and the annual Bonus. No employer employee relations will exist between the Company and Dr. Waymack therefore, the management fees constitute all the ancillary social expenses including compensation, convalescence and vacation pay required by law.

**Reimbursed expenses** - Dr. Paul Waymack will be entitled to be reimbursed against approved travel expenses paid by him in the course of executing his duties against presentation of receipts and references and subject to the approval of the Board of Directors.

**Agreement term and termination** – The engagement between the parties will enter into force upon signing this agreement and will be valid until the earliest of the following: (1) Complete the development of Kitov products according to the development program; (2) Dr. Waymack will cease to act as director in the Company's Board of Directors. Without derogating from the generality of the above mentioned, Dr. Waymack's Service Provider's Agreement will be immediately terminated in each of the occurrences below ; (1) Dr. Waymack will not be reappointed as director by the annual general meeting of Company shareholders; (2) Dr. Waymack will cease to fulfill his position in accordance with the Company's Articles of Association as will be updated from time to time, or in accordance with the provisions of the Law in Israel and Provisions of the Securities Law in the United States; (3) Dr. Waymack will be convicted for a criminal offence except for traffic violation; (4) Dr. Waymack breached the provisions of the Service Provider Agreement and did not amend his transgression after being required to do so or should he cease to fulfill his duties in accordance thereof and (5) Dr. Waymack was convicted for inappropriate behavior which in the Board of Directors' opinion may prove damaging to the Company's activities.



Without derogating from the generality of the aforementioned, Dr. Waymack will be entitled to end his engagement in the Service Provider Agreement subject to submitting, a month in advance, written notice to that effect. It should be noted that in the event that Dr. Waymack will cease to fulfill his position as director in the Company, for any reason whatsoever, the Company has undertaken to hire his services as an external consultant responsible for the development of all the Company drugs, as long as these drugs are developed, at the same scope of engagement and in consideration of an annual payment of USD 90 thousand.

**It is hereby clarified that all the resolutions on the meeting's agenda are interconnected resolutions, namely that the rejection of one of the resolutions may be deemed as a rejection of the other resolutions even though another resolution has been accepted and approved by the extraordinary general meeting of the Company's shareholders.**

**16. The Company's issued share capital, the number and rate of the Offerees and public holdings in the Company's share capital**

- 16.1. The registered share capital of the Company as at the date of this immediate report is NIS 70 million, divided into 700,000,000 ordinary shares of NIS 0.1 par value each.
- 16.2. The issued and outstanding share capital of the Company as at the date of this immediate report is NIS 22.9 million, divided into 229,362,160 ordinary shares of NIS 0.1 par value each.

16.3. Below is a table that presents the issued and outstanding share capital of the Company, the number and percentage holdings of the Offerees and interested parties in the Company, and the total holdings of other shareholders in the issued and outstanding share capital and voting rights in the Company before and after the allocation that will be executed on the Closing Date (first stage issuance):

Name	Before the private placement object of this allocation					After the private placement object of this allocation				
	Nr. of shares	Unregistered warrants	Warrants (series 2)	Before the substantial private placement according to this report.		Nr. Of shares	Unregistered warrants	Warrants (series 2)	Immediately after the substantial private placement according to this report (at the date of completion)	
				% in equity and voting	% in equity and voting (fully diluted) <sup>13</sup>				% in equity and voting (fully diluted) <sup>14</sup>	% in equity and voting
Alexander Rabinovitch <sup>15</sup>	43,132,361	—	573,750	18.81 %	17.08 %	43,132,361	—	573,750	18.12 %	16.46 %
David Bassa	21,705,987	—	—	9.46 %	8.48 %	21,705,987	—	—	9.12 %	8.17 %
Shalom Manova	17,175,573	—	—	7.49 %	6.71 %	17,175,573	—	—	7.21 %	6.47 %
Ben-Zion Weiner <sup>16</sup>	570,434	4,408,000	—	0.25 %	1.95 %	570,434	4,408,000	—	0.24 %	1.87 %
David Grossman <sup>17</sup>	—	3,110,000	—	—	1.21 %	—	3,110,000	—	—	1.17 %
Amit Yonay <sup>18</sup>	—	150,000	—	—	0.06 %	—	150,000	—	—	0.06 %
Marc Allouche <sup>19</sup>	—	150,000	—	—	0.06 %	—	150,000	—	—	0.06 %
Ronen Twito <sup>20</sup>	—	3,110,000	—	—	1.21 %	—	3,110,000	—	—	1.17 %
Dafna Cohen <sup>21</sup>	—	150,000	—	—	0.06 %	—	150,000	—	—	0.06 %

<sup>13</sup> Assuming that all warrants (series 2), and unregistered options of the Company, are exercised into Ordinary shares of the Company.

<sup>14</sup> Assuming that all warrants (series 2), and unregistered options of the Company, including warrants given to Offerees, are exercised into Ordinary shares of the Company.

<sup>15</sup> 23,574,902 Ordinary shares of the Company and warrants (series 2) are held by Green Forest Holdings Ltd. a company that, to the best of the Company's knowledge, is jointly and equally owned by Mr. and Mrs. Alexander and Sagit Rabinovitch.

<sup>16</sup> Director

<sup>17</sup> Director and CEO

<sup>18</sup> Chairman of the Company's Board.

<sup>19</sup> Director

<sup>20</sup> Deputy CEO and CFO

<sup>21</sup> External director

Name	Before the private placement object of this allocation				After the private placement object of this allocation				Immediately after the substantial private placement according to this report (at the date of completion)  % in equity and voting (fully diluted) <sup>13</sup>
	Nr.of shares	Unregistered warrants	Warrants (series 2)	% in equity and voting	% in equity and voting (fully diluted) <sup>13</sup>	Nr. Of shares	Unregistered warrants	Warrants (series 2)	
Jaron Diament <sup>22</sup>	—	150,000	—	—	0.06 %	—	150,000	—	—
Moshe Mittelman <sup>23</sup>	5,590,896	640,000	—	2.44 %	2.43 %	5,590,896	640,000	—	2.35 %
Total interested parties and officers	88,175,251	11,868,000	573,750	38.45 %	39.31 %	88,175,251	11,868,000	573,750	37.04 %
The public <sup>24</sup>	137,394,001	2,246,727	11,839,164	59.90 %	59.18 %	137,394,001	2,246,727	11,839,164	57.71 %
Total Offerees	225,569,252	14,114,727	12,412,914	98.35 %	98.49 %	225,569,252	14,114,727	12,412,914	94.75 %
JPW PCH LLC <sup>25</sup>	—	—	—	—	—	7,119,907	488,708	—	2.99 %

<sup>22</sup> External director<sup>23</sup> Medical Director

<sup>24</sup> The public - as defined in the TASE guidelines.

<sup>25</sup> A Company incorporated in the United States wholly held by Messers. Dr. Peter Hoyle and Dr. Paul Waymack.



Name	Before the private placement object of this allocation			After the private placement object of this allocation			Immediate after the substantial private placement according to this report (at the date of completion)	% in equity and voting (fully diluted) <sup>13</sup>		
	Nr.of shares	Unregistered warrants	Warrants (series 2)	Before the substantial private placement according to this report.		Nr. Of shares			Unregistered warrants	Warrants (series 2)
				% in equity and voting	% in equity and voting (fully diluted)					
Moshe Laster	—	—	—	—	—	1,589,145	109,078	—	0.67%	
Simcha Rock	—	—	—	—	—	—	23,851	—	—	
Clal underwriting	—	—	—	—	—	—	71,554	—	—	
<sup>26</sup> Ronen Kantor	3,792,908	60,000	—	1.65%	1.51%	3,792,908	174,486	—	1.59%	
Charity fund <sup>27</sup>	—	—	—	—	—	—	23,851	—	—	
Total Offerees	3,792,908	60,000	—	1.65%	1.51%	12,501,960	891,528	—	5.25%	
Total	229,362,160	14,174,727	12,412,914	100%	100%	238,071,212	15,006,255	12,412,914	100%	

<sup>26</sup> It should be noted that Mr. Ronen Kantor holds prior to this private placement object of this report 3,792,908 ordinary shares of NIS 0.1 par value each of the Company and 60,000 warrants exercisable into 60,000 ordinary shares of NIS 0.1 par value each.

<sup>27</sup> Kitov shareholders decided to donate 0.25% of Kitov to the Pelech charity.



The Company is entitled to pay the milestone payments, to the extent that they were fulfilled, in cash, therefore, should they be fulfilled and assuming that the Company fulfilled the conditions of milestone 2A and conditions 16.4. of milestone 2B and assuming that the Company has chosen to pay all the milestone payments in cash, the holdings of the Offerees in the Company equity will be as detailed in the table in paragraph 16.3 above and the Company will pay the Offerees the sums detailed below:

Name of Offeree	Total amount payable in USD (assuming the fulfillment of all milestones and conditions of milestone 2A)	<b>Total amount payable in USD (assuming the fulfillment of all milestones and conditions of milestone 2B)</b>
JPW PCH LLC <sup>28</sup>	48,421,402	40,483,029
Moshe Laster	10,807,536	9,035,710
Simcha Rock	151,791	126,906
Clal underwriting	455,374	380,718
Ronen Kantor	728,598	609,149
Charity Fund <sup>29</sup>	151,791	126,906
Total Payment	60,716,492	50,762,418

<sup>28</sup>A Company incorporated in the United States wholly held by Messers. Peter Hoyle and Dr. Paul Waymack.

<sup>29</sup> Kitov shareholders decided to donate 0.25% of Kitov to the Pelech charity.

16.5. The table below details the issues and outstanding share capital of the Company the number and percentage of holdings of the Offerees, of interested parties in the Company and the total holdings of other shareholders in the issued and outstanding capital and voting rights in the Company (after the Date of Completion) and after executing in full the milestone allocations by means of Company securities, and assuming that the Company has fulfilled conditions of milestone 2A and the assumption that the Company has fulfilled conditions of milestone 2B:

Name	After the private issuances against milestones (assuming that the Company fulfilled conditions of milestone 2A)				After the private issuances against milestones (assuming that the Company fulfilled conditions of milestone 2B)				% In equity and voting (fully diluted) <sup>30</sup>	% In equity and voting (fully diluted)
	Nr. of shares	Unregistered warrants	Warrants (series 2)	% In equity and voting	Nr. of shares	Unregistered warrants	Warrants (series 2)	% In equity and voting		
Alexander Rabinovitch <sup>32</sup>	43,132,361	—	573,750	13.07 %	43,132,361	—	573,750	13.36 %	12.48 %	
David Bassa	21,705,987	—	—	6.58 %	21,705,987	—	—	6.72 %	6.20 %	
Shalom Manova	17,175,573	—	—	5.21 %	17,175,573	—	—	5.32 %	4.91 %	
Ben-Zion Weiner <sup>33</sup>	570,434	4,408,000	—	0.17 %	570,434	4,408,000	—	0.18 %	1.42 %	
David Grossman <sup>34</sup>	—	3,110,000	—	—	—	3,110,000	—	—	0.89 %	
Amit Yonay <sup>35</sup>	—	150,000	—	—	—	150,000	—	—	0.04 %	
Marc Allouche <sup>36</sup>	—	150,000	—	—	—	150,000	—	—	0.04 %	
Ronen Twito <sup>37</sup>	—	3,110,000	—	—	—	3,110,000	—	—	0.89 %	

<sup>30</sup> Assuming that all warrants (series 2) (series B), and unregistered options of the Company, are exercised into Ordinary shares of the Company.

<sup>31</sup> Assuming that all warrants (series 2), and unregistered options of the Company, including warrants given to Offerees, are exercised into Ordinary shares of the Company.

<sup>32</sup> 23,574,902 Ordinary shares of the Company and warrants (series 2) are held by Green Forest Holdings Ltd. a company that, to the best of the Company's knowledge, is jointly and equally owned by Mr. and Mrs. Alexander and Sagit Rabinovitch.

<sup>33</sup> Director.

<sup>34</sup> Director and CEO.

<sup>35</sup> Chairman of the Company's Board.

<sup>36</sup> Director.

<sup>37</sup> Deputy CEO and CFO.

Name	After the private issuances against milestones (assuming that the Company fulfilled conditions of milestone 2A)				After the private issuances against milestones (assuming that the Company fulfilled conditions of milestone 2B)					
	Nr. of shares	Unregistered warrants	Warrants (series 2)	% In equity and voting	<b>% In equity and voting (fully diluted)</b> <sup>30</sup>	Nr. of shares	Unregistered warrants	Warrants (series 2)	% In equity and voting	
Dafna Cohen <sup>38</sup>	—	150,000	—	—	0.04 %	—	150,000	—	—	
Jaron Diament <sup>39</sup>	—	150,000	—	—	0.04 %	—	150,000	—	—	
Moshe Mittelman <sup>40</sup>	5,590,896	640,000	—	1.69 %	1.74 %	5,590,896	640,000	—	1.73 %	
Total interested parties and officers	88,175,251	11,868,000	573,750	26.72 %	28.15 %	88,175,251	11,868,000	573,750	27.31 %	
The public <sup>41</sup>	137,394,001	2,246,727	11,839,164	41.65 %	42.40 %	137,208,221	2,246,727	12,024,944	42.57 %	
Total Offerees	225,569,252	14,114,727	12,412,914	68.37 %	70.55 %	225,383,472	14,114,727	12,598,694	69.88 %	
JPW PCH LLC <sup>42</sup>	80,352,825	488,708	—	24.36 %	22.63 %	74,646,364	488,708	—	23.13 %	

<sup>38</sup> External Director.

<sup>39</sup> External Director.

<sup>40</sup> Medical Director.

<sup>41</sup> The public - as defined in the TASE guidelines.

<sup>42</sup> A Company incorporated in the United States wholly held by Messers. Dr. Peter Hoyle and Dr. Paul Waymack.



Name	After the private issuances against milestones (assuming that the Company fulfilled conditions of milestone 2A)				% In equity and voting )fully diluted) <sup>30</sup>							After the private issuances against milestones (assuming that the Company fulfilled conditions of milestone 2B)			
	Nr. of shares	Unregistered warrants	Warrants (series 2)	%In equity and voting	Nr. of shares	Unregistered warrants	Warrants (series 2)	% In equity and voting	Nr. of shares	Unregistered warrants	Warrants (series 2)	% In equity and voting			
Moshe Laster	17,934,549	109,078	—	5.44 %	5.05 %	16,660,881	109,078	—	5.16 %						
Simcha Rock	229,570	23,851	—	0.07 %	0.07 %	211,682	23,851	—	0.07 %						
Clal underwriting	688,711	71,554	—	0.21 %	0.21 %	635,045	71,554	—	0.20 %						
Ronen Kantor <sup>43</sup>	4,894,845	174,486	—	1.48 %	1.42 %	4,808,980	174,486	—	1.49 %						
Charity Fund <sup>44</sup>	229,570	23,851	—	0.07 %	0.07 %	211,682	23,851	—	0.07 %						
<b>Total Offerees</b>	104,330,070	891,528	—	31.63 %	29.45 %	97,174,634	891,528	—	30.12 %						
<b>Total</b>	329,899,322	15,006,255	12,412,914	100 %	100 %	322,743,886	15,006,255	12,412,914	100 %						

<sup>43</sup> It should be noted that Mr. Ronen Kantor holds prior to this private placement object of this report 3,792,908 ordinary shares of NIS 0.1 par value each of the Company and 60,000 warrants exercisable into 60,000 ordinary shares of NIS 0.1 par value each..

<sup>44</sup> Kitov shareholders decided to donate 0.25% of Kitov to the Pelech charity.



17. The Consideration for the offered securities and its determination

17.1. In consideration for the assignment of Kitov's share capital in full to NewCo in a manner that Kitov will become a company fully owned (100%) by the Company, the Company will issue to Kitov shareholders, at the date of completion of the Purchase Agreement 8,709,052 ordinary shares of NIS 0.1 par value each of the Company ("**The Shares**"), at a price per share of NIS 1.641<sup>45</sup> ("**the Price Per Share in the Private Placement** ") and also will issue to Kitov's service providers 218,728 warrants, unregistered, for the purchase of 218,728 Company shares ("**Services Providers Warrants**"). In addition to the aforementioned securities, the Company will issue to the Offerees 612,800 additional warrants for the purchase of 612,800 Company shares (hereinafter: "**The Additional Warrants**"). The securities issued by the Company at the date of completion constitute jointly approximately 3.66% of the Company's fully diluted issued and outstanding share capital and approximately 3.59% on a fully diluted basis.

17.2. It should be noted that the price per share in the private placement according to this report is determined through negotiations between the Company and the Offerees based, *inter alia*, on the share's average trading price on the Tel-Aviv Stock Exchange during the 21 days prior to the date of approval by the Company's Board of Directors and also, in consideration of the fact that the offered securities according to this report are "restricted" both by voluntary restriction according to the Purchase Agreement and also pursuant to provisions of paragraph 15c of the Israeli Securities Law 1968, and the Israeli Securities Regulations (details pertaining paragraphs 15a and 15c of the Law), 2000. For details regarding the restrictions in accordance with the Purchase Agreement see paragraph 21 below.

18. The price of the Company shares in the extraordinary private placement and their quoted market price on the stock exchange

18.1. It should be noted that according to the conditions of the Purchase agreement the shares issued to the Offerees, will be issued in consideration for the Offerees' assignment of their entire holdings and rights in Kitov which reflect a total of NIS 1.641 per share.

18.2. The average price per share over the six months prior to the date of publication of this transaction report is approximately NIS 1.307 per share, which is 20.4% lower than the price per share in the extraordinary private placement. The share price on the stock exchange close and prior to the Board of Director's resolution is NIS 1.381 and the price of Company share on the day before the date of this report is NIS 1.296.

18.3. The price per share in the Private Placement is higher than the share price on the stock exchange on the day before the date of this report by approximately 26.6%.

45 It should be noted that the price of the share in the private placement according to this report is determined through negotiations between the Company and the Offerees based, *inter alia*, on the share's average trading price on the Tel-Aviv Stock Exchange during the 21 days prior to the date of approval by the Company's Board of Directors and also, in consideration of the fact that the securities offered according to this report are "restricted" both by voluntary restriction and according to the Purchase Agreement and also pursuant to provisions of paragraph 15c of the Israeli Securities Law 1968, and the Israeli Securities Regulations (details pertaining paragraphs 15a and 15c of the Law), 2000. The price per share in the private placement according to the Tel Aviv Stock Exchange was calculated by way of dividing the relative part in Kitov's valuation (out of a total valuation of Kitov (approximately USD 40.2 million) USD 36 million, which are related to future consideration upon milestone payments were discounted of the total valuation of Kitov according to the valuation for this calculation) according to the valuation in a total of issued securities that are issued in the Completion Date.

..

19. Names of the controlling shareholders in the Company, major shareholders, directors and/or officers in the Company with personal interest in the private allocation and substance of their personal interest.

To the best of the Company's knowledge as at the date of this report the Company has no controlling shareholder. Additionally, to the best of the Company's knowledge, none of the officers or interested parties in the Company has personal interest in the private issuance object of this report.

**20. Required approvals and prerequisites:**

The Purchase Agreement stipulates that its implementation is contingent, among other things, to the fulfillment of the prerequisites detailed below:

Publication of an extraordinary private placement report with regard to the issuance of securities that will be issued  
a. on the date of completion of the agreement and also the shares that may be issued, at the Company's discretion, subject to fulfilling the milestones stipulated in the Purchase Agreement;

Approval of the Purchase Agreement by the general meeting of the Company and the resolutions in respect thereof including approval to consolidate the Company's capital at a ratio of 10:1, the appointment of Messers Dr. Paul Waymack and Mr. Simcha Rock as directors in the Company, the appointment of Dr. Paul Waymack as Chairman  
b. of the Company's Board of Directors, and also approval of the Company's engagement in a service agreement with Dr. Paul Waymack with regard to his position as Chairman of the Company's Board of Directors and as executive in charge of the clinical and regulatory development of all the Company's products in return for a monthly management fee of USD 9,166 plus VAT, as applicable;

The Pre-Ruling approval by the Israeli Tax Authority in accordance with paragraph 104h of the Israeli Income Tax  
c. Ordinance that the sale of Kitov shares and the issuance of the Company's securities to holders of Kitov securities will not constitute a tax event on the day of completion of the transaction;

Receipt of a valuation report from an independent third party that will support the consideration determined in the  
d. aforesaid agreement;

e. Approval of TASE to list the issued shares to the Offerees;

f. Any other approval required to execute the exchange of shares according to the law;

(hereinafter jointly: "**the Prerequisites**")

21. Limitations or restrictions in implementing transactions in securities issued to the Offerees

In accordance with the provisions of the Purchase agreement, the Offerees have undertaken a voluntary restriction<sup>47</sup> as detailed below:

<sup>47</sup> It should be noted that in certain circumstances, JPW will be permitted to sell Company shares out of the total first or second restricted shares, and up to a total amount of USD 2 million in a period of 9 months since their issuance (“the Free Shares”)

21.1. During the voluntary lock-up period applicable to the shares of JPW PCH LLC, owner of 80% of Kitov's issued and outstanding share capital (hereinafter: "**JPW**"), prior to the Purchase Agreement:

**The first restricted shares** – Holders of JPW will be prevented from selling the said shares for a period of 15 months from the Closing Date and followed by a 9 months period in which each month these shareholders may sell a. 1% of the Company shares they own, and after the passing of 24 months from the Closing Date these aforesaid shares will be freely tradable.

**The second restricted shares** - Holders of JPW will be prevented from selling the said shares for a period of 15 months from the date of fulfillment of the milestone according to the Purchase agreement followed by a 9 months b. period in which each month these shareholders may sell 1% of the Company shares they own, and after the passing of 24 months from the Closing Date these aforesaid shares will be free.

**The balance shares** – The balance shares issued to JPW according to the Purchase Agreement will be freely tradable and transferrable only subject and in accordance with the restriction provisions determined in paragraph c. 15c of the Israeli Securities Law 1968, and the Israeli Securities Regulations (details pertaining to paragraphs 15a and 15 to the Law) 2000.

21.1.1. The table below presents the restriction provisions applicable to the shares issued to JPW:

The Milestone	The first restricted shares	The second restricted shares	The balance shares
Completion shares	6,945,469	0	0
Milestone 1	8,559,692	0	0
Milestone 1A	3,804,307	1,902,154	5,706,461
Milestone 1B	0	2,853,231	2,853,230
Milestone 2A*	3,614,092	8,654,800	8,654,799
Milestone 2B*	5,706,461	4,755,385	4,755,384
Milestone 3	7,418,400	4,850,492	4,850,492
Milestone 4A	0	2,853,231	2,853,230
Milestone 4B	0	1,902,154	1,902,153

- 21.2. The voluntary lock-up period applied to the shares issued to the Offerees, except for JPW (hereinafter: "**The Balance Offerees**"), are as detailed below:

The Balance Offerees will be limited to sell their Company shares during 12 months from the Closing Date after which they may sell 50% of their holding, and at the passing of 24 months from the Closing Date these shareholders will be entitled to sell all of their shares in the Company.

- Should the Company choose, at its sole discretion, to pay the milestone payments by means of shares the aforesaid lock-up period will apply, by virtue of the milestones, also to the 50% of the shares issued to the Balance Offerees.
- b. 50% of the shares issued to the Balance Offerees for payment of the milestones will be locked-up for a period of 15 months from the date of closing followed by a 9 months period in which each month these shareholders may sell 1% of the Company shares they own, and after the passing of 24 months from the Closing Date these aforesaid shares will be freely tradable, all of these subject to the provisions of the law.

- 21.3. The lock-up provisions stipulated in paragraph 15c to the Israeli Securities Law 1968, and the Israeli Securities Regulations (details with regard to paragraphs 15a and 15c to the Law) 2000.

According to the Israeli Securities Law 1968 and the Israeli Securities Regulations (details with regard to paragraphs 15a and 15c to the Law) 2000, the issued shares (issued to the Offerees according to the Purchase Agreement) will be subject to the restrictions detailed below (hereinafter: "Lock-up Provisions")

- 21.3.1. During a period of 6 months from the date on which the issued shares will be issued according to this report, the Offerees will not be entitled to offer the shares issued to them as aforesaid, during trade on the stock exchange, without publishing a prospectus released for publication by the Securities Authority.

- 21.3.2. During a period of 6 consecutive quarters, which shall be counted as of the end of the aforementioned period, the Offerees will be entitled to offer as part of the trade on the stock exchange, without publishing a prospectus released for publication by the Israeli Securities Authority, on any trading day, not more than the average daily turnover the issued shares on the stock exchange, during a period of 8 weeks prior to the proposal date, providing that the quantity offered each quarter will not exceed 1% of the Company's issued and outstanding share capital (hereinafter: the "Drizzling Period")

**"Issued and outstanding capital"** - except shares derived from exercise or conversion of convertible securities allocated until the date of the placement and not yet realized or converted.

The above mentioned will apply also to shares purchased from the Offeree during absolute lock-up period or the Drizzling Period aforesaid, without a prospectus and not during trade on the stock exchange.



22. Discussion of the Board of Directors regarding approval of the placement, value determined for shares and the consideration in respect thereof

The Audit Committee and the Company Board of Directors have approved the Company's engagement in the Transaction agreement and the submission of this Transaction Report in its meeting dated September 9, 2012, according to the reasons detailed below:

a. The Audit Committee and the Company Board of Directors were of the opinion that Kitov is active in the same fields the Company is traditionally active in, and that its acquisition will increase the overall products it develops, with emphasize on those products in advanced stages of development (phase 3).

b. The Audit Committee and the Company Board of Directors were of the opinion that the Company's engagement in the Purchase Agreement will enable the Company to enter immediately Phase III clinical trials for a drug of significant market potential.

c. The Audit Committee and the Company Board of Directors were of the opinion that the Company's engagement in the Purchase Agreement and the assets that it will receive as a result of its completion are worthy assets and based on the valuation, are transferred to the Company at a worthy and proper value with potential to better the Company and strengthen the volume of its assets.

d. The Audit Committee and the Company Board of Directors were of the opinion that the terms of the Purchase Agreement are in the benefit of Company and its shareholders, *inter alia*, since the transaction is executed mostly based on payments subject to the fulfillment of scientific and commercial milestones, a fact the decreases the Company's exposure.

23. Names of directors who approved the extraordinary private placement

At the meeting of the Company's Board of Directors convened on October 21 2012, at which submission of this report was approved, Amit Yonay (Chairman of the Board of Directors), Ben-Zion Weiner (Director), Marc Allouche (Director), Dafna Cohen (External Director), Jaron Diamant (External Director) and David Grossman (Director and CEO), participated.

24. Date of implementation of the extraordinary private placement



On the Record Date and subject to the fulfillment of the prerequisites the Company will issue on the Date of Completion the securities issued to the Offerees and at the same time assign the whole of the Offerees holdings in Kitov to the Company.

**25. Announcement regarding convening an extraordinary general meeting of the Company shareholders**

In accordance with the Companies Law announcement is hereby transmitted regarding convention of an extraordinary meeting of the Company's shareholders, to be held on Wednesday, November 28 2012, at 09:00 at the law offices of Kantor and Co., 12 Abba Hillel Silver St., 8<sup>th</sup> floor, Ramat-Gan, Israel with on its agenda the Purchase Agreement including the extraordinary private placement in respect thereof, as described above presented for approval, to remove any doubt, as a whole with all the engagements and resolutions required to complete it, as detailed below:

25.1. Approve the Company's engagement in a Purchase Agreement with Kitov and an extraordinary private placement in respect thereof, which includes the Completion Shares, Additional Warrants, Service Providers Warrants, and issuance of shares in accordance with the milestones stipulated in the Purchase Agreement.

25.2. Approve to consolidate the Company's capital at a ratio of 10:1 in a manner that every 10 Company shares of NIS 0.1 par value each will be consolidated as one share of NIS 1.0 par value each.

25.3. Approve the appointment of Dr. Paul Waymack and Mr. Simcha Rock as Directors in the Company – the proposed version of the resolution: to approve in accordance with the Company's Articles of Association the appointments of Dr. Paul Waymack and Mr. Simcha Rock as Directors in the Company until next year's annual general meeting. The vote regarding each of the directors as aforesaid will be done separately. Declarations of candidates for appointment as directors are enclosed as Appendix B to the report.

25.4. Approve the Company's engagement in a service agreement with Dr. Paul Waymack with regard to his position as Chairman of the Company's Board of Directors and as executive in charge of the clinical and regulatory development of all the Company's products in return for a monthly management fee of USD 9,166 plus VAT, as applicable.

**It is hereby clarified that all the resolutions on the meeting's agenda are interconnected resolutions, namely that the rejection of one of the resolutions may be deemed as a rejection of the other resolutions even though another resolution has been accepted and approved by the extraordinary general meeting of the Company's shareholders.**

## **26. Meeting venue and date**

26.1. The extraordinary general meeting will convene on Wednesday, November 28, 2012 at 09:00 at the law offices of Kantor & Co. on 12 Abba Hillel Silver, 8th floor, Ramat-Gan, Israel. A deferred meeting, if necessary, will convene on Wednesday, December 5, 2012 at the same place and time

26.2. In the extraordinary general meeting, a legal quorum will constitute the presence of at least two (2) shareholders, represented by themselves or by their proxies, who hold or represent together at least 33.33% of the voting rights in the Company. If at the elapse of thirty minutes from the meeting's scheduled date, the legal quorum is not achieved, the meeting will be automatically deferred to the same day of the following week, at the same time and place as scheduled for the original meeting; or to a different time or place as decided by the board of directors in an announcement to the shareholders. If in such deferred meeting no legal quorum is obtained within thirty minutes from the scheduled date, two shareholders that are present by themselves or by a proxy will form a legal quorum and the meeting will be entitled to discuss the issues on the agenda.

26.3. The date for establishing the shareholders' right to vote in the general meeting, as stipulated in Section 182 to the Companies Law, is Monday, October 29, 2012 ("**the meeting participation record date**").

Any existing shareholder of the Company on the record date, whether or not the shares are registered in its name or are held by him through a member of the Stock Exchange, is entitled to participate in the meeting by himself or via a proxy. Pursuant to the Israeli Companies Regulations (Proof of Share Ownership for Voting in General Meetings), 2000, a Company shareholder whose shares are held by a member of the Stock Exchange will be

26.4. able to participate in said meeting by himself or via a proxy provided that an original proof of Company share ownership on the meeting participation record date is delivered to the Company before the meeting (to be obtained by that member of the Stock Exchange). Any documents appointing proxies ("**the letters of appointment**") as well as the original authorizations under which the letters of appointment (if any) were signed must be deposited with the Company's registered headquarters up to 48 hours prior to the date of the meeting.

A written format of the voting paper and statements of position, if any, can be found at the Israel Securities Authority's site at [www.magna.isa.gov.il](http://www.magna.isa.gov.il) and at the TASE's site at [www.tase.co.il](http://www.tase.co.il). In addition, a shareholder may apply to the Company directly for receiving the written format of the voting paper and statements of position, if any. A member of the Stock Exchange will send, at no consideration, via e-mail, a link to the written format of the voting paper and statements of position, if any, to each shareholder that is not registered with the Company's shareholders' registrar and whose shares are listed with that member of the Stock Exchange, if the shareholder has notified the member of the Stock Exchange of its wish and provided that the notice was made

26.5. with respect to a certain securities account and prior to the record date. Any shareholder whose shares are listed with a member of the Stock Exchange is entitled to receive proof of ownership from the relevant member of the Stock Exchange at the member of the Stock Exchange's branch or by mail to their address in return for payment of delivery fees only, if so requested, and this application will be granted in advance to the relevant securities account. Pursuant to the Israeli Companies Regulations (Voting Paper and Statements of Position), 2005, that shareholder will vote on the second part of the voting paper and specify the manner of voting and deliver it to the Company or mail it via registered mail whereby the proof of ownership must reach the Company's headquarters no later than 72 hours prior to the meeting date

26.6. The Company does not allow voting via the internet.

One or more shareholders that hold at least five percent or more of total voting rights and also hold such rate of the total voting rights that are not held by the controlling shareholder in the Company, as defined in Section 286

26.7. to the Companies Law, are entitled to review the voting papers as detailed in Regulation 10 to the Companies Regulations (Voting Paper and Statements of Position), 2005.

The last date for producing statements of position is within ten days after the meeting participation record date ("**the last statement of position date of delivery**"), namely: Thursday, November 8 2012 and the last date for

26.8. producing the board of directors' response to the statements of position is five (5) days after the last statement of position date of delivery, namely Tuesday, November 13 2012.

27. Required majority for decision

The required majority for approval of the decision stated in paragraphs 25.1 – 25.4 above is a regular majority of the participants in the voting.

28. Securities Authority

Within 21 days from the date of submission of this immediate report, the Israel Securities Authority (“**the Authority**”) is entitled to instruct the Company to provide, by a certain date, explanation, details, information, data and documents regarding the engagement in the transaction object of this mediate report, and to instruct the Company to amend this immediate report, in such manner and as such time as determined.

In the event of such instruction for amendment, the Authority or an employee thereof is entitled to determine deferral of the date of the general meeting until a date not earlier than three business days and not later than twenty one (21) days from the date of publication of the amendment to the immediate report.

29. Review of documents

Documents relating to this immediate report may be reviewed at the offices of Kantor & Co. Law Offices, Abba Hillel Silver Street 12, 8<sup>th</sup> Floor, Ramat Gan, Israel, during regular work hours and after advance coordination by telephone: +(972)-3-6133371.

30. Company representatives

The Company’s representatives responsible for the immediate report are Advocate Ronen Kantor and/or Ron Solma of Kantor & Co. Law Offices, 12 Abba Hillel Silver, 8<sup>th</sup> Floor, Ramat Gan, Israel, during regular work hours and after advance coordination by telephone: +(972)-3-6133371.

Yours sincerely,

XTL Biopharmaceuticals Ltd.



OUTLINE

KITOV PHARMACEUTICALS LTD.

1. GENERAL

1.1 Legend

For the convenience of the readers, the following terms shall have the meaning assigned to them below:

"EMA"	<b>European Medicines Agency</b> - the EU's regulatory agency responsible for the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. See more details about the EMA in paragraph 23.2 below.
"FDA"	<b>U.S. Food and Drug Administration</b> - an agency of the United States Department of Health and Human Services (" <b>HHS</b> "), responsible for protecting and promoting public health through the regulation and supervision of food safety, prescription and over-the-counter pharmaceutical drugs (medications), beauty products, medical devices and blood products in the U.S. See paragraph 23.1 below.
"FDC" or "combination products"	<b>Fixed Dose Combination</b> - a single drug that combines two (2) known fixed dose drugs whose efficacy and safety are individually proven.
"NCE"	<b>New Chemical Entity</b> - a new chemical product approved under a unique regulatory process which differs from the process applied for existing products. See details of the NCE product approval process in the table in paragraph 2.2 below.
"GMP"	<b>Good Manufacturing Practice</b> - rules and standards defined by the various pharmaceutical regulatory authorities to ensure quality drugs to be used on humans.
"IND"	<b>Investigational New Drug</b> - a new experimental drug approved by the FDA for clinical testing on humans.

"NDA"	<b>New Drug Application</b> - application filed with the FDA for commercial approval of a new drug.
"Therapeutic effect"	Measurable change in the clinical condition of subjects as a result of use of a specific drug or medical device.
"Disease model"	Experimental methodology for testing the therapeutic effect of a drug based on modeling the disease features in non-human subjects such as cells or animals.
"Generic product"	A product developed not by its original inventor but which contains the same active ingredient as in the original product; a generic product may be completely identical to the original product or different from it, based on the active ingredient in the original product. The range of differences between the generic and original products according to which a product may be recognized as generic by a regulatory agency are specifically determined for each product by the relevant regulatory authorities during the process of its approval. From a regulatory perspective, the recognition of a product as generic is mostly based on approval processes that are adapted to this type of product, as opposed to approval processes for an NCE.
"Formulation"	The entirety of inactive ingredients contained in a final medical product.
"Pre-clinical"	Measurable effect or experiment performed on cells or animals.
"Pharmacokinetics" / "PK"	The specific features of the absorption, distribution and excretion of a certain substance from the body; among others, the pharmacokinetic indices provide information on the extent and time of a subject's exposure to this substance.
"Clinical"	A measurable effect or experiment conducted on humans.
"Osteoarthritis" or "OA"	Inflammation caused by the degradation and degeneration of cartilage in the joints and subchondral bones. The inflammation makes the joint bones rub against each other in a manner that induces pain, swelling and limited motion instead of sliding against each other with the help of normal cartilage. See more details in paragraph 7.4 below.
"COX-1" and/or "COX-2"	Enzymes responsible for the development of inflammation and related pain.
NSAIDs	<b>Non-steroidal anti-inflammatory drugs</b> - a non-steroidal drug for treating inflammation by inhibiting the COX-1 and COX-2 enzymes. The main side effects caused by this drug are elevated blood pressure and peptic ulcers.



"COX-2 enzyme inhibitors"	A non-steroidal drug for treating inflammation which directly focuses on inhibiting COX-2 and minimizing the peptic ulcer side effect.
"HTN"	Hypertension.

## 1.2

## Introduction

Kitov Pharmaceuticals Ltd. ("**Kitov and/or the Company**") was incorporated in Israel on June 13, 2010 as a private company pursuant to the Israeli Companies Law, 1999 ("**the Companies Law**") under the name of JPM Pharmaceuticals Ltd. On August 1, 2010, the Company changed its name to its present name, Kitov Pharmaceuticals Ltd.

As of the outline date, Kitov is engaged in research and development of combination drugs for treating two clinical conditions simultaneously - pain caused by OA on the one hand and HTN on the other.

Hypertension directly affects the increase in global morbidity and mortality rates which are caused, among others, by heart attacks, strokes and other cardiovascular diseases. As of the outline date, there are currently dozens of drugs in the global pharmaceutical industry which cause elevated blood pressure as a direct result of their use. High blood pressure, as opposed to many other diseases, has no symptoms and that is why it is known in the professional literature as the "silent killer". The FDA's attempts to encourage treatment of hypertension have led to the establishment of a new policy which grants numerous exemptions to drugs which lead, among other things, to decreased blood pressure, including a Black Box Warning that decreased blood pressure reduces the chances of heart attacks, strokes and other cardiovascular diseases without needing to prove the reduction in the morbidity rate using clinical trials, namely, the fact that there is a decrease in blood pressure alone is sufficient. In discussions held by Kitov with the FDA regarding the outline of its clinical trials, said exemptions were addressed. See more details of the Company's clinical trial outline in paragraph 2.2 below.

As of the outline date, Kitov's objectives consist of developing new chemical drugs with added clinical and commercial value based on known and approved active substances.

After building value in said products or completing the development, including obtaining approvals, Kitov aims to engage with international companies for the purpose of granting them sublicenses based on upfront payments, milestones and royalties and/or signing marketing agreements, all depending on the product's and the market's position. See more details of Kitov's targets and strategy in paragraph 26 below.

## 2. The Company's operations and development of its business

Kitov was founded by Dr. Peter Hoyle and Dr. Paul Waymack, two former FDA scientists ("**Kitov's founders**") in order to develop innovative drugs and products with added clinical and commercial value based on known and approved active chemical substances. It is important to note that Kitov's R&D activity has been conducted by  
2.1 Kitov's founders since 2008, before Kitov's foundation. Kitov's founders are professionals with vast experience in both the Israeli and foreign pharmaceutical industry and in the scientific and regulatory fields underlying Kitov's expertise, including chemistry, pharmaceutical development, pharmacological models for various diseases, conducting clinical trials and bringing drugs to final licensing stages and obtaining the required regulatory approvals.

Kitov's operations focus on the development of two (2) different drugs, each of which comprised of a combination of two (2) existing drugs for treating two clinical conditions simultaneously. As of the outline date, Kitov has  
2.2 development plans for two (2) combination drugs (KIT-301 and KIT-302) for treating both pain caused by OA and HTN. These combination drugs are used for treating said diseases on the one hand while extensively reducing the side effects of existing drugs for treating these diseases on the other.

HTN is very common among adult populations: one (1) of three (3) adults in the United States is diagnosed with HTN<sup>1</sup>. Moreover, many existing drugs for treating OA and Attention Deficit-Hyperactivity Disorder ("**ADHD**") greatly increase blood pressure. Numerous studies have demonstrated that increased blood pressure in the circulatory system, even the smallest of increases (1m Hg) increase the risk of heart attacks, stroke and other cardiovascular diseases by about 2-3%<sup>2</sup>.

The drugs which Kitov aims to develop combine ingredients of various familiar drugs such as Naproxen and Celecoxib whose individual use leads to extensive elevated blood pressure. In addition, populations with HTN who take these drugs are exposed to aggravating their condition. The right combination of a drug for reducing blood pressure with one of the drugs comprising the combination drugs under development by Kitov is liable to treat both the pain and the blood pressure, whether the patient suffered from this condition prior to using the drug or whether this problem is caused by the drug itself.

<sup>1</sup>

[http://www.nhlbi.nih.gov/health/dci/Diseases/Hbp/HBP\\_WhatIs.html](http://www.nhlbi.nih.gov/health/dci/Diseases/Hbp/HBP_WhatIs.html).

<sup>2</sup> Julius S et al Lancet 2004;363:2022-2031. Singh G et al j Rheumatol 2003;30:714-719 Grover SA et al Hypertension. 2005;45:92-97.

As of the outline date, Kitov assesses that the products being developed by it have several unique advantages such as (a) providing a solution for the concerns experienced by physicians when prescribing treatment that is liable to cause elevated blood pressure, whether in addition to the patient's existing condition or as a side effect of other drugs; (b) offering a single drug that treats high blood pressure, whether as the patient's existing condition or as a side effect of other drugs - a solution which makes sure that the patient receives the proper treatment for the disease for which the drug is administered and for the side effects; (c) dissipating the concern of physicians whether patients actually take both drugs. Such concern experienced by physicians arises from their legal liability to offer patients forward-looking treatment which also addresses potential side effects; (d) allowing the patient to save the expenditure of purchasing separate drugs instead of purchasing only one. This advantage is also expressed in overriding the patient's judgment whether to purchase only one of the drugs based on personal considerations as opposed to receiving dual medical care by taking only one drug.

In addition to the abovementioned medical benefits, Kitov's combination drugs under development offer several commercial benefits which are expressed by shortening the development time compared to the development time of innovative products and reducing the risk factor inherent in the development activity. These benefits result from the fact that the combination ingredients are known and approved drugs and therefore the regulatory track of their FDA approval is unique and condensed as designed for the **505(b)(2) track**<sup>3</sup>. This track allows filing for product approval applications based on the results of safety and efficacy trials conducted on the combination ingredients in the past and not by the applicants. Accordingly, the 505(b)(2) approval track is relatively short and cost-effective compared to the NCE approval process.

Kenneth V. Phelps, The 505(b)(2) Alternative - An NDA that Saves Time and Money, DIA Forum, March 2005, <http://www.camargopharma.com/Userfiles/Docs/camargo-505b2.pdf>. See also: Guidance for Industry, Applications Covered by Section 505(b)(2) prepared by the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (1999).

Below is a description of the phases and development time of the NCE drug compared to a drug on the 505(b)(2) track<sup>4</sup>:

Phase	Phase description	Development time	
		in years	
		NCE	505(b)(2)
1 Discovery and characterization	A study for discovering an active chemical substance that has the potential of serving as a drug for a certain disease. Improving the structure-operation ratios of the chemical substances, testing their efficiency in preliminary trials and understanding their Mechanism of action. Specifically for Kitov's products, identifying the combined activity potential and the high efficacy potential in treating the specific disease.	2-5	Up to a year
2 Pre-clinical trials	Testing the active ingredient in disease simulating models that allow obtaining information on the drug's efficacy and safety. In NCE cases, controlled trials are conducted during advanced phases as a basis for receiving approval for testing the drug on humans. In the majority of cases, these phases are not required when dealing with known drugs.	2-3	1-2

Filing an Investigational New Drug ("IND") application:

Phase	Phase description	Development time	
		in years	
		NCE	505(b)(2)
3 Phase 1	Initial testing to assess the drug's safety and determine safe human dosage as well as PK features - drug absorption and distribution, latency, biological availability etc. (usually involves several dozens of subjects, mostly healthy ones).	5-8	1-3
4 Phase 2	Initial trials of the drug's efficacy on patients. Initial characterization of maximum doses and administration in patients. Simultaneously, continued testing of drug safety on patients (usually between several dozens and several hundreds of affected subjects). Trials conducted on a larger number of patients for obtaining additional information on the drug's efficacy and safety. Determining the manner of administering the right drug and details such as the disease phase more affected by the treatment and the nature of patients who respond to the treatment.		
5 Phase 3	After this phase is successfully concluded, applications may be filed to the health authorities for receiving drug marketing approval (variable number of patients, usually several hundred, depending on the disease and results).		

4

See footnote 3 above.



Filing a New Drug Application ("NDA"):

		Development time	
		in years	
Phase	Phase description	NCE	505(b)(2)
6	Testing the data from pre-clinical and clinical trials, the manufacturing process and the substance stability data, deciding whether or not the drug can be marketed for use in patients.	1-2	Up to a year
<b>Total development time</b>		10-18	4-7

It should be noted that in addition to the development times which depend on regulatory requirements (and which are abbreviated in said track), the commercialization potential of a combination drug based on existing drugs depends on existing patent protection of existing drugs. As of the outline date, some of the drugs which Kitov intends to use are generic and are not patent protected whereas others are bound to become generic by the time of obtaining approval for marketing Kitov's combination drugs. Since Kitov has filed a patent application for the combination drugs under its development as above, Kitov may have a significant edge if such patent is indeed approved. It should be noted that filing IND applications and conducting clinical trials on patent-protected drugs as part of the ingredients of Kitov's combination drugs does not represent an infringement of patent rights but these products can only be marketed after the protected ingredient's patent expires.

As discussed above, Kitov is developing combination drugs for treating both OA-induced pain and HTN. This medical field addresses large markets where the present solutions are not optimal given the high prevalence of HTN in the population and the side effects caused by existing drugs for treating said diseases.

As stated above, starting from 2008, even before Kitov was founded, Kitov's founders began developing the first combination drug by filing regulatory applications to the FDA. The Company filed a Pre-IND application following which two (2) official meetings were held with the FDA in the first quarter of 2011 where the principles for the development of Kitov's products were set.

In these meetings, the FDA granted an approval in principle to Kitov's development outline in accordance with the 505(b)(2) track, namely with no need for pre-clinical or phase 1 or 2 clinical trial. The FDA also suggested that Kitov conduct a single Phase 3 trial as a uniform trial for testing each of the drugs being developed by it - a fact which significantly shortens the period of time needed for completing the development, estimated at 20-24 months only.

On May 6, 2011, Kitov filed an IND application to the FDA for conducting the drug-drug interaction (DDI) trial that will test the drug's safety and the levels of the drug's ingredients in the blood. This application was approved on June 10, 2011 and as of the outline date Kitov may conduct the DDI trial. On September 8, 2011, Kitov filed a Special Protocol Assessment ("**SPA**") to the FDA towards conducting a Phase 3 trial on the KIT-301. On October 24, 2011, the FDA approved Kitov's SPA, including the Phase 3 outline and stipulated conditions underlying the product's approval. According to the FDA's approval, it is agreed that the KIT-301 approved development plan will remain in effect also for the KIT-302 development plan.

Kitov estimates that in order to obtain EU approval it may need to conduct an additional trial. Kitov intends to negotiate with the relevant authorities to examine the proceedings needed for obtaining EU approvals.

For more details about the development stage of Kitov's products and future development plans, see paragraph 8.4 below.

For more details about the budgeting of the clinical development plans of Kitov's combination drugs, see paragraph 16.6 below.

### **3. Investments in Kitov's share capital and share transactions**

Excluding an agreement for the acquisition of assets of October 13, 2010 in which the Company allocated 8,000,000 of its shares to JPW starting from the date of the Company's foundation, no other share transactions were carried out by Kitov and no investments were made in Kitov's share capital. For details of said agreement for the acquisition of assets, see paragraph 24 below.

### **4. Dividend distribution**

Starting from the date of Kitov's foundation to date, Kitov has not distributed any dividends and has no distributable earnings as stipulated in Article 302 to the Israeli Companies Law. As of the outline date, Kitov has no dividend distribution policy.

**Financial information on Kitov** Following is financial information about Kitov starting from the date of its establishment in U.S. dollars:

	Year ended December 31,		
	2011	2010	2009
Revenues	-	-	-
Research and development expenses *)	(36,990 )	(224,657)	(488,586)
General and administrative expenses	(90,365 )	(36,009 )	(7,845 )
Operating loss	(127,355)	(260,666)	(496,431)
Financial expenses	2,230	(185 )	-
Loss for the period	(125,125)	(260,851)	(496,431)
Loss per share *)	(0.016 )	(0.033 )	(0.062 )

Research and development services were granted by related parties.

## 6. General information on the areas of operation

### 6.1 Structure of the area of operation and changes therein

The global pharmaceutical development industry is an extremely large business segment which is the basis of a huge billion-dollar highly developed and competitive market. Many companies around the world develop drugs for the same diseases in direct competition for market share. Any newly developed and approved drugs entering the market will be in constant competition with existing drugs and therapies as well as drugs under development. The pharmaceutical market is affected by numerous factors, including aging populations, which enhances the demand for old age related and quality of life improving drugs.



## **6.2 Kitov's area of operation and products under development**

As stated above, Kitov is developing combination drugs under the 505(b)(2) track. As of the outline date, Kitov is focusing on the development of two (2) combination drugs each of which combines the ingredients of two (2) known and approved drugs into a single innovative added value drug as described below:

### **Combination drugs for treating OA-related pain and HTN ("KIT-301" and "KIT-302")**

In the context of Kitov's existing development plans, Kitov has characterized two (2) combination drugs for treating OA-related pain and HTN (see information about OA in paragraph 7.4 below). These combination drugs are comprised of known approved drugs which create a combined effect of treating both the pain caused by Osteoarthritis and Hypertension (see information about Hypertension in paragraph 7.3 below). A study shows that about 16 million patients in the U.S. have been diagnosed with both OA and HTN simultaneously<sup>5</sup>.

It should be noted that as of the outline date, the drugs comprising the KIT-301 are not patent protected; however, one of the KIT-302 ingredients (Celecoxib) is patent protected until 2014. See information on the combination ingredients in paragraphs 8.1 and 8.2 below.

Kitov intends to initially focus on the development of the KIT-302 and therefore, as of the outline date, the KIT-301 combinations have been accumulated for the purpose of the future development of products by the Company. As described above, Kitov will initially focus on the KIT-302 since it will address a larger population and by the time it receives approval for the drug, the KIT-302 ingredients will no longer be patent protected. Furthermore, the future development of any other combinations will be done gradually based on commercial and scientific priorities and given the resources at Kitov's disposal as they will be from time to time.

## **6.3 Limitations, legislation, regulations and special restrictions applicable to the area of operation**

From the initial stages of development, the pharmaceutical development segment is subject to international regulations and standards designed to protect the public of consumers in this segment (as well as in other segments such as food, veterinary services etc.), such as the U.S. FDA and the European EMA. See more information on the limitations, legislation, regulations and special restrictions applicable to Kitov's operations in paragraph 23 below.

5 Medscape CME: "The Link Between NSAID'S, BP and CV Events in patients With Osteoarthritis".

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## **7. General environment and impact of external factors on Kitov's operations**

Below are Kitov's projections of the principal trends, events and developments in its macroeconomic and industrial environments, which are expected to impact Kitov's operating results based on its existing knowledge and estimations.

### **7.1 Macroeconomic and industrial effects**

#### **7.1.1 Global economy**

Due to Kitov's need to raise capital to develop its products, it is highly affected by the global and local economic environment. Market recession and economic uncertainty are liable to adversely affect Kitov's ability to raise the funds needed for its operating activities.

#### **7.1.2 Regulation**

Kitov's area of operation is subject to regulation needed to supervise prices of public health products. Stricter regulations in various countries around the world (mainly in Israel and the U.S.) might create a need to extend the timetables until Kitov's products are manufactured and marketed and increase the required development costs. For details of limitations, legislation, regulations and special restrictions applicable to Kitov's operations see paragraph 23 below.

#### **7.1.3 U.S. healthcare reform**

In March 2010, the Compilation of Patient Protection and Affordable Care Act came into effect in the U.S., a policy enacted by the U.S. president, Barack Obama, which is the largest reform enacted in the U.S. healthcare system since the 1960s<sup>6</sup>. This reform is expected to enable another 30 million U.S. citizens to qualify for healthcare insurance. According to this reform, each U.S. citizen above 65 will be entitled to receive extended medical coverage through Medicare, sponsored by the U.S. Government, as well as a significant discount on medications, 50% of which will be financed by the pharmaceutical companies and the remaining 50% by the U.S. Government<sup>7</sup>.

6

<http://docs.house.gov/energycommerce/ppacacon.pdf>.

7

<http://www.rsc.org/chemistryworld/News/2010/March/25031003.asp>.



As for over 30 million Americans without medical insurance, the reform will allow them to purchase Government subsidized medical insurance policies at lower costs than those charged by insurance companies. People with low income who cannot afford medical insurance will qualify for the Medicare plan <sup>8</sup>.

To the best of Kitov's knowledge, the cost of the plan is estimated at hundreds of billions of dollars and the plan is expected to play a significant role in enhancing the U.S.'s healthcare insurance market. Extensive treatment for patients with HTN and OA-related pain who are mostly part of the adult population which the reform sets out to protect coincides with the reform's professed targets; however as of the outline date, Kitov cannot assess whether the reform will have a direct effect on its business.

It should be noted that since each of the ingredients in Kitov's drugs is included in the list of products which qualify for extended medical reimbursement under the Medicare plan, Kitov estimates that once the development of its products is completed, they will be included in the list of qualifying Medicare drugs. Moreover, Kitov intends to file an application for obtaining such an approval, whether by itself or through a third party, only after the development of its products and their approval are finalized.

#### **7.1.4**

#### **FDA guidelines for HTN related drugs**

In March 2011, the FDA issued a new guideline whereby drugs aimed at lowering blood pressure will include a clarification that decreased blood pressure reduces the chances of heart attacks, stroke and cardiovascular diseases<sup>9</sup>. It should be noted that Kitov has no intention of announcing that its products indeed reduce the risk of said diseases. However, Kitov anticipates that the new guideline will have a positive effect on the combination drugs which it is developing given that its combination drugs are designed to prevent elevated blood pressure caused by the use of certain drugs as a side effect. See details on competition and risk factors in paragraphs 14 and 28 below, respectively.

**Kitov's assessments regarding developments in its general environment and external factors which affect its operations such as the global economy, regulation, the U.S. healthcare reform and the FDA's guidelines, all as discussed above, are forward-looking information which is beyond Kitov's control. These parameters, based on the underlying trend, may either improve or impair Kitov's business results. The extent of their effect on Kitov, if any, is contingent, among others, on the intensity of the events, their scope, duration and Kitov's ability to deal with them. Furthermore, there is no certainty that Kitov's assessments of said trends will indeed be realized.**

<sup>9</sup> <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075072.pdf>.

7.2

**The global pharmaceutical market**

The global pharmaceutical R&D industry is principally ruled by large international pharma companies that are capable of allocating huge resources needed to complete all the development stages, the clinical trials, drug registration and marketing. In addition to these large pharma companies there are also smaller companies (such as Kitov) and research institutes and universities that are engaged in pharmaceutical R&D which usually work on the early stages of discovery of drugs and, with the advancement of research, aspire to collaborate with the large pharma companies. These collaborations may be realized during every stage of development, starting from early research to clinical trials.

**Combination products in the global pharmaceutical industry**

In the last few years, numerous global companies, including the largest pharma companies, have developed successful combination products in various medical areas which combine two generic drugs. The most prominent areas in which combination therapy has proven to have the most significant advantages<sup>10</sup> are (1) AIDS treatment, with the majority of effective HIV treatments being a combination of two or more drugs (for example, the scope of sales of Truvada by Gilead in 2011 reached some \$ 2.88 billion in the U.S.) and (2) respiratory diseases, mainly asthma, for which drugs combining two active ingredients have proven to be most effective (for example, the scope of sales of Symbicort by AstraZeneca in 2011 in the U.S. amounted to approximately \$ 3.1 billion).

In addition to the two areas mentioned above, and similarly to Kitov's combination drugs under development, as of the outline date, other combination drugs and manufactured and sold such as Vimovo, a combination of Naproxen and Prilosec, manufactured by AstraZeneca and Pozen for relieving pain and preventing peptic ulcers simultaneously which was approved in May 2010<sup>11</sup> and whose sales in the first year of its commercialization (2011) totaled approximately \$ 33.8 million; Caduet is a combination of Lipitor and Amlodipine manufactured by Pfizer for treating both elevated cholesterol levels and HTN whose sales in 2011 are estimated at \$ 339 million<sup>12</sup> and Janumet, a combination of Glucophage and Sitagliptin manufactured by Merck for treating diabetes whose sales in 2011 totaled approximately \$ 1.36 billion<sup>13</sup>.

<sup>10</sup> Business Insight report, Launching Combination Products Brand extension and franchise development strategies, by Steven Seget.

<sup>11</sup> <http://www.pozen.com/product/vimovo.asp>.

<sup>12</sup> <http://www.pfizer.com/files/annualreport/2011/financial/financial2011.pdf>.

<sup>13</sup> <http://www.merck.com/investors/financials/form-10-k-2011.pdf>.

The advantages of most combination drugs are medical advantages which are manifested in improved medical treatment offered to patients who are diagnosed with two combined diseases and by the convenience afforded when using a single drug instead of two different drugs. Moreover, combination drugs offer significant commercial benefits by retaining and even increasing the market share of active ingredients whose patent period is terminated even after their patent has expired by extending the lifecycle of the active ingredient used in combination drugs (Extension Branch Strategy)<sup>14</sup>. For an entity which develops combination drugs based on active ingredients developed by other makers, the tendency of the makers of the active ingredient may render them an attractive target for acquisition by the original developer.

Another example of a combination drug which created a new market for generic ingredients which are individually marketed with low profits is Aggrenox for treating stroke which is a combination of two generic ingredients: Dipyridamol and Aspirin. These two substances, which have been generic substances for many years, are sold either individually or as ingredients in other products and therefore their sales are distributed among many dozens of products and manufacturers with very low profits. In contrast, the scope of sales of Aggrenox in 2009 approximated \$ 260 million in the U.S.<sup>15</sup>, nearly with not generic competition owing to the important clinical benefits of the synergy between the combination ingredients and the delayed release formulation of one of the ingredients which does not exist in the individual product.

### 7.3

### Hypertension / HTN

HTN is the most common chronic condition in the western world, prevalent among 20% of the population and in about half of the elderly population. The term hypertension is physiologically defined as the pressure exerted by the circulating blood on the walls of the blood vessels<sup>16</sup> (the term blood pressure refers to the arterial blood pressure which is the pressure in the arteries providing blood to the various body organs and caused as a result of the contraction of the heart muscle, unless specified otherwise in this outline).

Blood pressure is measured according to mm Hg units. In order to diagnose high blood pressure in an adult, at least two measurements are required on two different occasions. There are two blood pressure indices:

1. Systolic pressure is defined as the maximum pressure in the arteries in the heart's cycle during the heart's contraction (systole).
2. Diastolic pressure is the lowest pressure point during the heart's relaxation (diastole).



Business Insight report, Launching Combination Products Brand extension and franchise development strategies, by Steven Seget.

15

<http://www.drugs.com/top200.html>.

16

<http://www.clalit.co.il/HE-IL/Family/parents/familys+health/articles/Blood+pressure.html>.

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Hypertension is one of the most common problems among adult populations - studies show that nearly half of the adult population in the U.S. has hypertension of at least 130/90 mm Hg<sup>17</sup> which indicates how prevalent this problem is.

The cause of HTN for 95% of patients is unknown and in these cases the blood pressure is defined as primary hypertension. However, there are studies which presume that the initial development of hypertension involves both hereditary and environmental factors such as high levels of salt intake, obesity, excessive alcohol consumption and perhaps even mental and behavioral factors caused by various circumstances such as certain occupations. Extreme hypertension is liable to lead to deteriorated functioning and health but those who suffer from it might not necessarily feel and/or be aware of it and that is why it is often called the silent killer.

The dangers of Hypertension consist of prolonged damage to the blood vessels of sensitive tissue such as the heart, the blood vessels themselves and the cranial nerves, with risk of stroke. Moreover, damage to the blood vessels may lead to Atherosclerosis, a condition in which the arteries are blocked, or to their tearing. These complications might cause various diseases and even death. The methods of treating Hypertension focus on lowering the patient's blood pressure to normal values thereby preventing long-term complications.

Even slightly elevated blood pressure levels are liable to cause crucial cardiovascular conditions, for example, an increase of about 5 mm Hg alone enhances the risk of stroke by about 67% and the risk of heart disease by about 15%.

Following the publication of various blood pressure studies, the global medical community issued a new diagnosis for **Pre-hypertension**<sup>18</sup>, which states that populations with systolic blood pressure of 115-130 mm Hg are also exposed to the risk of heart attacks and cardiovascular diseases, as opposed to the formerly common diagnosis of people with blood pressure levels higher than 120/80 mm Hg and lower than 130/90 mm Hg to be at a high risk of cardiovascular diseases. The studies also state that the majority of adult population is expected to greatly benefit from taking medications for lowering blood pressure<sup>19</sup>.

<sup>17</sup>Fisher N and Williams G, Hypertensive Vascular Disease in Harrison's Principles of Internal Medicine, 16<sup>th</sup> edition, 2005 pages 1463-1481.

<sup>18</sup>

Collins et al. 1990 Lancet. 335: 827-838).

<sup>19</sup>

Thompson A, et al 2011;305:913-22.

As discussed above, blood pressure levels are subject to radical fluctuations based on the objective of the trial, the tested population, the tested drugs etc. These fluctuations may range between 3 mm Hg and 5 mm Hg with significantly different effects. Studies conducted on the increase caused by the use of different drugs whose side effects include elevated blood pressure diagnosed an increase of about 3.5 mm Hg after taking Naproxen<sup>20</sup> and found that taking Celecoxib leads to an increase of about 2.5 mm Hg<sup>21</sup>.

#### 7.4

#### Osteoarthritis / OA

OA is the most prevalent form of arthritis or joint disorder, mainly among adult population. Younger OA patients usually develop OA due to joint injuries. The main symptom of OA is pain which starts gradually, worsens after exercise and is alleviated during rest.

The pain sustained by OA is described by patients as deep pain or as a burning sensation associated with the muscles and tendons of the inflamed area. OA mainly affects the cartilage and disrupts the joint cartilage structural balance by enhancing the cartilage cells' production of new raw materials for creating cartilage but simultaneously producing enzymes that destroy the cartilage. This enhanced cycle of cartilage production and destruction is expressed in decreased cartilage levels which make the adjacent bone tissue osteoporotic (thinner) and weakened. The bone healing processes needed to repair the bone damage appear in the form of swelling or bumps in the affected area.

OA is one of the most common disorders in the world which causes physical disability among adults. Over 27 million people in the U.S. have been diagnosed with OA and it is expected that some 70 million (or 20%) of people aged 65 and above in the U.S.<sup>22</sup> will suffer from OA by 2030. More than half of the people over 65 who have had x-ray were diagnosed with OA in at least one joint. Moreover, due to the rise in life expectancy in the western world more people suffer from OA and the disease is more common among men in the 45 age group whereas in people over 45, it is more common in women<sup>23</sup>.

<sup>20</sup><http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisDrugsAdvisoryCommittee/ucm2114>

<sup>21</sup> [http://journals.lww.com/cardiovascularpharm/fulltext/2006/05001/blood\\_pressure\\_effects\\_of\\_cox\\_2\\_inhibitors.8.aspx](http://journals.lww.com/cardiovascularpharm/fulltext/2006/05001/blood_pressure_effects_of_cox_2_inhibitors.8.aspx).

<sup>22</sup> <http://arthritis.emedtv.com/osteoarthritis/osteoarthritis.html>.

<sup>23</sup> <http://www.wrongdiagnosis.com/o/osteoarthritis/stats.htm>.

As of 2007, the global pharmaceutical market for OA drugs targeted some 27 million patients in the U.S. alone. The pharmaceutical expenses for treating OA include a variety of drugs targeting the different levels of severity of the disease, beginning with Paracetamol and Optalgin for lighter cases of OA, Voltaren and Naproxen for more serious cases, Celecoxib and Arcoxia for severe cases of OA and ending with Tramadol and Oxycodone for the most severe cases. Total sales of NSAIDs and COXIBs collectively amounted to some \$ 13.7 billion<sup>24</sup> of which approximately \$ 10 billion for NSAIDs and \$ 3.7 billion for COXIBs. It should be noted that Kitov intends to target this aggregate market share. The market's growth rate in 2007 was about 10% and is expected to continue growing at a rate of about 10% per annum in the coming years<sup>25</sup>.

As of the outline date, there are alternative treatments designed mostly to alleviate pain, preserve the joints and improve their functions. Changes in the patient's lifestyle consisting of a special diet, physical therapy and exercise, classified as conservative therapy, will help strengthen the joint muscles and increase their range thereby reducing body weight and minimizing some of the strain on the joints in order to relieve the pain.

In most cases the conservative therapy is not sufficiently beneficial, which requires most patients to seek medical treatment. The most common medical treatment is taking NSAIDs or COX-2 enzyme inhibitors as specified below based on a potency scale<sup>26</sup>: (a) preliminary care for mild OA commences with taking painkillers such as Paracetamol; (b) if Paracetamol is non-successful, physicians prefer prescribing drugs such as Ibuprofen (Artofen/Nurofen) followed by Naproxen and/or other NSAIDs (over 20 types of drugs including COX-2 enzyme inhibitors); (c) if these drugs are inefficient, steroids will be injected into the inflamed area; (d) if all of the above treatments fail, the patient should consider surgery for replacing the disabled joint.

As of the outline date, Kitov has been developing two (2) combination drugs based on Naproxen or Celecoxib which are known and approved drugs for relieving OA-related pain and for treating HTN and elevated blood pressure levels caused as the main side effect of currently available OA drugs.

<sup>24</sup> <http://knol.google.com/k/global-arthritis-market-review-2008-world-top-ten-ra-drugs>.

<sup>25</sup> IMS Health Report Global Biotech Sales 2007; Lundbeck Annual report 2006 (See: <http://www.materials.lundbeck.com/lundbeck/87/82/>).

<sup>26</sup> <http://www.mayoclinic.com/health/osteoarthritis/DS00019/DSECTION=treatments-and-drug>.

KIT-301 and KIT-302, the drugs being developed by Kitov for treating OA are based on two different drugs. According to the data published on the Center for Disease Control ("CDC") website<sup>27</sup>, about 27 million patients have been diagnosed with OA (of whom about 13.5 million have been diagnosed with both OA and HTN). Kitov estimates that, assuming a market penetration rate of about 10% and a monetary expenditure of approximately \$ 40 per month by each patient, Kitov may reach sales of approximately \$ 648 million in the U.S. alone within three (3) years, this without taking into consideration the size of the market for OA patients only, some of whom are potential consumers of the Company's combination drugs. See more details of the competition in the OA pharmaceutical market in paragraph 14.1 above.

Kitov's market penetration strategy for KIT-301 and KIT-302 for treating OA and HTN is based on the Company's assessment that the use of these drugs will provide patients and physicians additional certainty in view of the combined treatment of pain and Hypertension at certain doses. Kitov estimates that the additional certainty afforded by its drugs is expected to minimize the negative effect of elevated blood pressure caused by taking the painkillers. In addition, in keeping with the FDA's new policy, as described in paragraph 7.1.4 above, regarding blood pressure lowering drugs, Kitov will act to issue a boxed recommendation on its drugs which specifies the advantages of the drug as reducing the risk of heart attacks, stroke and cardiovascular diseases. Kitov estimates that this fact will have a positive effect in prioritizing its drugs at certain doses at the expense of currently sold alternatives. It should be noted that contrary to the aforesaid, the Black Box Warning on NSAIDs and COX-2 inhibitors informs the patients of the risk of heart attacks, stroke and cardiovascular diseases as a side effect of increased blood pressure when taking these drugs.

Furthermore, Kitov considers the convenience of combining the drugs into a single drug as a benefit for the patients who can receive combined treatment for pain and HTN. HTN usually does not produce tangible symptoms in patients, a fact which endangers the patient who is unaware of the need for treating it and therefore the combination of drugs may reduce the risk of HTN. Kitov believes that the combination of known and proven ingredients which are safe and known to the public of users (physicians, medical organizations and patients) and an improved medical effect for treating and preventing HTN will minimize the time and costs of introducing a new product into the pharmaceutical market.

**Kitov's assessments regarding the advantages of its drugs and their market penetration expectations are forward-looking information which is beyond Kitov's control or which is uncertain and relies, among others, on Kitov's subjective evaluations and estimates based on its past experience and on publications, data and surveys issued by professional entities in connection with the current state of the market in which Kitov operates.**



## **7.5 Critical success factors in the area of operation**

Kitov's pharmaceutical development activity has several main success factors as follows:

- a. Skilled personnel with experience in Kitov's development areas - chemistry, pharmacology, medicine and clinical trials.
- b. Identifying and selecting development products with potential and which may be adapted to Kitov's knowhow.
- c. Successfully protecting Kitov's patents and IP and/or obtaining exclusivity in marketing the drug by the regulatory authorities.
- d. Engaging with large pharmaceutical companies for collaborating in development and/or marketing efforts.
- e. Raising sufficient capital for achieving Kitov's development objectives.
- f. Obtaining regulatory approvals for marketing the drugs.
- g. Kitov's operations do not constitute infringement of any existing patents.

## **7.6 Barriers to entry into the area of operation**

Kitov's pharmaceutical development activity has several main barriers to entry as follows:

- a. The need for unique knowhow and vast experience in the relevant scientific areas.
- b. The need for large capital investments considered as high risk.
- c. Obtaining the required regulatory approvals for using the products.
- d. Obtaining comprehensive understanding of the pharmaceutical development industry in general and specifically of combination drugs.

e. Protecting Kitov's IP.

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### **7.7 Alternative products and changes therein**

As of the outline date, the pharmaceutical market does not offer a single product that fully replaces the KIT-301 and KIT-302 products being developed by Kitov given that in order to obtain an identical effect to that being developed by Kitov, the patient will have to take several drugs simultaneously. However, there are currently several alternative treatments for OA, including medicinal therapy, Chinese acupuncture, electric nerve stimulation therapy etc. See more details of alternative treatments for OA in paragraph 7.4 above.

### **7.8 The structure of competition in the area of operation and changes therein**

The pharmaceutical development market is host to large international corporations which develop a wide spectrum of drugs, both generic and NCEs, alongside smaller companies which develop a specific drug or combination drugs such as Kitov. Accordingly, the majority of smaller companies tend to interact with giant corporations at one stage or another of the drug's development in order to continue the drug's development and/or market the drug owing to the means available to the giant corporations (financing, marketing channels etc.). Large companies also tend to interact with smaller companies during the development stages in order to save development time and resources. For details of the competition for Kitov's products, see paragraph 14 below.

**Kitov's assessments regarding the developments in its economic environment and of the external factors that affect its activities contain forward-looking information which is beyond Kitov's control or which is uncertain and relies, among others, on Kitov's subjective evaluations and estimates based on its past experience and on publications, data and surveys issued by professional entities in connection with the current state of the market in which Kitov operates.**

## **8. The products being developed by Kitov**

Kitov's products are combinations of existing drugs which had successfully undergone the development stages and are sold on the pharmaceutical market. As specified above, these combinations are designed to treat elevated blood pressure levels and OA-related pain.

It should be noted that Kitov's founders possess vast professional experience in the biopharmaceutical sector and previously served as FDA's health and toxicity inspectors. They have accumulated considerable knowledge in the field of Kitov's expertise. In addition, Kitov's founders serve as advisors to various biotechnological companies. Their vast experience in this field and acquaintance with the regulatory requirements applicable to companies such as Kitov grants Kitov an edge in adopting the regulatory procedures required for developing its products.



The combinations being developed by Kitov have received the FDA's approval in principle for filing an application for approval of the combinations under the 505(b)(2) track, as specified in paragraph 2.2 above.

Prior to Kitov's foundation, and based on an agreement for the purchase of assets signed on October 13, 2010 between Kitov and JPW PCH LLC, a private U.S. company controlled by Dr. Peter Christian Hoyle and Dr. John Paul Waymack, Kitov's founders<sup>28</sup> ("**the asset purchase agreement**" and "**JPW**", respectively), Kitov was assigned JPW's rights to several patents and additional medical information underlying the development of the combinations. See details of the asset purchase agreement and patents acquired according thereto in paragraph 24 below.

As of the outline date, all of the combinations being developed by Kitov are designed for oral usage. Moreover, all of these combinations are FDCs combining two (2) known drugs with individually proven safety and efficacy. Below is a description of Kitov's combination products, the diseases which they target and their stage of development:

### **8.1 KIT-301 for treating high blood pressure and OA-related pain**

KIT-301 is a product based on two known generic drugs (Naproxen and Anti-HTN) for treating two medical conditions simultaneously - HTN and pain caused by OA. Studies show that about 13.5 million people in the U.S. alone have been diagnosed with both HTN and OA. As of the outline date, the drugs available for relieving OA-related pain cause elevated blood pressure in patients, which significantly enhances the risk of heart attacks, stroke and other cardiovascular diseases. Accordingly, Kitov believes that treating both these conditions simultaneously is essential.

As discussed above KIT-301 which Kitov is developing will combine two approved generic drugs for efficiently treating both HTN and OA-related pain, at its various stages and levels of severity.

Despite the fact that the pharmaceutical market currently offers a combination drug for treating HTN and cholesterol (Caduet), or a combination drug for treating joint pain and peptic ulcers (Vimovo), as of the outline date, there is no similar combination drug such as Kitov's KIT-301 and therefore KIT-301 offers significant benefits over currently available drugs by allowing patients to take a single drug for a combined treatment instead of several drugs thereby increasing patient compliance to taking all the required medications.



In addition, and given the FDA's new policy, as described in paragraph 7.1.4 above, regarding drugs for lowering blood pressure, Kitov will act to issue an additional indication on its KIT-301 labeling stating that KIT-301 decreases blood pressure and thereby reduces the chances of heart attacks, stroke and cardiovascular diseases. See more details about OA in paragraph 7.4 above.

### **The drug's development stage**

As stated above, as of the outline date, Kitov has received approval in principle for the KIT-301 and KIT-302 under the 505(b)(2) track. According to meetings held between Kitov and the FDA and the agreements reached between the parties, Kitov will conduct a phase three (3) trial based on the SPA outline which consists of a two-week treatment course in order to characterize the product's effect on blood pressure. In addition, Kitov will conduct a Drug-Drug Interaction ("DDI") trial aimed at proving that administering the combination of the two (2) drugs does not alter blood pressure levels compared to administering the drugs separately. Kitov is in the process of preparing the protocols for conducting the clinical trials and formulating a manufacturing design for marketing the final drug.

## **8.2 KIT-302 for treating high blood pressure and OA-related pain**

Similar to KIT-301, KIT-302 is an FDC product which relies on two known drugs whose efficacy and safety have been proven individually (Celecoxib and anti-HTN) and which works to treat two diseases simultaneously. Also in this case, the present drugs for treatment of Osteoarthritis pain induce elevated blood pressure in patients and, thereby, significantly raise the patients' chances to have a heart attack, stroke, and other cardiovascular diseases. Therefore, Kitov believes that it is very important to call for simultaneous treatment of both problems. The combination of drugs, as above, provide treatment of Osteoarthritis pain and, simultaneously, treat the current blood pressure and create an intense therapeutic effect in such a manner which reduces and even eliminates the patient's exposure elevated blood pressure as a result of Celecoxib.

For further details regarding Osteoarthritis, see paragraph 7.4 above.

### **The drug's development stage**

As stated above, as of the outline date, Kitov has a received approval in principle for the drug under the 505(b)(2) track. Kitov received guidance and answers from the FDA regarding protocols for Phase 3 and the DDI trial. For details, see table in 8.4 to the outline.



**8.3 Below are details of the components of the aforesaid combinations, the targeted diseases and the current development phases**

Name of product under development *)	Targeted disease of product under development	Expected benefits of the product compared to existing treatments	Development phase (status) as of the date of the outline	First expected clinical trial (505(b)(2))	Next milestone and the expected date to reach it
Naproxen - KIT-301 Anti-hypertensive FCDP	Osteoarthritis pain and high blood pressure	Combination of existing generic drugs (Naproxen and Anti blood pressure) whose integration allows treatment of current blood pressure problem or blood pressure problem which is caused from taking Naproxen. Another benefit is the convenience of taking one drug compared to taking two different drugs. Also, Kitov will act to issue an additional indication in the KIT-301 labeling stating that KIT-301 decreases blood pressure and thereby reduces the chances of cardiovascular diseases and risks.	The development of the product is delayed until Phase 3 of KIT-302 is carried out.	It was not yet decided when the trial will begin.	Not decided
KIT-302 - Anti-hypertensive Celecoxib FCDP	Osteoarthritis pain and high blood pressure	Combination of existing drugs (Celecoxib and anti-HTN) whose integration allows treatment of current blood pressure problem or blood pressure problem which is caused from taking Celecoxib. Another benefit is the convenience of taking one drug compared to taking two different drugs. Also, Kitov will act to issue an additional indication in the KIT-302 labeling stating that KIT-302 decreases blood pressure and thereby reduces the chances of cardiovascular diseases and risks.	Preparations to carrying out Phase 3 trial.	Within 1 to 2 quarters after closing.	Selecting and closing with medical suppliers the production and CRO for carrying out the trial.

\*) The products' names are internal denotation of  
Kitov.

\*\*) It is indicated that the estimated time to complete development under the 505(b)(2) track takes as long as 20-24 months from its start.

29 <http://knol.google.com/k/global-arthritis-market-review-2008-world-top-ten-ra-drugs>.



**Kitov's assessments regarding the target dates for the above trials are forward-looking information which is based on data currently available to Kitov regarding the potential development of the combinations and the grant of the appropriate regulatory approvals. These assessments may be realized in a different manner or not realized in full or in part due to a variety of factors including non-compliance with deadlines and/or endpoints and/or achieving the required funding to continue to develop and/or receiving appropriate regulatory approvals and/or other factors that are beyond Kitov's control such as the risk factors that are discussed in paragraph 28 to the outline.**

#### **8.4 The selected development phases for Kitov's products**

As part of its development plans, Kitov demonstrates two combinations which are designated to treat blood pressure and Osteoarthritis pain. These combinations integrate known and approved ingredients whose combination creates an intense therapeutic effect which lowers blood pressure and minimizes the side effects of elevated blood pressure as a result of taking the present drugs for treating said diseases. According to discussions with the FDA, it is agreed in principle that to approve the combinations which were demonstrated by Kitov, as above, no pre-clinical trials nor Phase 1 or 2 trials should be conducted, and all that Kitov is required to perform in order to approve them is a pivotal Phase 3 clinical trial as well as certain related trials.

First, Kitov aims to develop KIT-302 under the 505(b)(2) track based on the guidance that Kitov received from the FDA and based on the development strategy as elaborated below:

To begin with, Kitov will carry out a double blind pivotal Phase 3 clinical trial to examine blood pressure reduction in four groups each one of forty (40) patients during an overall period of two weeks. The first (1) group will receive Inabo (placebo). The second (2) group will be treated with a standard drug that exists in the market to treat blood pressure (one of the ingredients of KIT-302). The third (3) group will be treated only with Celecoxib and the fourth (4) group will be treated with KIT-302. According to Kitov's principal agreements with the FDA, the above trial will mainly rely on a simple test of the average of blood pressure among the groups.

It is indicated that the objective of this trial is to prove that the addition of Celecoxib reduces the blood pressure lowering effect of the blood pressure medication by less than 50%. As of the outline date, the FDA approved the protocol which Kitov presented at the SPA to carry out the above trial.

If Phase 3 trial meets its endpoints, under 505(b)(2) track, Kitov will carry out a clinical trial in a group of some 18 subjects whose objective is to examine the interaction between the two drugs that compose KIT-302 to ensure that their combination does not lead to a change in the quantity of the chemical material of the drugs' ingredients in the blood as a result of taking them together. As of the outline date, the FDA approved Kitov application for IND.

The trial, as above, will meet its endpoints if the level of Kitov's combination drug in the patient's blood will be like the level of the drug in the blood of a patient who has taken the ingredients of the combination drug separately.

Kitov aims to enter into an agreement with a company that will compose for it a new formulation such that both active ingredients in KIT-302 will be taken in one capsule only. After the necessary chemical procedures to consolidate the ingredients are complete and the ingredients are stable, Kitov will carry out a relatively minor clinical trial to examine the pharmacokinetics of the combination drug.

If the results of the above trials will clearly demonstrate evidences of the efficacy of KIT-302 in reducing blood pressure, Kitov will use the development strategy discussed above in the trial procedures of its other products.

Further, Kitov estimates that positive results in the above trials will support the patent applications that it had filed, which are expected to entitle the company to some 20 years of exclusivity from the date of the patent application. Despite the above, it is indicated that if the combining of the ingredients of KIT-302 is not registered as a patent, and Kitov files with the authorities the NDA for registration before any other competitor, it may be that Kitov will be granted regulatory exclusivity in relation to its products for a period of 3 to 6 years in the U.S. and up to 10 years in most of the European countries.

**Below are data pertaining to the projected trial plans for Kitov's products:**

It is indicated that Kitov expects to start to carry out the trials listed below even before the formulation is complete and applying the formulation will take place after the trials have been concluded.

Name of trial	Development stage in which the trial is included	Was an IND application for the trial approved or filed	The objective of the clinical trial	The medical institution where it will take place	The planned number of subjects taking part in the trial	Number of subjects taking part in the trial as of the outline date	Nature and status of the trial	Duration of the trial
Drug-drug interaction study	As part of the development process, it is necessary to carry out the DDI before filing the NDA however this will not limit the Hypertension study.	KIT-301, KIT-302 - IND approval was obtained	To examine whether there is any interaction between the drugs that changes the quantity of the chemical material of the drugs in the blood.	One institution in Israel	18	0	Under planning	Four months
Hypertension study	Phase 3 - Pivotal <sup>30</sup>	SPA approved and validated for KIT-301 and KIT-302	To quantify the effect of the different products on blood pressure with or without treating the blood pressure.	Several different institutions in Europe	160	0	Under planning	One year
Final formulation PK study	To produce and market the final product, it is necessary to carry	Application not filed	To ensure that the results of taking Kitov's combination drug	One institution in Israel	24 - 36	0	Under planning	Five months

out the PK study  
before filing the  
NDA.

leads to a  
equivalent result to  
taking two different  
drugs to treat the  
disease.

As stated in the SPA, the execution of the outline will be valid both for KIT-301 and KIT-302. After the completion  
30of the merger, the Company intends to submit an additional protocol for KIT-302 based on the protocol which has  
been already approved.

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**Kitov's assessments regarding the target dates for carrying out the above trials, the drug's approval track by the FDA and the respective expected costs are forward-looking information which is based on data currently available to Kitov regarding the potential development of KIT-302 and the grant of the appropriate regulatory approvals. These assessments may be realized in a different manner or not realized in full or in part due to a variety of factors including non-compliance with deadlines and/or endpoints and/or achieving the required funding to continue to develop and/or receiving appropriate regulatory approvals and/or other factors that are beyond Kitov's control such as the risk factors that are discussed in paragraph 28 to the outline.**

## **9. Patents**

Kitov owns two full patent applications and two preliminary applications which have been transferred to it under an asset purchase agreement from October 13, 2010 which was entered between Kitov and JPW, as discussed in paragraph 24 to the outline. It was also agreed to transfer the intellectual property from JPW to Kitov, as discussed in paragraph 17 to the outline.

As of the outline date, Kitov has in its hands an undertaking from JPW which confirms that to the best of its knowledge all the necessary records to register patents have been made legally as well as renewal, payment and ongoing maintenance of the patent applications. Further, JPW has undertaken that the summary of patents registration contains details of all the names of the patent inventors, that the patents do not violate the rights of any third party and that the patent registration does not omit any significant details. Of examinations that Kitov conducted with its patent consultants, there is no prevention and/or limitation on Kitov's activity that is an outcome of intellectual property protection.

## **10. Breakdown of revenues and profitability of products and services**

As of the outline date, Kitov has no sales and/or revenues since all its endeavors up to date focused on identifying indication for the combinations it develops, filing the respective patent applications and receipt of approvals to carry out trials.

## **11. New products**

As of the outline date, Kitov has no new products apart from the products under development as described in this outline.

## 12. Clientele

**12.1** As of the outline date, Kitov has not yet started to market and distribute its products and, accordingly, it has no customers.

**12.2** The potential customers for Kitov's products are international or local drug companies and/or international distributors and/or local distributors.

## 13. Marketing and distribution

**13.1** As of the outline date, Kitov has not yet started to market and distribute its products.

**13.2** The marketing and distribution policy that Kitov examines is mainly cooperation with strategic partners such as international or local drug companies and/or international distributors and/or local distributors.

## 14. Competition

The global pharmaceutical development industry is an extremely large business segment which is the basis of a huge billion-dollar highly developed and competitive market. Kitov is exposed to competition in its business segment since most of the drugs it develops have competitive drugs which companies and other entities develop simultaneously, as discussed in paragraph 8 to the outline. However, in the field of drug development there is a constant risk that a competitive factor will complete the development phases in advance of other entities that develop a treatment for the same disease. Also, new drugs in respect of which all development phases are complete and are introduced to the market challenge drugs and therapies that exist in the market.

#### 14.1 Osteoarthritis

As of the outline date and to the best of Kitov's knowledge, there are several medications on the pharma market that address Osteoarthritis pain, mostly of the type called NSAID - non-steroidal anti-inflammatory drugs such as Naproxen, Ibuprofen (Artofen), Voltaren and etc. Treatment using these medications induces major two side effects in patients taking them: the first is elevated blood pressure which increases the risk of cardiovascular diseases such as heart attack, stroke, and the second is peptic ulcer.

Nicox, which develops a Naproxen-based candidate under the name of Naproxcinod which is intended to treat pain and reduce blood pressure, has carried out Phase 3 trial in this candidate however, considering the fact that the results of this trial did not meet expectations, during May 2010 the FDA advisory committee recommended not to approve the drug and thereafter the FDA rejected the application for approval. To the best of Kitov's knowledge<sup>31</sup>, to receive this approval, Nicox has to perform several more clinical trials<sup>32</sup>. Further, Pozen and AstraZeneca developed a combination of Naproxen and anti-peptic ulcer medication. The joint effect which derives from this combination is intended to relieve Osteoarthritis pain and, at the same time, to reduce and eliminate peptic ulcer which also constitutes a side effect when taking this drug. However, in contrast to KIT-302 which Kitov develops, peptic ulcer pain represents a motivation for the patient to take antacid drugs for stomach where high blood pressure is not expressed by pain. This combination is not intended to treat diseases similar to those treated by KIT-302 which is intended to relieve Osteoarthritis pain while preventing blood pressure to rise. Accordingly, Kitov does not consider this combination a direct competitor of KIT-302 which it develops.

#### 15. Manufacturing capacity

As of the outline date, Kitov has no manufacturing capacity and, currently, it does not plan to manufacture its products alone. As of the outline date, Kitov's strategy is to manufacture its products by appropriate subcontractors. According to the development progress, Kitov will contemplate about manufacturing its products by strategic partners or collaborate in manufacturing and marketing.

<sup>31</sup> To the best of the Company's knowledge, Nicox application for patent does not exclude and/or prevents the Company's right to file an application for patent on its products.

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<http://www.nicox.com/files/pdf/AG20120606EN.pdf>

## **16. Fixed assets and facilities**

### **16.1 Lease agreement**

As of the outline date, Kitov has not entered into any lease agreements.

### **16.2 Company's labs**

As of the outline date, Kitov has no labs.

### **16.3 Research and development**

From time to time Kitov intends to enter into agreements with various consultants and/or service providers in connection with the research and development plans that it intends to perform. According to these agreements, Kitov will receive research services from such consultants in consideration of payments for their services. It is clarified that agreements entered into by Kitov define that the results of the services and all rights derived from the agreements including the rights to intellectual property are owned by Kitov and Kitov remains the sole proprietor and these consultants and/or service providers have no privilege thereto.

### **16.4 Details of amounts expensed for research and development**

In the year ended December 31, 2010 and in the year ended December 31, 2011, research and development expenses of \$ 224,657 and \$ 36,990 have been recorded, respectively. The accumulated balance of Kitov's research and development expenses as of December 31, 2010 and December 31, 2011 was \$ 1,094,880 and \$ 1,131,870, respectively. It is indicated that if Kitov does not comply with deadlines it may incur additional expenses in connection with development and this may even prevent products from being developed.

### **16.5 Research and development activity within 12 months from the date of the outline**

- 1. Combination for treatment of high bold pressure and Osteoarthritis pain**



The future plans for research and development of KIT-302 and KIT-301 for treatment of Osteoarthritis pain within 18 months after the date of the outline mainly describe the administration of Phase 3 clinical trial for KIT-302 with the respective cost involved being estimated at approximately \$ 1.5 million.

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**16.7** Below is a table which summarizes Kitov's research and development activity including the respective costs involved in its administration after the date of the outline (subject to additional fundraising by the Company after closing the transaction which is the issue of this report as well as the Company's Board approval to this development course):

Combination	Phase	Estimated cost
KIT-302	Phase 3 trial	\$1.5-1.8 million
	GMP for the production of the product for use in DDI and in Phase 3 human trials	\$150 thousand
	DDI trial	\$500 thousand
	Formulation and GMP for the production of the product for use in PK human trial and marketing	\$2.3 million
	Planning the clinical strategy for PK human trial	\$200 thousand
	Planning the regulatory strategy and planning the clinical strategy	\$350 thousand
	Patent protection - domestic stage - planning the regulatory strategy	\$75 thousand
	Preparing a marketing report	\$75 thousand
KIT-301	Chemical preparations and formulation	\$200 thousand
	Regulatory work	\$50 thousand
Current expenses		\$800 thousand
Total		\$6.2-6.5 million

**Future development, planned trials and their costs are forward-looking information which is based on data about the potential development of the combinations and drugs which, as of the outline date, was available to Kitov. These assessments may be realized in a different manner or not realized in full or in part due to a variety of factors including non-compliance with deadlines and/or endpoints and/or achieving the required funding to continue to develop and/or receiving appropriate regulatory approvals and/or other factors that are beyond Kitov's control such as the risk factors that are discussed in paragraph 28 to the outline.**

## 17. Intellectual property

Kitov owns two full patent applications and two preliminary applications which have been transferred to it under an asset purchase agreement which was entered with JPW. Kitov also filed registration applications for two patents for different but related technologies however, as of the outline date, Kitov has not received approval regarding all patents.

Below is a brief description of Kitov's main patent applications:

Kitov acquired a patent application in the U.S., Japan, Australia, Canada, Europe and Mexico (PCT/US/2009/044966). In the context of the legal preference granted in connection with the patent, two (2) preliminary applications were filed under the patent during 2008, 61/056,789 and 61/097,972. The first patent

1. application relates to a medicine that addresses a population who take anti-inflammatory drugs, pain relief drugs or antipyretic drugs type NSAID with the combination of treatment of high blood pressure with the aim of preventing or reducing the side effects related to the cardiovascular system.

In addition, Kitov acquired another application for a patent US 20110136793 and in the context of the legal preference in connection with the patent Kitov filed two (2) preliminary applications (61/304,243 and 61/320,477). These applications relate to a drug for the treatment of blood pressure or rapid heart rate induced by energizer treatment (i.e., anti-obesity or ADHD medications). The patent application claims the combination of a known and

2. proven drug that fights hypertension combined with ADHD medication treatment including energy drugs (such as CNS energizers). The application claims combination of the drugs and taking the two drugs separately and this to prevent rise in the blood pressure or rapid heart rate which is caused from taking such energizer. Similarly to the first PCT acquired by Kitov as above, the second patent application contains additional claims which are based on NSAID which causes elevated blood pressure or rapid heart rate.

**17.2 The table below summarizes Kitov's patent applications and their status as of the outline date:**

Number of patent	Description of patent	Kitov's rights to the parent	Priority date	Date of filing	Countries where the patent was approved	Countries where the patent application was filed
PCT/US/2009/044966	Pharmaceutical drugs and dosage methods which combine non-steroidal and anti-inflammatory drugs along with anti-hypertensive compounds.	100%	(1) 28.5.2008 (2) 18.9.2008 <sup>33</sup>	22.5.2009	Not approved	U.S., Japan, Australia, Canada, Europe and Mexico
<i>US 2011-0136793</i>	Improvement in hypertension caused by taking at least one drug that is used to treat hypertension.	100%	(1) 12.22.2010 (2) 2.4.2010 <sup>34</sup>	14.2.2011	Not approved	U.S.

**18. Human capital**

**18.1** As of the outline date, Kitov does not have employees but benefits from the activity of one of its founders, Dr. Morris Laster who also acts as the Company's interim CEO and chairman.

**18.2** Kitov's founders and employees consist of several key individuals who are essential to Kitov's activity as described below:

Dr. Morris Laster, has more than 20 years of biopharma industry experience. In the past he was the CEO and the founder of BioLineRx (Nasdaq: BLRX) where he was responsible for establishing the company as well as the development of drugs that were commercialized under transactions with a total of approximately \$ 650 million (combination of payments upon closing, milestones and royalties). He was also the chairman and the CEO of KERYX (Nasdaq: KERX) and the founder of three (3) other companies that went public on the Nasdaq. Dr. Laster also acted as a Deputy CEO Healthcare Venture Capital in Paramount in New York.

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The differences between the two preliminary requests will be supplemented later.

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See footnote 33 above.



Dr. John Paul Waymack has more than 20 years of biopharma industry experience. In the past he was a lecturer in surgery in the University of Texas and a medical reviewer to the FDA. Dr. Waymack also volunteered to the army as a major in the medical corps where he served as head of the research department of the Army Institute of Surgical Research.

In his 10 year academic career Dr. Waymack published over one hundred (100) scientific papers mainly in the field of prostaglandins immunology<sup>35</sup>. During the last fifteen (15) years, he serves as a consultant to biotechnology companies that are engaged in the development of pharmaceutical products such as Pfizer, Roche, Pharmacia, Warner, Lambert and Schering.

As of the outline date, Kitov is to a certain extent dependent on Dr. Paul Waymack in his capacity in Kitov.

## **19. Raw materials and suppliers**

Kitov is to engage with different suppliers in Israel and across the world for the purchase of materials that are necessary to develop Kitov's products. Substantially all of the materials that Kitov will purchase do not require manufacturing process and/or special qualifications and they will be purchased from a variety of suppliers in the chemical and pharmaceutical industry. Considering the above and as of the outline date, Kitov is not dependent on any particular supplier.

## **20. Financing**

From the date of its formation to December 31, 2011 Kitov was financed from the personal capital of its founders with a total of \$ 62,182 (JPW controlling shareholders and Dr. Morris Laster, \$ 32,513 and \$ 29,669, respectively).

Kitov's management expects that in the near future it will incur further losses as a result of its research and development activity which will be reflected in negative cash flows from operating activities. Kitov's management is of the opinion, based on its work plan, that the activity described above is dependent on closing the transaction under this outline. Further, the completion of the development plans described in this outline is subject on fundraising.

Prostaglandins - the research of the immune system with an emphasis on the hormonal substance in the organ's tissues which causes many side effects such as induce labor, aggregate platelets, sensitize pain and produce fever - <http://he.wikipedia.org>



## **21. Charges and bank guarantees**

As of the outline date, Kitov has no charges and/or guarantees.

## **22. Taxation**

Since the formation of Kitov in 2010 and as of the outline date, Kitov did not have any sales and/or revenues since all its endeavors up to date focused on identifying indication for the combination it develops, filing the respective patent applications and receipt of approvals to carry out clinical trials in the combination. Accordingly, Kitov does not pay taxes and does not file tax reports. Tax reports for 2011 were indeed filed.

## **23. Limitation of legislations and regulation and special restrictions applicable to Kitov**

As of the outline date, Kitov's primary activity is in the pre clinical trial phase. Kitov intends to start the human trial phase in the coming year and to that end Kitov acts with the assistance of the appropriate consultants and regulators to prepare the necessary clinical and regulatory strategy. Kitov's activity as to drug development is subject, from the initial stages of research and afterward, to regulation which was developed as a result of the public need to supervise these products. As much as Kitov proceeds in the development stages so the regulatory requirement will get stricter. Different authorities exist in different countries which supervise drug development process to ensure that the drugs being manufactured and marketed in that country meet high standard of safety, efficacy and quality. Performing clinical trials in any of the above phases requires the approval of the regulatory authorities in the countries where they take place. Only successful results in early stages will enable to transfer to advance phases.

### **23.1 U.S. Food and Drug Administration ("FDA")**

The FDA is a federal agency that is part of the U.S. Department of Health and Human Services, responsible for protecting the health of the American public through setting up and enforcing high standard for products and different regulatory requirements for safety and efficacy of products such as drugs to be taken by humans and animals, biological products, medical devices and beauty products.



Foreign companies that manufacture and/or develop drugs that are imported into the U.S. must comply with FDA regulatory requirements before importing into the U.S. because the FDA does not recognize regulatory approvals from authorities of other countries. The FDA requirements include, among others, quality system regulation, receipt of scientific reports on the medical devices or drugs and giving the FDA representatives the option to supervise the manufacturing process at the site.

Yet, it is indicated that Kitov's products, in both groups of products, have an advantage in the regulatory field: the combinations are composed of known ingredients whose efficacy and safety has been proven and they will be approved under the FDA short and rapid track, the 505(b)(2) track. As of the outline date, Kitov has no intention to apply for another track.

**Kitov's assessments regarding the approval tracks that will be required by the FDA are forward-looking information which is based on Kitov's familiarity with the above approval tracks and on professional consulting it received in this issue. Kitov's assessments may not be realized if the FDA does not approve the above approval tracks for Kitov.**

The 505(b)(2) is a unique approval track of the FDA which is intended to approve new products that are based on known drugs that have been approved in the past. The benefits of the track are that it enables applicants to rely on safety and efficacy data of the original drugs however they have to prove that the differences do not compromise safety and efficacy. The normal requirements for clinical trials to approve an absolutely unknown new drug are generally reduced under this track.

## **23.2 European Medicines Agency ("EMA")**

To the best of Kitov's knowledge and based on public publications, EMA is the agency responsible for the public health in the European Union through regulatory requirements, standardization and supervision of safety and efficacy of drugs and medical devices. Kitov's activity will be subject to EMA permits.

If Kitov will want to perform trials in Europe and/or market or sell its products in Europe, it will address the EMA with a request to authorize its drugs under the MRP track (Mutual Recognition Procedure) as applicable under European Directive No. 2001/83/EC as a track for authorization to place a medicinal product (drug) on the market in 27 states in the European Community. The MRP approval is a process where the authorization is given in one member state with a view to recognizing the decision in another member state.

### 23.3 Israeli Ministry of Health

Kitov's activity is subject to permits of the Israeli Ministry of Health in two realms:

1. In the realm of importing drugs and/or raw materials to be used in the research conducted by Kitov - Kitov is subject to the approval of the Unit for Medical Devices and Instruments at the Pharmacological Department of the Ministry of Health.

2. In the research and development realm, if Kitov performs studies in human subjects they will be subject to the approval of the Helsinki committee which operates by virtue of the Israeli Public Health Regulations (Clinical Trials in Human Subjects), 1980 ("**Regulations regarding Trials in Humans**") and in accordance with the principles of the Helsinki declaration<sup>36</sup> or any other authorizations demanded by the Israel Ministry of Health. According to the Regulations regarding Trials in Humans, the role of Helsinki committee is to design and perform each research study involving human subjects. Helsinki committee is an institutional committee that operates in the medical institution where the study takes place and constitutes the entity that approves and monitors ongoing studies. In practice, the physician who is the chief researcher submits on behalf of the applicant, namely Kitov, a research protocol to the committee. The committee will transfer to the director of the medical institution its decision regarding the requests for clinical trials which the director is authorized to approve without additional approval by the Ministry of Health. According to the procedure for trials in humans of the Ministry of Health, Helsinki committee will not approve the conduct of a clinical trial unless it has been convinced to its satisfaction that the conditions detailed below, among others, have been met: (a) the expected benefits to the trial participant and to society justify the risk and the discomfort to the trial participant; (b) currently available medical and scientific information justifies the conduct of the proposed clinical trial; (c) the scientific design of the clinical trial allows to answer the test question and is described clearly, accurately and in detail in the study protocol and complies with the principles of the Helsinki declaration; (d) the risks to the trial participant are minimized to the greatest extent possible; (e) the study plan will include a structured mechanism for optimal monitoring of the study; (f) the sponsor, principal investigator and medical institution are able and undertake to allocate the resources needed for the proper conduct of the clinical trial, including skilled personnel and necessary equipment; (g) the nature of commercial contract with the principal investigator and the medical institution in which the trial is being conducted does not prejudice the appropriate conduct of the clinical trial<sup>37</sup>.

<sup>36</sup> Helsinki declaration - ethical principles for medical research involving human subjects so they will conform with medical ethical standard.

<sup>37</sup> Guidelines for Clinical Trials in Human Subjects of the Ministry of Health, in accordance with the Regulations regarding Trials in Humans, see at the website of the Ministry of Health at [http://www.health.gov.il/Download/pages/nohal\\_k\\_human2006.pdf](http://www.health.gov.il/Download/pages/nohal_k_human2006.pdf)



## **24. Significant agreements**

### **24.1 Asset purchase agreement between Kitov and JPW PCH LLC ("JPW")**

On October 13, 2010, Kitov entered into an asset purchase agreement with JPW according to which JPW transferred to Kitov's ownership the rights to all patent applications (including the related goodwill) and the know-how in the biotechnology and drug development field as well as all documents and other information that is associated with Kitov's activity in the development of unique ethic drugs based on the know-how that was collected by the shareholders and directors of JPW in drug development and regulatory procedures of drug development in the U.S. ("**the assets**"), as described in paragraph 8 to the outline.

The assets purchased under the agreement contained an initial application to register a patent which JPW had filed in May 2008 and also an additional application to register a patent and two other preliminary applications to register a patent which had been filed later. As for details regarding the patent applications which have been filed and assigned to Kitov, as above, see paragraph 17 above.

As consideration for the purchase of assets, Kitov paid to JPW \$ 100 in cash and allocated to JPW 8,000,000 Ordinary shares of Kitov of NIS 0.01 par value each, representing 80% of Kitov's issued and outstanding capital.

According to the agreement, the parties agreed that the ownership to both full patent registration applications and two other preliminary applications which had been filed by JPW would be transferred to Kitov.

The agreement also determines that if after eighteen (18) months from closing Kitov (a) did not offer its shares to the public or (b) Kitov's Board did not approve financing for Kitov, JPW will be entitled to repurchase the assets which have been transferred to Kitov's ownership, as above, as well as any improvements that Kitov did in the assets and any right that derives from or is associated with the intellectual property of the assets sold under the agreement in consideration of \$ 100 and eighty percent (80%) of Kitov's share capital as of that date. It is clarified that this paragraph will be cancelled after closing takes place according to this outline.

According to the agreement JPW has undertaken that to the best of its knowledge there are no defects in the assets and that all the necessary records to register patents have been made legally as well as renewal, payment and ongoing maintenance of the patent applications. Further, JPW has undertaken that the patent registration applications which were transferred to Kitov contain details of all the names of the patent inventors, that the patents do not violate the rights of any third party and that the patent registration does not omit any significant details.

## **25. Legal proceedings**

As of the outline date, Kitov is not a party to any legal proceedings and it is not aware of any threat to a legal action against it.

## **26. Objectives and business strategy**

As of the outline date, Kitov's targets consist of developing new chemical drugs with added clinical and commercial value based on known and approved active substances.

Kitov's objectives are:

To develop combination products with clinical and commercial advantages in the treatment of blood pressure and a. Osteoarthritis pain which are based on the combination of several existing drugs and to undergo approval by the FDA and EMEA.

After building value in said products or completing the development, including obtaining approvals, Kitov aims to b. engage with international companies for the purpose of granting them sublicenses based on upfront payments, milestones and royalties and/or marketing agreements, all depending on the product's and the market's position.

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Below are details about Kitov's targets and business strategy in connection with the products it develops for the treatment of Osteoarthritis and ADHD through 2015 (subject to fundraising by Kitov as well as the Kitov's Board approval to the plans described below):

Labeling	Present status	2013	2014	2015
KIT-302	SPA for KIT-301 was approved by the FDA. Also, a written indication that the conditions contained in the SPA will also apply on KIT-302's development outline. For carrying out a clinical trial, Kitov must obtain the FDA's approval for the KIT-302 SPA.	Start clinical studies - conducting said procedure is expected to last approximately 18 months	Start to market to international companies	Filing NDA, receipt of approval and start sales

## 27. Anticipated development in the coming year

In the coming year Kitov aims to start the development activities of KIT-302 with a view to prove its benefits in treating patients who have been diagnosed with Osteoarthritis and blood pressure.

For details regarding the studies that Kitov intends to conduct, see 8.4 above. Without derogating from the generality of the above, Kitov does not exclude the option to apply for Chief Scientist's grants under the Israeli Law for the Encouragement of Industrial Research and Development, 1984 as will be determined by Kitov's Board.

## 28. Risk factors

### 28.1 Macroeconomic risk factors

The macroeconomic trends, events and development may impact Kitov's activity in addition to the following trends:

#### 1. Exchange rate risk

The Company's activity is exposed to exchange rate risk of the NIS in relation to the dollar which mainly arises from the fact that the Company expects to raise capital in NIS but most of its projected expenses are in dollars.

#### 2. Economic risk

A recession and decline in share prices of companies in the pharmaceutical industry may impede Kitov in locating partners to its development plans and in raising the funds required to finance Kitov's research and development plans.

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## **28.2 Risks related to the business**

### **1. Risk of competition**

Development of technologies and/or products that compete with the technologies and/or products of Kitov may cause decline in the demand to products developed by Kitov (if and to the extent their development is complete).

### **2. Risk during the development process**

As in any plan to develop drugs, Kitov's ability to complete the development of the product is uncertain due to difficulties and/or technological problems. Even if Kitov's drugs are developed it is uncertain that they will be evaluated as efficacious and safe to use. Further, it is uncertain the Kitov will be able to complete the development of the drugs in the time frame and/or according to the costs listed in the outline. Non-compliance with deadlines may cause Kitov additional expenses in connection with development and may even prevent completion of drug development.

### **3. Uncertainty regarding receipt of a patent and protection of intellectual property rights**

Kitov's success is dependent on its ability to receive protection for the intellectual property rights to drugs which it develops. In fact Kitov estimates that it would be possible to register patents on its intellectual property but it cannot be determined with certainty if and when such patents will be approved. Further, even if the above patents are approved it cannot be assessed whether Kitov will be able to protect and/or enforce them in the future among others due to attempts to develop products that are similar to Kitov's products while over-taking Kitov's registered patents, if any.

### **4. Regulatory risk**

A change in regulatory requirements and rigorous regulatory requirements in connection with the permit to use the products Kitov develops may lengthen the planned development schedules of Kitov's products and may significantly increase product development costs.

Government's policy regarding allocation of research and development sources may impact Kitov's activity which is carried out, among others, by receiving Government support through Israel Chief Scientist.





**5.**

**Legal risk**

Kitov is exposed to different types of legal proceedings such as it is exposed to legal proceedings due to potential side effects of drugs it develops, or due to other problems associated with the products and their production. In most cases the side effects are discovered during the development stage of the drug but they may be revealed also in later stages. If the side effects are discovered for one or more of the drugs Kitov develops, Kitov may be exposed to legal claims in substantial sums. Kitov may be also sued for patent infringements by third parties. As of the outline date, Kitov is not aware of any claim or demand against it.

**28.3 Risks factors specific to Kitov**

**1. Uncertainty regarding demand and pricing of Company's products**

Demand for Company's products after being developed that justifies production and commercialization is uncertain. Also, setting a price for products to be developed by Kitov, to the extent developed, and the cost of their production is uncertain.

**2. Insurance risk**

The clinical trials that Kitov aims to conduct are subject to insurance policy that allows carrying them out. It may be that Kitov will not procure such insurance policy and, accordingly, Kitov's ability to complete its development plans on a timely manner is uncertain.

**3. Dependency on key personnel**

As stated in paragraph 18 above, the Company depends to a certain extent on Dr. Paul Waymack, one of Kitov's founders ("**key personnel**"). Kitov estimates that if it no longer retains the management service of its key personnel, the development of its products and/or the commercial aspect of its activity may be delayed until these key personnel are fully replaced.

**28.4 Table of risk factors**

The table below summarizes the risk factors that may impact Kitov's activity and its business results and Kitov's assessments as to the ratings for the impact of the risk factors on Kitov's overall activity:

	Ratings for the impact of the risk factors on Kitov		
	<b>Large impact</b>	<b>Moderate impact</b>	<b>Minor impact</b>
Macro risks			
Exchange rate risk			X
Economic risk		X	
Risks related to the business			
Risk of competition	X		
Risk during the development process		X	
Uncertainty regarding receipt of a patent and protection of intellectual property rights		X	
Regulatory risk	X		
Legal risk			X
Risk factors specific to Kitov			
Uncertainty regarding demand and pricing of Company's products		X	
Dependency on major customer			X
Insurance risk			X
Dependency on key personnel		X	

**Kitov's assessments regarding the above risk factors as well as the degree of impact of the risk factors on the Company contains forward-looking information which is based on data available to Kitov as of the outline date as well as Kitov's estimates and plans. In the future Kitov may be subject to other risk factors and the impact of any risk factor, if realized, may be different from Kitov's assessments.**

Kitov Pharamceuticals Ltd.

Valuation Study - As of September 30, 2012

BDO Ziv Haft  
Amot Bituach House Building B, 48  
Menachem Begin Road, Tel Aviv  
66180  
Israel  
www.bdo.co.il

October 23, 2012

To whom it may concern,

Per your request, BDO Ziv Haft Consulting & Management Ltd. (Hereinafter: "**BDO**") has performed a valuation analysis of the IP of Kitov Pharmaceuticals Ltd. (Hereinafter: "**Kitov**" or the "**Company**"), as of September 30, 2012 (Hereinafter: the "**Valuation Date**"). The valuation is carried out in light of XTL Biopharmaceuticals Ltd. (Hereinafter: "**XTL**") intention to acquire the Company's shares.

This report, the analysis and conclusions are based on information that has been generated by the companies, and therefore, has not been subject to our independent verification.

The analysis and conclusions contained in this report are based on various assumptions which may or may not be correct, being based upon factors and events subject to uncertainty. Such assumptions were developed solely of illustrating the principal considerations. Future results or values could be materially different from the forecasts and analysis contained here. In addition, this report shall not be deemed to contain or provide a fair price opinion.

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Please note that some of the financial data received, was in electronic spreadsheet format and did not include any audited, reviewed or otherwise formulated financial statements, as should be the case in a standard valuation study.

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**Kitov** Pharamceuticals Ltd. |

In the valuation analysis, we relied on the following data:

- The Company's audited financial statements for 2011;
- The Company's outline, as of October, 2012;
- The Company's presentation as of July, 2012;
- The Company's KIT-302 development plan;
- The Company's KIT-302 projected development costs;
- Other information provided by Management, either written or oral;

Publicly available information (Articles, websites) regarding the OA and HTN market; and Yahoo Finance, Bloomberg and other relevant financial websites.

The following table summarizes the results of the valuation:

Dollar in thousands  
Total IP's Value, as of September 30, 2012 40,236

*Source: BDO Analysis.*

Should you have any questions concerning our analysis or report, please contact us at 972-3-6374391.

**Respectfully submitted,**

**BDO Ziv Haft**

**Consulting & Management Ltd.**

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**Kitov Pharamceuticals Ltd.** |



**Glossary**

NIH	National Institute of Health
EMA	European Medicines Agency
FDA/ FDAC	U.S. Food and Drug Administration
FDC	Fixed Dose Combination
NCE	New Chemical Entity
GMP	Good Manufacturing Practice
IND	Investigational New Drug
NDA	New Drug Application
OA	Osteoarthritis
COX-1 / COX-2	"Cyclooxygenase" enzymes which causes inflammation and thus pain
HTN	Hypertension = high blood pressure.
CMC	Chemistry Manufacturing and Control

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Section 1

Company Profile

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## Company Profile<sup>1</sup>

### General

Kitov is an Israeli biotechnology company engaged in drug development. The Company was incorporated on June 13, 2010, under the name J.P.W Pharmaceuticals Ltd., and on August 1, 2010, changed its name to its current one. On November, 2010 the Company commenced operations.

As of the Valuation Date, the Company is engaged in research and development of two Fixed Combination Drug Products (Hereinafter: "**FCDP**"), each consisting of two existing effective drugs, combined together for one drug with the aim of treating the pain caused by Osteoarthritis (Hereinafter: "**OA**"), and Hypertension (Hereinafter: "**HTN**").

The following table presents the Company's FCDPs, KIT-301 and KIT-302, specifications:

Product	Indication	Combination
KIT-301	Osteoarthritis+HTN	Naproxen (Aleve) + Anti-HTN
KIT-302	Osteoarthritis+HTN	Celecoxib (Celcox) + Anti-HTN

As of the Valuation Date, the drugs consisting of the KIT-301 are classified as a Generic Drugs, while the Celecoxib which is one of the KIT-302's components is patent protected (until 2014). Accordingly, at the beginning the Company thought to focus on the development of KIT-301.

As of the Valuation Date, the Company intends to initially focus on the development of KIT-302, due to the fact that by the time the Company is expected to finish KIT-302's development, the Celecoxib would become generic, hence patent free resulting in Celecoxib outselling Naproxen in the market. Hence, as of the Valuation Date the Company's KIT-301 is part of its future development products' pipeline.

### Development History

Prior to its establishment, the Company founders began developing the KIT-301, by applying regulatory approval requests for the FDA. The Company applied a Pre-IND request, and following the request, two formal meetings were

held with the FDA in the first quarter of 2011, setting the principals for the Company's product development. The FDA essentially approved a lineation for developing the drugs according the 505(b) (2) track (as described henceforth). Moreover, the FDA proposed that the Company would perform a single Phase III clinical trial - as a single experiment for examining each of the drugs being developed - significantly shortening the development completion timetable to only 20-24 months.

On May 6, 2011, the Company applied the FDA for IND, in order to perform a Drug-Drug Interaction study (Hereinafter: the "**DDI Study**") for the drug's safety and blood levels. The IND was approved on June 10, 2011, and the Company is currently allowed to perform the DDI Study. On September 8, 2011, the Company applied for SPA (Special Protocol Assessment), in advance for the KIT-301 Phase III clinical trial. On January 24, 2012, answers for the SPA were received, along with answers for the Company's questions from October 24, 2011. **It is important to note, the FDA commented that the KIT-301's development plan aforementioned is also valid for KIT-302.**

<sup>1</sup> Source: The Company's outline and the Company's presentation, as of July, 2012.

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## Company's Profile

### **Development History**

The Company's management estimates that in order to receive EU approval, the Company might have to conduct another clinical trial, and consultation with the regulatory agencies in different countries in Europe would have to be conducted.

### **Products**

#### *General*

As described above, the Company's products are combinations of existing drugs, which already successfully passed the development phases and are marketed in the pharmaceutical market.

The following is a description of the Company's products under development:

**KIT-301** - KIT-301 based on two known Generic Drugs - Naproxen, which is an OA treatment drug, and Anti-HTN drug. It is aimed at treating the pain caused by OA and HTN simultaneously, and at ameliorating the negative side effects of hypertension (HTN), caused from the OA treatment drug.

**KIT-302** - KIT-302 based on two known Generic Drugs - Celecoxib, which is OA treatment drug, and Anti-HTN drug. It is aimed at treating the pain caused by OA and HTN simultaneously, and at ameliorating the negative side effects of hypertension (HTN), caused from the OA treatment drug.

### **The Products' Advantages**

According to the Company, its products have a few main medical advantages, which distinguish them from their competitors:

Ability to simultaneously treat both the medical condition and the drug's side effects, hence reducing physician's concerns of providing a medicine to a patient, due to its side effects.

Providing a clinically tested combination of a drug and a treatment for its side effects, rather than imposing the legal responsibility for providing a suitable side effects' treatment over the physician.

Reducing the self-participation drug purchase costs, by allowing patients to purchase a two-in-one medicine, instead of two different products.

In addition to the Company's medical advantages detailed above, the FCDPs which the Company develops have several commercial advantages reflecting in a significant shortening of the development completion timetable compared to those of new drugs, and in a decrease of the risk element in the development activity.

These advantages derive from the fact that the Company's FCDPs' components are known and approved for use drugs, and therefore the necessary regulatory track for the approval of the product basing on them in the FDA, is the 505 (b) (2) track.

In this regulatory track, you can submit an application for product approval, which is based on the outcomes of the safety and efficacy tests done on the FCDP's components by others in the past. Accordingly, the approval procedure of the 505 (b) (2) tracks is shorter and cheaper than NCE (New Chemical Entity) drugs' approval procedures.

### *The Products' Development Stages*

#### **Clinical Trials**

In discussions between the Company and the FDA it was agreed in principal that in order to get a marketing approval by the FDA approval for the Company's FCDPs, there is no need to perform pre-clinical trial or additional safety or efficacy trials, but only to perform a Phase III pivotal clinical trial and two additional minor trials.

As mentioned above, the Company intends to initially focus on the development of KIT-302 in the 505 (b) (2) track, according to the FDA's guidance, and the development strategy, as described below:

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Company's Profile

Products

*The Products' Development Stages (Cont.)*

**Clinical Trials (cont.)**

**One Phase III HTN clinical trial** - The Company will perform a double blind Phase III pivotal trial to test lowering blood pressure in four groups of 40 patients for a period of two weeks. One group will get placebo, the second group will get Anti-HTN, the third group will get Celecoxib and the fourth group will receive KIT-302.

The trial only requires that at least half of the blood pressure lowering effects of the antihypertensive drug remains when the Celecoxib component is added, i.e. KIT-302.

As of the Valuation Date, the FDA approved the protocol presented in the SPA that was submitted by the Company for the performance of this trial.

**Two additional minor clinical trials**

**DDI Study** - The Company will perform a minor clinical trial on a group of 18 healthy individuals in order to test Drug-Drug Interaction between the two active ingredients in KIT-302, and to ensure that the combination between them does not cause a change in the chemical material quantity of these drugs in the blood.

This trial will be regarded as a successful one if the level of the Company's FCDP in the patient's blood will be similar to the level of the drug in patient who took the Company's FCDP's components separately.

As of the Valuation Date, the FDA approved the NDA application that was submitted by the Company for the performance of this trial.

**Final Formulation PK study (Hereinafter: the "PK Study")** - The Company will perform a minor clinical trial on a group of between 24 and 36 healthy individuals in order to test levels of the drug in the blood for the new KIT-302 combination. This trial will be carried out after the completion of all the chemical processes required to both consolidate the materials into one pill, and to get a stability of materials, and before the submission of the NDA documents.

If these aforementioned trials show clear evidence of KIT-302's efficacy in lowering blood pressure, the Company will use this development strategy for clinical processes of its other products.

In addition, the Company estimates that the positive results of these trials will strengthen the patent applications submitted by the Company, and a new drug if approved, would provide the Company with 20 years of exclusivity. However, as of the Valuation Date there is no real evidence for such approval.

It should be noted, that if KIT-302 is not registered as a patent and the Company filed the NDA for its drug's registration to the authorities before any other competitor, it will be given 3 years of exclusivity in relation to its product. Moreover, if the Company succeeds in an additional minor trial it will receive an additional 3 years of exclusivity.

In Europe, the Company can expect to receive up to 10 years of marketing exclusivity in the larger countries. However, due to the fact that as of the Valuation Date it is hard to estimate the size and the probability of the Company's FCDDP's potential penetration to the European market, this valuation doesn't take into account this market potential and focuses only on the USA market potential.

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**Kitov** Pharamceuticals Ltd. |

## Company's Profile

## Products

*The Products' Development Stages (Cont.)***Clinical Trials (cont.)**

The following table presents the Company's products trial plans:

Name of Clinical Trial	The Development Stage	IND Application	The Trial Purpose	Medical Facility	No. of Tested Individuals	Trial Status
DDI Study	The DDI Study has to be performed before the NDA application, but it does not limit the conduction of the Phase III HTN Study.	An IND approval was given to KIT-301 and KIT-302	To test Drug-Drug Interaction between the two active ingredients in the FCD, and to ensure that the combination between them does not cause change in the chemical material quantity of these drugs in the blood.	A single Facility in Israel	18	In Process
HTN Study	Phase III Pivotal	SPA was approved and is valid for KIT-301 and KIT-302	To prove the antihypertensive drug retains at least half of its effect when Celecoxib is added.	Several Facilities in Europe	160	In Process
PK Study	The PK Study has to be performed before the	As of the Valuation Date,	To test levels of drug in blood for	A single Facility in Israel	24-36	In Process

NDA application the Compant did the new  
not submit an combination.  
application.

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Company's Profile

Products

*The Products' Development Stages (Cont.)*

**Chemistry Manufacturing and Control (Hereinafter: "CMC")**

The over-encapsulation of the Celecoxib capsules and Anti-HTN tablets is planned to use microcrystalline cellulose as filler. The matched placebos might contain the microcrystalline cellulose filler only. Clinical trial supplies could be ready to ship approximately three to four months after project initiation, as described below:

- One month for production, packaging, labeling, and testing of the over-encapsulated RLDs and matched placebos.

- One month of stability data are needed for regulatory submissions.

Estimated costs of production and testing of the phase III clinical trial supplies will be approximately \$130,000, including sourcing of the RLDs. The clinical trial supplies will be manufactured by a contract manufacturer under GMPs.

Formulation development studies of the final FCDP will be initiated with three basic studies typically performed for this type of formulation:

- Confirmation of the Anti-HTN and Celecoxib stability when mixed and stored for at least three months under accelerated conditions. The samples will be tested for assay and related substances to confirm whether the two drug substances can be co-formulated or not.

- Confirmation of the separate Anti-HTN and Celecoxib stability when mixed with the excipients expected to be used in the final FCDP. The mixtures of the drug substances with excipients will be stored for at least three months under accelerated conditions and tested for assay and related substances to identify any incompatibilities that may exist.

Deformulate Celecoxib capsules in order to determine the quantitative composition of the capsules based on the listing of excipients in the Celebrex labeling.

The third study will provide a starting point for formulation development studies of the FCDP. These studies are expected to take approximately five months to execute and are expected to cost up to \$100,000, or more, depending on the complexity of the deformulation studies on Celecoxib capsules. The two stability studies may be extended by up to six months as well.

Parallel to the conduction of the 3 experiments aforementioned, analytical method development studies will also be conducted. Primarily, these studies will be focused on developing analytical methods for assay, related substances (impurity), and dissolution testing of the Celecoxib and Anti-HTN components of the FCDP. The analytical method development studies are expected to take about three months and cost approximately \$140,000.

The final analytical procedures will then need to be validated for the final FCDP. The validation studies are expected to take about two months and cost approximately \$200,000.

Final FCDP formulation studies will be conducted on the basis of the short-term stability studies for the drug substances and excipients as well as the deformulation study conducted on Celecoxib capsules. The proposed formulation development plan is to create a copy of Celecoxib capsules (Celebrex capsules) and then determine the most appropriate way to co-formulate the Anti-HTN component.

There will be three targeted strengths of the FCDP. The single strength of the Celecoxib component is based on the currently approved labeling for which the 200 mg strength is approved for treatment of osteoarthritis whereas the three strengths of the Anti-HTN component reflect the currently approved strengths of Anti-HTN tablets.

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## Company's Profile

## Products

### *The Products' Development Stages (Cont.)*

#### **CMC (Cont.)**

Two approaches will be evaluated. In one approach, the required amounts of Anti-HTN will simply be added to the determined Celecoxib formulation. In the second approach, a comparable weight of the Celecoxib capsule filler, lactose, will be removed from the formulation and a comparable weight of Anti-HTN added to the formulation. The critical quality controls for the final formulation include acceptable blend uniformity and flowability data demonstrating that the final blend is both uniform and flows in the capsule filling process.

The formulation development studies are targeting a hard gelatin capsule to simulate dissolution characteristics of Celecoxib capsules to ensure the best likelihood of achieving bioequivalence between the final FCDP and the two RLDs. Celecoxib is a poorly water soluble compound and the Celecoxib capsules contain povidone which is used as a disintegrant for poorly water soluble drugs to enhance the relative bioavailability. Anti-HTN is water soluble and is present at relatively low doses in the final FCDP, and so bioavailability issues for the Anti-HTN component are not envisioned at this time.

These formulation development studies are expected to take about four months, and cost about \$200,000.

The formulation development studies can be initiated based on the three month results of the short-term drug substance-drug substance and drug substance-excipient stability studies as well as the Celecoxib capsule deformation studies described above. Comparative short-term stability studies will be conducted through at least three months on at least two prototype formulations.

The final FCDP will be selected on the basis of the above formulation development and short-term stability studies. The manufacturing process will be transferred to a contract manufacturer where design of experiment studies will be conducted. These studies are intended to confirm the manufacturing procedures at laboratory scale and confirm the critical process controls. These studies are anticipated to take approximately two to three months and will cost about

\$60,000. The manufacturing process will then be scaled up and at least two feasibility lots will be manufactured to confirm the manufacturing procedures in the same manufacturing equipment that will be used for manufacture of the registration stability lots. The scale-up batches are expected to take one to two weeks and cost about \$100,000.

Registration of the stability lots of the FCDP will be manufactured upon successful completion of the feasibility lots. Three lots per strength will be manufactured and put on long-term and accelerated stability testing in two packaging configurations. The packaging configurations will consist of a 100-count plastic bottle and a 30-count plastic bottle or blister package. The 30-count package will be used as a physicians sample pack. The registration stability lots will take approximately six to eight weeks to manufacture and will cost about \$1,000,000. Stability testing will be carried out for at least 24 months and will cost approximately \$500,000.

Upon NDA approval, the manufacturing process will be validated prior to product launch. Process validation studies will take about three months and will cost around \$300,000 with production costs per lot expected to be about \$75,000 per lot. Three validation lots of each strength will be manufactured, so a total of nine lots will be manufactured at a cost of about \$670,000. Routine production lots are expected to cost about \$75,000 per lot of 1,000,000 capsules or about \$7.44 per 100-count bottle. For comparison, a 100-count bottle of Celebrex has a retail price of \$557.99.

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Company's Profile

Products

*The Products' Development Stages (Cont.)*

FDA Submission

Prior to initiating clinical trials, an IND must be submitted to FDA and FDA must grant approval to begin any clinical trial. This has already happened.

Prior to obtaining marketing approval, an NDA must be submitted to FDA and FDA must approve the NDA. NDAs are voluminous and are generally tens of thousands or hundreds of thousands of pages in length, even for a 505(b) (2) type of NDA. The time and cost for preparing an NDA is highly dependent upon the management and operating style and experience of the NDA sponsor, combined with the allocation of adequate resources to the unique characteristics of the specific investigational new drug and anticipated format and content of the NDA. There will also be a requirement for a significant commitment of manpower to prepare the NDA.

The Company estimates that the cost of NDA Filing related to the KIT-302 will amount to approximately \$ 500,000.

The Development Plan Timetable

The following table present KIT-302's submission timetable:

Task	2012		2013			2014			2015				
	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
CMC													
Overencapsulation	√	√	√	√	√	√							
New Pill Formulation + Stability	√	√	√	√	√	√							
Clinical Trials													



## Company's Profile

## Products

*The Products' Development Stages (Cont.)*

## The Development Plan Costs

The following table presents the Company's KIT-302's full development plan costs:

Drug Development Task Expenses (Thousands USD)	2012	2013				2014				Total 2 Years
Development Stage Task	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3		
		88	20	20	–	–	–	–	128	
	408	408	51	1,430	102	102	26	26	2,553	
CMC	–	–	–	–	100	100	100	–	300	4,326
	–	–	–	–	225	225	225	–	675	
	–	–	–	–	–	–	–	670	670	
	315	80	80	–	–	–	–	–	475	
Clinical Trials	–	–	600	500	400	400	–	–	1,900	
	–	–	–	–	–	215	–	–	215	
	–	–	25	25	–	–	–	–	50	
Others	25	25	–	–	–	–	–	–	50	600
	–	–	–	–	–	–	500	–	500	
Total Development Costs	748	601	776	1,975	827	1,042	851	696	7,516	
	748	4,179					2,589			
Management and corporate operation expenses	210	205	195	195	195	195	195	195	1,585	
	210	790					585			
Total Expenses	958	806	971	2,170	1,022	1,237	1,046	891	9,101	

Source: The Company's management.

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## Company's Profile

### Patents

On October 13, 2010, the Company signed an agreement with JPW PCH LLC (Hereinafter: "**JPW**"), to Acquire all of JPW's activity, which included:

All of JPW's patents rights (including goodwill);

JPW's Know-How in biotechnology and drug development;

The documentation and other information regarding the unique ethical drug development selling activity, based on JPW's executives and shareholders knowledge in drug development and US drug development regulatory.

In exchange, the Company paid JPW one hundred dollars and allocated 8 million regular company shares (0.01 NIS each), which represents 80% of the Company's share capital.

The Company received JPW's written obligation that, to its best knowledge:

The patent registration, including the renewal, payments and maintenance, were made according to law;

The requests contain all of the patent inventors' names, and the patents are not violating any 3<sup>rd</sup> party rights or missing substantial details.

In addition, the Company filed two patent applications, but as of the Valuation Date it didn't receive approval for any of them.

The following table summarizes the Company's patents' applications:

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Patent	Description	Priority Date	The Submission Date	The Countries in which the Patent was Approved	The Countries in which the Application was Submitted
PCT/US2009/044966	Pharmaceutical drugs and methods of using compounds that combine non-steroidal anti-inflammatory compounds with anti- hypertension	(1) May 28, 2008 (2) September 18, 2008	May 22, 2009	The Patent has not yet been approved	USA, Japan, Australia, Canada, Europe, Mexico
PCT/US2011/024707	Improving rise in blood pressure caused by drug use by giving at least one anti-hypertension drug	(1) February 12, 2010 (2) April 2, 2010	February 14, 2011	The Patent has not yet been approved	USA

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## Company's Profile

### Sales

As of the Valuation Date, the Company has no sales and/or income, as it focused on finding an indication for its development combinations, registration of the patent' applications concerning these combinations and completion of all the necessary approvals for its relevant trials.

### Customers

As of the Valuation Date, the Company had not begun marketing or distributing its products, and therefore has no customers. The Company's potential customers are international or local drug companies and/or international or local distributors.

### Marketing and Distribution

As of the Valuation Date, the Company had not begun marketing or distributing. The Company's marketing and distribution strategy is based mainly on cooperation with strategic partners, such as international or local drug companies and/or international or local distributors.

### Development Team

The Company's development team is as follows:

**Paul Waymack (M.D., Sc.D. Chairman, and CMO)** - Former academic transplant surgeon and former FDA medical officer. Over 15 years of experience in drug development.

**Peter Hoyle (PhD, Co-Founder, and Consultant)** - Former FDA Pharmacologist/Toxicologist. Over 25 years experience in drug development and consulting to multi-national and emerging biotech and pharma companies.

**Morris Laster (M.D., President)** - Healthcare entrepreneur with two decades of experience. Founding CEO of BioLineRx (TASE: BLRX).

**Simcha Rock (CPA, MBA, CFO)** - Formerly Senior VP at Edmond de Rothschild Private Equity Management Ltd.

**Bill Berlin (PhD, VP CMC)** - Former FDA chemist.

**Debbie Kirshling (PhD, VP Regulatory Affairs)** - Over a decade of experience in drug development.

## Business Strategy

The Company's objectives are:

To develop FCDPs with clinical and commercial advantages in the treatment of HTN and pain caused by OA that are based on combination of several existing drugs, and to approve them in the FDA and EMEA.

To cooperate with international companies for the purpose of granting them a sub-licence based on upfront payments, milestone payments and royalties, and/or marketing contracts, immediately after the development completion.

## The Company's Specific Risk Factors

Following is a description of the Company's specific risk factors:

**Uncertainty concerning the demand and pricing of the Company's products** - Uncertainty that there will be a demand for the Company's products, which justifies their production and commercial marketing. In addition, there is uncertainty concerning the pricing and costs of those products.

**Insurance risk** - The clinical trials that the Company intends to perform are dependent on the Company's engagement in an insurance policy that enables their performance. There is a possibility that such a policy will not be approved.



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Company's Profile

**The Company's Specific Risk Factors**

**Dependence on key personnel** - The Company is dependent on its founders (Hereinafter: the "**Key personnel**"). Therefore, the Company estimates that in case these Key personnel will stop being involved in the Company's management, there is a chance of a delay in its products' development.

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## Company's Profile

## Income Statement

The following table presents the Company's audited Income Statement:

A period of 14 Months Ended 31/12/11	Audited (Thousands NIS)	Translated* (Thousands USD)
Revenue	–	–
Expenses		
Salaries & Related Expenses	65	18
Research & Development	21	6
Communication Expenses	0	0
Legal and Accounting	288	80
Travel	19	5
Office Supplies	7	2
Taxes and Fees	10	3
Bank Charges	2	1
Total Expenses	413	115
Net Profit (Loss)	(413 )	(115 )

**Balance Sheet**

The following table presents the Company's audited Balance Sheet:

As of 31/12/2011	Audited (Thousands NIS)	Translated* (Thousands USD)
Assets		
Cash and Cash Equivalents	2	1
Due From VAT	28	7
Intangible Assets, Net	80	21
Total Assets	111	29

Liabilities			
Payroll and Payroll Taxes Payable	15		4
Account Payables	186		49
Other Creditors	1		0
Due to Related Party - WayMack	98		26
Due to Related Party - Hoyle	21		6
Shareholder Loans - Laster	102		27
Total Liabilities	424		112
Shareholders' Equity	(313	)	(83
			)
Total Shareholders' Equity & Liabilities	111		29

*\* The balance sheet and Income Statement were directly translated to USD using the USD/NIS currency rate as of December 31, 2011, and the average rate for the precedent 14 months, respectively. The translation is merely for readers' convenience, and was not conducted according to any accounting standards requirements.*

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Section 2

Market Overview

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## Market Overview<sup>2</sup>

### **General**

As described above, the Company is engaged in research and development of two FCDPs, each consisting two existing effective drugs, combined together to one drug, aiming, on one hand, to treat both the pain caused by OA, and HTN, and, on the other hand, to ameliorate the negative side effects of hypertension (HTN), caused from the OA treatment drugs. Accordingly, trends and events in the pharmaceutical development market, in general, and in the FDC market, the HTN treatment market and the OA treatment market, in particular, have an essential effect on the Company's operation and financial outcomes. Following is an overview of the market in which the Company operates.

### **The Pharmaceutical Development Market**

#### *General*

The pharmaceutical development market is very wide market on which a market of hundreds of billions of dollars is based. This market is highly developed and competitive. Many companies in the world develop simultaneously drugs for the same diseases, and therefore there is a direct competition to those drugs or competition on the market share that these drugs are related to. In addition, new approved drugs which enter to the market will always be in a competition with the existing drugs and treatment in it.

The pharmaceutical development market is influenced by many factors, among others the rise in the population age, which increases the demand for drugs treating old diseases and improving quality of life.

The pharmaceutical development market is ruled in the world mainly by international pharmaceutical companies that are capable to allocate the required large resources for the completion of all the development stages, the clinical trials, the registration and marketing of drugs. In addition to these major pharmaceutical companies, there are also small pharmaceutical companies in this market that operate in the research and development of drugs, and research institutions and universities are usually working on the early stages of drug discovery, and seek, with the process of research, to collaborate with major pharmaceutical companies. These collaborations can be realized in each of the different development stages, starting from early research to clinical trials.

***Fixed Dose Combination Market (FDC)***

In recent years, pharmaceutical companies around the world have developed some successful FDCPs for different medical purposes, some of which the FDCP treatment was proven to have significant benefits over single drugs, such as the AIDS treatment, where large portion of the available efficient treatments consists of a combination of two or more drugs, and also for respiratory diseases, such as Asthma, where two-drugs compounded treatments were proven to be more efficient.

In addition to the aforementioned fields and similarly to the FDCPs that the Company develops, as of the Valuation Date, there are additional FDCPs that are produced and sold in this market, such as:

**VIMOVO** - VIMOVO is a combination of two drugs - Naproxen and Prilosec – produced by AstraZeneca and Pozen. This FDCP is intended to treat pain and ulcer simultaneously. VIMOVO was approved on May 2010 and its first year sales (2011) amounted to \$33.8 million.

<sup>2</sup> Source: The Company's outline and the Company's presentation, as of July, 2012.

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## Market Overview

### The Pharmaceutical Development Market

#### *Fixed Dose Combination Market (FDC) (Cont.)*

**CADUET** - CADUET is a combination of two drugs - Lipitor and Anti-HTN - produced by Pfizer. This FDCP is intended to treat cholesterol and HTN simultaneously. CADUET sales in 2011 amounted to approximately \$339 million.

**JANUMET** - JANUMET is a combination of two drugs - Glucophage and Sitagliptin - produced by Merck. This FDCP is intended to treat diabetes. JANUMET sales in 2011 amounted to approximately \$1.36 billion.

The FDCP benefits are:

- **Medical benefits**, by improving the medical treatment for two medical conditions diagnosed patients;
- **Convenience benefits**, by allowing to use a single drug instead of two;

**Commercial benefits**, by keeping and even broadening active materials market share, when their patents are about to expire, and also making a FDCP developer attractive for acquisition by the original drugs developer. The commercial value of combination products primarily relates to maximizing market share and protecting that share following the expiry of key patents. Brand extension strategies involve the introduction of combination products as part of a more general product lifecycle development program for a key brand.

#### *The HTN Treatment Market*

### HTN Disease And Its Market Size

HTN is the most common chronicle medical condition in the western world - over 20% of the general population and over half of the elderly population is suffering from it.



HTN, by its physiological definition, is the pressure applied by the blood over the blood vessels. HTN is measured by units of Mercury Millimeters ("mm Hg"), and it has to be

There are two blood pressure values:

**Systolic blood pressure** - Systolic blood pressure is defined as the peak in the arteries during the cardiac cycle while the heart contracts (systole).

**Diastolic blood pressure** - Diastolic blood pressure is the lowest pressure point while the heart relaxes (diastole).

HTN medical condition is one of the most common diseases among the elderly population. Research show that approximately half of the elderly population in the USA suffers from blood pressure of at least 130/90.

### **HTN Treatments**

Among 95% of the people who suffer from HTN, the cause is unknown, but studies assume that the initial development of HTN involves genetic factors, along with different environmental factors, such as: increased salt consumption, obesity, exaggerated alcohol consumption, and even mental and behavioral factors derived from different circumstances, including working in certain professions.

HTN, might lead for disturbance in the individual's functioning, and a decline in the medical condition, but the patient wouldn't necessary be aware of or feel the HTN. Accordingly, blood pressure is known as the "Silent Killer".

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## Market Overview

### **The Pharmaceutical Development Market**

#### *The HTN Treatment Market (Cont.)*

#### **HTN Treatments (Cont.)**

The danger imposed by HTN is mainly the accumulated arteries damage, especially within sensitive tissues, such as the heart, eyes and brain. Even the slightest rise in blood pressure may cause significant cardiovascular problems (e.g. A 5 mm Hg increase in blood pressure increases the risk for stroke by 67% and increases the chance for heart diseases by 15%). The HTN treatments focuses on decreasing the blood pressure for normal values. As a result of different studies relating to blood pressure, a new diagnosis for pre-hypertension was recognized by the medical community, which provides that a population with a blood pressure of 115-130 Hg is exposed also to heart attacks, strokes, and cardiovascular diseases. This recognition is opposed to the former one that assumes that only population with blood pressure levels that are higher than 120/80 Hg and lower than 130/90 Hg is considered high risk population for cardiovascular diseases.

In addition, these studies have shown that most of the elderly population is expected to significantly benefit from taking Anti-HTN drugs.

Studies conducted on the increase in blood pressure caused by using different drugs that one of their side effects is an increase in blood pressure have shown that one of the Naproxen and Celecoxib side effects are a 3.5 mm Hg and 2.5 mm Hg increase in blood pressures, respectively.

#### *The OA Treatment Market*

#### **OA Disease And Its Market Size**

OA is the most common Arthritis, mainly among the elderly population, where younger population mostly suffers OA due to joints injuries. The main symptom of OA is a gradually appearing pain in joints that increases in effort and relieved in rest.

OA is one of the most common physically disability inflicting conditions among elders. According to the Centre for Disease Control (Hereinafter: the "CDC") as of 2007, over 27 million people in the US suffer from some level of OA, and it is estimated that by the year 2030 around 70 million (or 25%) of the people over 65 in the US will suffer from it. When tested in X-Ray, more than half of the 65 year old people were diagnosed of suffering from OA in at least one joint. In addition, as a result of the life span increase among the western population, the number of people who suffer from OA has raised. Among people younger than 45, more men suffer from OA, and among people older than 45, more women suffer from OA.

## OA Treatments

Currently, there are different alternative treatments for OA, mainly designed for pain reduction, joints preservation and function improvement. Changes in lifestyle (e.g. Diet, Physiotherapy, and Exercise) can strengthen the joints muscles and enlarge their range, and reduce the body weight and the load over the weight bearing joints, thus reducing the intensities of pain. Nevertheless, most of the conservative treatments aren't efficient enough hence most patients are applying for medical treatment. The most common drugs are Non-Steroid Anti-Inflammatory Depressors (NSAID) or COX-2 Inhibitors, as described below, in an deteriorating order:

- Mild OA in initial treatment will begin taking drugs, such as: Paracetamol and Optalgin.

If the Paracetamol treatment isn't effective, the doctor will prefer to seek treatment using NSAID's such as Ibuprofen (Artofen/Nurofen), Naproxen, and/or other NSAID's (there are over 20 kinds of drugs including enzyme COX-2 inhibitors).

- If the aforementioned drugs treatment isn't effective, a direct injection of Steroids will be given into the Joint.
- If all of the above treatments fail, the patient should consider the possibility of joint replacement procedure.

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## Market Overview

### **The Pharmaceutical Development Market**

#### *The HTN and OA Combined Market*

As described above, the Company's FCDPs is aiming, on one hand, to treat both the pain caused by OA, and HTN, and, on the other hand, to ameliorate the negative side effects of hypertension (HTN), caused from the OA treatment drugs.

As detailed above according to the CDC over 27 million people in the US suffer from some level of OA. According to discussion with the Company's medical director, Prof. Moshe Mittelman (Hereinafter: "**Prof. Moshe Mittelman**") this number include also mild cases of the disease treated by mild pain relievers such as Paracetamol and/or ointments such as Voltaren, while the relevant market for the Company's FCDPs is those patients suffer from severe and chronic OA.

Accordingly and based on discussions with Prof. Moshe Mittelman, in order to estimate the HTN and OA combined market size, it is better to use the HTN market size as a starting point, since this market size is easier to estimate and therefore more valid.

As detailed above, HTN is the most common chronic medical condition in the western world - over 20% of the general population is suffering from it. According to Prof. Moshe Mittelman the ratio between OA patients and HTN patients in the USA is approximately one fifth (20%). Moreover, according to CDC and Prof. Moshe Mittelman, 50% of OA patients in the USA suffer from both diseases (OA and HTN).

According to Prof. Moshe Mittelman the potential market size for the Company's FCDPs is only 33% of the above calculated market, based on the fact that most doctors are conservative, and therefore prefer to give two known drugs instead of a new one.

#### *Drug Development Processes*

The Pharmaceutical Development Market is subject to international regulations and standards aiming to protect the public in this field, such as the American FDA and the European EMA.

Drug development is a complex process that generally includes the following primary stages. Each stage must comply with the health agencies' criteria before the next stage can begin, as follows:

**Preclinical Phase** - This phase includes trials in labs and on animals in order to demonstrate the Efficacy of the drugs in models that simulate the disease for which the drug is being investigated. The preclinical phase also includes trials under meticulous conditions in order to determine whether the drug has any toxic adverse events and to learn about the various characteristics in animals. In addition, the preclinical stage includes development of manufacturing methods under GMP (Good Manufacturing Practice - which is a collection of manufacturing requirements that the drug must comply with in order to allow the administration of the drug to patients in the future).

**Phase I** - This is the first clinical phase in drug development in which an initial test is carried out on humans. The phase is designed to assess the safety of the drug as well as the maximum dosage that can be safely administered to patients. This phase may also include additional tests such as drug dispersal in the body and how long the drug remains in the blood, measurements that will help assess its biological availability, etc. There are instances in which this trial phase is carried out on healthy individuals and in other cases; the trial is carried out on patients with the investigated disease.

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## Market Overview

### **The Pharmaceutical Development Market**

#### *Drug Development Processes (Cont.)*

**Phase II** - In this phase, an initial test of the Efficacy of the drug is carried out in patients. In addition, this phase attempts to determine the optimal dosage of the drug to treat patients. At the same time, the phase continues to test its safety. These Several Phase II trials are often carried out while the first Phase II trial (Phase 2a) is designed to serve as proof of concept and the second Phase II trial (Phase 2b) is a broader trial that includes a larger number of patients and that is carried out in a larger number of medical centers than was Phase 2a.

**Phase III** - The decisive phase of multinational, multicenter, randomized, placebo controlled, double blind trials. This phase includes the largest number of subjects (hundreds and even thousands) and the trial is carried out in a large number of medical centers around the world. The purpose of this phase is to prove the Efficacy and safety of the drug in a large number of patients in a way which simulates as much as possible (more than the previous phases) the manner in which the drug will be used in the clinical practice. Following successful conclusion of this phase, applications can be submitted to the health agencies for receipt of approval to register the drug.

It should be emphasized that the conduct of clinical trials on human beings in each of the phases, Phase I, Phase II and Phase III requires the prior approval of the Helsinki Committee/ IRB and of the regulatory agencies in the countries where the clinical trials are being conducted. It should be noted that only successful results in the preliminary phases will guarantee the possibility of moving on to the next stage.

Once all of the said phases (including completion of Phase III) have been successfully completed, the Company can submit an application for approving the drug's registration by the relevant regulatory agency, e.g. the FDA in the US.

The development process, as previously mentioned, takes many years and requires extensive funding due to the prolonged duration of the trials, the process for obtaining approval, and obtaining information and results from the trials, at the end of which the Group will be able to submit an application for approval to register the drug by the FDA or any corresponding regulatory agency in any other country. Occasionally, the clinical development, including the conduct of clinical trials, is carried out with the assistance of expert subcontractors who are entrusted with operating under the meticulous professional standards dictated by the regulatory requirements.

In light of the fact that the Company's FCDPs' components are known and approved for use drugs, the necessary regulatory track for the approval of the product basing on them in the FDA, is the 505 (b) (2) track.

In this regulatory track, one can submit an application for product approval, which is based on the outcomes of the safety and efficacy tests done on the FCDP's components in the past (the Company needs to perform only a single Phase III trial and additional two minor trials). Accordingly, the approval procedure of the 505 (b) (2) track is shorter and cheaper than NCE (New Chemical Entity) drug approval procedures.

### **The 505(b)(2) Application<sup>3</sup>**

As aforementioned, the Company is planning to use the FDA's 505(b)(2) application, which is supposed to shorten the overall time until marketing.

A 505(b) (2) application is one for which one or more of the investigations relied upon by the applicant for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted" (21 U.S.C.355 (b) (2)).

<sup>3</sup> **Source:** <http://www.fda.gov/downloads/Drugs/.../Guidances/ucm079345.pdf>

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## **Market Overview**

### **The Pharmaceutical Development Market**

#### ***Drug Development Processes (Cont.)***

#### **The 505(b) (2) Application (Cont.)**

An applicant should submit a 505(b) (2) application if approval of an application will rely to any extent on published literature (a literature-based 505(b)(2)).

If the applicant has not obtained a right of reference to the raw data underlying the published study or studies, the application is a 505(b)(2) application; if the applicant obtains a right of reference to the raw data, the application may be a full NDA (i.e., one submitted under section 505(b)(1)).

An NDA will be a 505(b)(2) application if any of the specific information necessary for approval is obtained from literature or from another source to which the applicant does not have a right of reference, even if the applicant also conducted clinical studies to support approval. Note, however, that this does not mean any reference to published general information (e.g., about disease etiology, support for particular endpoints, methods of analysis) or to general knowledge causes the application to be a 505(b)(2) application. Rather, reference should be to specific information (clinical trials, animal studies) necessary to the approval of the application.

An applicant should submit a 505(b) (2) application for a change in a drug when approval of the application relies on the Agency's previous finding of safety and/or effectiveness for a drug. This mechanism, which is embodied in a regulation at 21 CFR 314.54, essentially makes the agency's conclusions that would support the approval of a 505(j) application available to an applicant who develops a modification of a drug.

Section 314.54 permits a 505(b) (2) applicant to rely on the agency's finding of safety and effectiveness for an approved drug to the extent such reliance would be permitted under the generic drug approval provisions at section 505(j). This approach is intended to encourage innovation in drug development without requiring duplicative studies to demonstrate what is already known about a drug while protecting the patent and exclusivity rights for the approved



drug.

A 505(b)(2) application may be submitted for an NCE when some part of the data necessary for approval is derived from studies not conducted by or for the applicant and to which the applicant has not obtained a right of reference. For an NCE, this data is likely to be derived from published studies, rather than FDA's previous finding of safety and effectiveness of a drug. If the applicant had a right of reference to all of the information necessary for approval, even if the applicant had not conducted the studies, the application would be considered a 505(b)(1) application.

For changes to a previously approved drug product, an application may rely on the agency's finding of safety and effectiveness of the previously approved product, coupled with the information needed to support the change from the approved product. The additional information could be new studies conducted by the applicant or published data.

This use of section 505(b)(2), described in the regulations at 21 CFR 314.54, was intended to encourage innovation without creating duplicate work and reflects the same principle as the 505(j) application: it is wasteful and unnecessary to carry out studies to demonstrate what is already known about a drug.

An applicant should file a 505(b)(2) application if it is seeking approval of a change to an approved drug that would not be permitted under section 505(j), because approval will require the review of clinical data.

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## **Market Overview**

### **The Pharmaceutical Development Market**

#### *Drug Development Processes (Cont.)*

#### **The 505(b) (2) Application (Cont.)**

However, section 505(b) (2) applications should not be submitted for duplicates of approved products that are eligible for approval under 505(j) (see 21 CFR 314.101(d) (9)).

In addition, an applicant may submit a 505(b)(2) application for a change in a drug product that is eligible for consideration pursuant to a suitability petition under Section 505(j)(2)(C) of the Act.

In the preamble to the implementing regulations for the Hatch-Waxman amendments to the Act, the agency noted that an application submitted pursuant to section 505(b)(2) of the Act is appropriate even when it could also be submitted in accordance with a suitability petition as defined at section 505(j)(2)(C) of the Act (see 57 FR 17950; April 28, 1992).

Unlike a full NDA for which the sponsor has conducted or obtained a right of reference to all the data essential to approval, the filing or approval of a 505(b)(2) application may be delayed due to patent or exclusivity protections covering an approved product. Section 505(b) (2) applications must include patent certifications described at 21 CFR 314.50(i) and must provide notice of certain patent certifications to the NDA holder and patent owner under 21 CFR 314.52.

A 505(b)(2) application may itself be granted 3 years of Waxman-Hatch exclusivity if one or more of the clinical investigations, other than BA/BE studies, was essential to approval of the application and was conducted or sponsored by the applicant (21 CFR 314.50(j); 314.108(b)(4) and (5)). A 505(b)(2) application may also be granted 5 years of exclusivity if it is for a new chemical entity (21 CFR 314.50(j); 314.108(b)(2)). A 505(b)(2) application may also be eligible for orphan drug exclusivity (21 CFR 314.20-314.54(a) (1)(v)).

Approval or filing of a 505(b)(2) application, like a 505(j) application, may be delayed because of patent and exclusivity rights that apply to the listed drug (21 CFR 314.50(i), 314.107, and 314.108 and section 505A of the Act). This is the case even if the application also includes clinical investigations supporting approval of the application.

*Exclusivity Strategies in the United States and European Union<sup>4</sup>*

Pharmaceutical companies generally obtain patents over their products or processes long, before launching their products into market. Since it can take up to 12 years for a company to obtain market approval, there is often little, if any, patent protection left, when the product is marketed.

In order to provide pharmaceutical companies an opportunity to recoup their drug research and development investment and to incentivize continuing innovation, the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) has implemented numerous provisions to extend the period of which companies can market their drugs free of generic competition.

The non-patent exclusivity provisions, allow pharmaceutical companies to market products without competition from incoming generics, which results significant financial benefits for the original drug manufacturer, and making it is essential for pharmaceutical company valuate its exclusivity options and develop its competitive strategy early in the drug development process. In the United States, the FDCA provides several exclusivity opportunities, including: (a) New chemical entity exclusivity; (b) Clinical investigation exclusivity; (c) Orphan drug exclusivity; and (d) Pediatric exclusivity.

<sup>4</sup> *"Exclusivity Strategies in the United States and European Union"*, C.Hathaway, J.Manthei and C.Scherer, June 2009

## Market Overview

### The Pharmaceutical Development Market

#### *Exclusivity Strategies in the United States and European Union (Cont)*

Similar forms of non-patent exclusivity are available to pharmaceutical companies marketing drugs in the EU.

#### United States Overview

Recent FDCA amendments have led to exclusivity periods that can be twice as long as they were 20 years ago, when companies were required to rely almost exclusively on the drug product's patent term.

The "*Drug Competition and Patent Term Restoration Act*", or the Hatch-Waxman Act, passed in 1984, provides up to five years market exclusivity to companies introducing a new chemical entity to the market (NCE Exclusivity) and up to three years market exclusivity for conducting clinical trials to support changes to products already on the market (Clinical Investigation or CI Exclusivity).

Pharmaceutical companies are not required to apply for the Hatch-Waxman exclusivities. The Center for Drug Research and Evaluation (CDER) decides the forms of exclusivity that are available for each new pharmaceutical product entering the market. In addition, exclusivity may be granted for Orphan Drugs, as described henceforth.

#### *New Chemical Entity Exclusivity*

A pharmaceutical manufacturer can gain NCE Exclusivity in the US by introducing a drug that contains an "active moiety" (e.g. molecule or ion responsible for the drug substance's physiological or pharmacological action), that had not been previously approved by FDA in a new drug application (NDA). Since the NCE Exclusivity attaches to the drug's active moiety, FDA cannot approve or even accept a competitor's abbreviated new drug application (ANDA) or 505(b)(2) application (that relies on investigations that were not conducted by or for the 505(b)(2) applicant) for a generic or follow-on product that is based on the same active moiety during the five-year exclusivity period,

regardless of whether the drug is intended for the same indication as the original innovative drug, or for another indication.

Since the approval process for an ANDA averages approx. two years and the FDA cannot accept an ANDA for review during the period of NCE exclusivity, the period of exclusivity from generic competition can exceed seven years. However, NCE exclusivity does not prevent FDA acceptance and approval of another NDA for a product with the same active moiety that relies on clinical trials conducted by or for the second NDA applicant.

#### Clinical Investigation Exclusivity

Drug companies that sponsor additional clinical testing on a previously-approved drug, which leads to changes in the marketed product pursuant to an approved new NDA or supplemental NDA, may be granted three additional years of Clinical Investigation Exclusivity. Sponsors may receive CI Exclusivity for the following changes: new dosage forms, new indications and a product's change from prescription to over-the-counter (OTC).

Unlike NCE Exclusivity, FDA can accept an ANDA and start the review process during the CI Exclusivity period. However, FDA may not deliver its approval of the competitor's application until the period of exclusivity is over.

#### Orphan Drugs Exclusivity

The "*Orphan Drug Act*" provides drug manufacturers with seven years of market exclusivity period after FDA's approval of the drug, as well as research grants and tax credits for each new orphan drug developed.

## **Market Overview**

### **The Pharmaceutical Development Market**

#### *Exclusivity Strategies in the United States and European Union*

#### **United States Overview (Cont.)**

##### Orphan Drugs Exclusivity (Cont.)

Orphan drugs are defined as drugs that intended to treat diseases and conditions that affect 200,000 or fewer Americans, or for which the sales in the United States are not reasonably expected to cover the drug manufacturer's cost of research and development for the drug.

If a product is granted orphan drug exclusivity, FDA may not approve (but may accept) applications for generic or second innovator products that contain the same active ingredient and are labeled for the same orphan indication.

However, FDA may accept and approve applications for drugs having the same active moiety, for a different indication.

In addition, FDA may accept and approve a subsequent orphan drug application for the "same drug" and the "same orphan indication," if the applicant demonstrates that the product is "clinically superior"- safer, more effective or significantly more convenient than the first drug. This provides an incentive for drug companies to continue to develop innovative and effective products for the orphan drug market.

##### Pediatric Exclusivity

Pediatric exclusivity relates for products that have already another form of marketing exclusivity. Therefore, a sponsor who obtains pediatric exclusivity will have its patent, NCE Exclusivity, Clinical Investigation Exclusivity, or orphan drug exclusivity extended by six months. Pediatric exclusivity is granted to a sponsor with an approved NDA for a particular drug, who conducts a pediatric study or studies, following a FDA request to evaluate the pediatric effectiveness and safety of the drug. Pediatric exclusivity, once attained for a drug, applies not only to the specific drug product studied in the pediatric population, but to all of the applicant's dosages, formulations and indications for drugs with existing marketing exclusivity or patent life that contain the same active ingredient.

A pediatric study does not have to be successful for the sponsor to obtain pediatric exclusivity. The drug will be awarded six months of pediatric exclusivity, as long as the sponsor submits a study, which fits the FDA's request.

### ***Critical Success Factors***

Following are the critical success factors in the pharmaceutical development market:

- Having skilled human resources in chemistry, pharmacology, medicine, and clinical trials;
- Selecting products to develop that bare potential, and are suitable for the company's knowledge;
- Successfully protecting the patents and intellectual properties;
- Engaging with large companies that work in the field, for cooperation with the development and/or marketing;
- Recruiting enough capital to achieve the development goals;
- Accepting regulatory approvals to market the drugs;
- Avoiding from violation of existing patents.

### ***Barriers to Market Entry***

Following are the barriers to enter the pharmaceutical development market:

· Having the unique knowledge and long-years experience in the relevant science fields;

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## Market Overview

### The Pharmaceutical Development Market

#### *Barriers to Market Entry (Cont.)*

Raising large capital investments, which are considered at high-risk;

Accepting regulatory approvals for using the drugs;

Having a broad understanding in the drug development field in general, and especially in combination drugs.

Protecting the intellectual properties.

#### *Significant Regulatory Effects*

Following is a description of the significant regulatory effects in the pharmaceutical development market:

**FDA instructions regarding HTN drugs** - On March 2011, a new FDA instruction was published, directing to add a clarification for the Anti-HTN drugs usage instructions, that "Decrease in HTN reduces the chance for heart-attacks, stroke and cardiovascular diseases". The Company expects that the aforementioned instruction would have a positive effect over its FCDP developed drugs, given the fact that its FCDPs are supposed to have an Anti-HTN effect.

**The US HealthCare Reform** - The "Compilation of Patient Protection and Affordable Care Act", Commencing March 2010, is the biggest American Healthcare System reform since the 60's. It is supposed to allow over 30 million American Citizens to be entitled to healthcare insurance. According to the act, every citizen above the age of 65 will receive an extended medical coverage from the Medicare program that is subsidized by the American government, and will receive substantially discounted drugs, where 50% of the discounts would be given by the pharmaceutical companies and 25% of the Drug's price would be subsidized by the American government. The Act's cost is estimated for hundreds of billions of dollars, and it is supposed to be an important tier in the US healthcare volume increment. An extended treatment in both OA and HTN, of which most people who suffer from are elderly people, is consistent with the intended reform goals, but as for today, the Company doesn't know whether the reform would have a direct effect over its business. Given that each of its FCDP components are currently included in the Act

aforementioned, the company estimates that after its products development would be completed, its products will be included within the benefited drugs list. The Company intends to apply for such approval, whether by itself or using a third party, only after its products would be completed and authorized.

### *Competition*

As of the Valuation Date, and to the Company's best knowledge there are variety of medicines for pain caused by OA, mostly from NSAID type, which are non-steroidal anti-inflammatory drugs against pain, such as: Naproxen, Artofen, Voltaren, etc. The treatment with these drugs has two major side effects in patients: (1) increase in blood pressure; and (2) gastric ulcers.

As of the Valuation Date, there are no available complete substitute products in the drug market for the Company's KIT-302, as described below:

**Naproxcinod** - Nicox has developed a Naproxen-based drug called Naproxcinod, supposed to treat pain and decrease blood pressure, and preformed the phase III trials, but given that the trial has failed withstanding its expectations, and the FDA's consulting committee negative recommendation, the FDA consequently decided not to authorize the drug. Currently, Nicox has to conduct more clinical trials and decide on its future steps, and it seems that Nicox would not continue without a strategic partner.

**VIMOVO** - Pozen has developed a Naproxen-based drug called VIMOVO, supposed to treat pain and gastric ulcer, that was approved on May 2010, have sold more than \$33.8 million in 2011. The Company doesn't refer to the VIMOVO as a direct competitor to the KIT-302. However, given the existing drugs in the market, this drug is the best reference to the Company's drug.

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## Market Overview

### The Pharmaceutical Development Market

#### *Competition (Cont.)*

Accordingly, below are some main details about the VIMOVO drug:

· **VIMOVO's price** - The following table presents the average cost of VIMOVO's monthly treatment in 2011 (\$) <sup>6</sup>:

Vimovo - 500-20 mg		
Quantity*	Price (\$)	Monthly (\$)
60	93	47
60	92	46
60	89	44
60	88	44
60	87	44
60	85	43
60	85	42
60	84	42
60	74	37
Average	86	43

\* The VIMOVO treatment includes two pills a day. As of the fact that the KIT-302 treatment will include one pill a day, we adjusted the monthly cost of VIMOVO accordingly.

**VIMOVO's transaction with AstraZeneca**<sup>5</sup> - In this transaction, AstraZeneca provided Pozen with \$40 million upfront, \$45 million in approval milestones, and potentially \$290 million in sales milestones plus roughly 10% royalties on sales.

#### *Risk Factors*

Following are the risk factors in the pharmaceutical development market:

### Macroeconomics Risks

**Economic risk** - Economic depression and uncertainty might negatively affect the companies' ability in this field to raise capital, necessary for continues of their activity.

### Sectoral Risks

**Regulation risk** - Drug development is submitted to international regulations and standards, aimed to protect the public, such as the American FDA and the European EMA. Further broadening of regulation demands in countries around the world (especially the US and Israel) might extend the timetable for products production and marketing commencement, and increase the needed development costs. The Company expects that as the regulation procedures would become more global, the international markets would become more important, causing the pharmaceutical companies to act for extended cooperation between the international regulators, in order to allow faster products' market penetration and to save the resources allocated for meeting different regulators standards.

<sup>5</sup> <http://scr.zacks.com/News/Press-Releases/Press-Release-Details/2012/POZN---Pozen-Q4-As-Expected---PA325-Phase->

<sup>6</sup> Source:

<http://www.pharmacychecker.com/compare-drug-prices-online-pharmacies/Vimovo-500-20+mg/83517/167658/>.

## Market Overview

### The Pharmaceutical Development Market

#### *Risk Factors (Cont.)*

**Competition risk** - Development of competitive technologies and/or products in the market may lead to a decrease in the demand of the existing products in the market.

**Development process risk** - Uncertainty in the capability to complete the product development due to difficulties and/o technological problems; in the outcomes of the development phases; and in the ability to finish the development process within the time framing.

**Uncertainty regarding patent and intellectual property protection** - The companies' success in this market depends largely on the ability to protect intellectual property rights concerning their developed drugs. Even in a situation where a patent on a drug approved, there is uncertainty in the ability to protect and/or enforce it.

**Legal risk** - The companies in this market are exposed to legal proceedings following possible side effects of the drugs they develop or following other problems relating to the products and its production.

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**Section 3**

Valuation Methodology

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## **Methodology**

### **Background**

The generally accepted approaches to valuation are commonly referred to as the following:

- Market approach;
- Income approach; and
- Asset-based approach.

Within each category, a variety of methodologies exist to assist in the estimation of fair value. The following sections contain a brief overview of the theoretical basis of each approach, as well as a discussion of the specific methodologies relevant to the analyses performed.

### **Market Approach**

The market approach references actual transactions in the equity of the enterprise being valued or transactions in similar enterprises that are traded in the public markets. Third-party transactions in the equity of an enterprise generally represent the best estimate of fair market value if they are done at arm's length. In using transactions from similar enterprises, there are two primary methods. The first, often referred to as the Guideline Transactions Method, involves determining valuation multiples from sales of enterprises with similar financial and operating characteristics and applying those multiples to the subject enterprise. The second, often referred to as the Guideline Public Company Method, involves identifying and selecting publicly traded enterprises with financial and operating characteristics similar to the enterprise being valued. Once publicly traded enterprises are identified, valuation multiples can be derived, adjusted for comparability, and then applied to the subject enterprise to estimate the value of its equity or invested capital.

### **Income Approach**

The income approach is based on the premise that the value of a security or asset is the present value of the future earning capacity that is available for distribution to investors in the security or asset. A commonly used methodology under the income approach is a discounted cash flow analysis. A discounted cash flow analysis involves forecasting the appropriate cash flow stream over an appropriate period and then discounting it back to a present value at an appropriate discount rate. This discount rate should consider the time value of money, inflation, and the risk inherent in ownership of the asset or security interest being valued.

### **Asset-Based Approach**

A third approach to the valuation is the asset-based approach. The discrete valuation of an asset using an asset-based approach is based upon the concept of replacement as an indicator of value. A prudent investor would pay no more for an asset than the amount for which he or she could replace the asset new. The asset-based approach establishes value based on the cost of reproducing or replacing the property, less depreciation from physical deterioration and functional obsolescence, if present and measurable. This approach generally provides the most reliable indication of the value of land improvements, special-purpose buildings, special structures, systems, and special machinery and equipment.

### **Selected Valuation Approach**

As described in details in the Company's Profile section, as of the Valuation Date, the Company intends to initially focus on the development of KIT-302. Therefore, we estimate the value of this Company's IP (Hereinafter: the "**IP Valuation**" or "**KIT-302 Valuation**"). KITOV's IP valuation was performed according to the discounted cash flow (DCF) approach.



**Section 4**

Kitov's IP Valuation

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## Kitov's IP Valuation

### General

As aforesaid, we applied the discounted cash flow (DCF) approach to estimate the Company's IP.

We estimated KIT-302 future cash flows for the period between Q4 2012 (the Valuation Date) and Q3 2021 (the end of the expected exclusivity period in the USA market over six years from Q4 2015) (Hereinafter: the "**Forecasted Period**").

As described in the Company's overview section, in Europe, the Company can expect to receive up to 10 years of marketing exclusivity in the larger countries. However, due to the fact that as of the Valuation Date it is hard to estimate the size and the probability of the Company's FCDP's potential penetration to the European market, this valuation doesn't take into account this market potential and focuses only on the USA market potential.

The future cash flows were built under the assumption that the Company will sign a distribution agreement only after the completion of the KIT-302's development - or the completion of Phase III clinical trial. After the completion of phase III clinical trial it was estimated that the Company will receive from the distributor, an upfront payment, milestone payment, and royalties from the distributor's drug sales.

To succeed in the trial and generate future cash flows, a number of milestones must be met.

The probability of each milestone being achieved was estimated separately, with each milestone dependent on all the milestones preceding it. The milestones are:

· Completing Phase III clinical trial;

· Successful completion of the registration process (NDA Filing) and KIT-302's entry into the USA market for sales;

Receiving of 3 years exclusivity in case the Company would be the first to file the NDA for KIT-302's registration to the authorities.

- Receiving of 3 additional years of exclusivity, in case the Company succeeds in an additional minor trial.

The revenues flow takes into consideration the successes expectancy of drugs development in each of the milestones described above by multiplying the predicted revenues by the probability of success. For example, the predicted upfront payment was multiplied by the probability of success of the phase III clinical trial, and the milestone payment was multiplied by the accumulated probability of success of the phase III clinical trial and Filing NDA. Eventually, the Company's predicted revenues are the expectancy of revenues.

The expenses on behalf of the development product include the Company's predicted expenses due to the performance of the Phase III clinical trial and NDA preparations. In addition, it was taken into account that the Company will bear general and administration expenses (G&A), which reflects its operational existence. These expenses reflect the Company's necessity to manage a collection system for future covenants, to maintain its patents and to identify new technologies, etc.

The predicted expenses were multiplied by the accumulated probability of success of each of the milestones. Eventually, the Company's predicted expenses are the expectancy of expenses.

The cash flow multiplied by the accumulated probability of success was discounted at the relevant price of capital estimated by us. The discounted cash flow constitutes the IP's value.

**Kitov's IP Valuation****Revenues Expectancy Forecast**

The following table presents the Company's predicted future cash flows in the Forecasted Period (dollars in thousands):

Dollars in thousands	Beg. CMC + Phase III Q4 2012	<b>End CMC + End Phase III +NDA Preparations and Submission</b>		NDA Filing + Beg. Of 3 Years of Exclusivity + Beg. sales			Beg. Of 3 Additional Years of Exclusivity			End of Exclusivity
		2013	2014	2015	2016	2017	2018	2019	2020	Q1-Q3 2021
Company's potential royalties - USA				3,888	20,928	26,400	31,968	32,256	32,544	24,624
Revenues' expectancy - Covenants			24,400	24,980						
Revenues' expectancy - Royalties				2,158	11,617	14,655	15,971	16,115	16,259	12,302
Total Revenues' expectancy			24,400	27,138	11,617	14,655	15,971	16,115	16,259	12,302
Cost of Phase III	748	4,179	2,089							
Cost of NDA Filing	–	–	305							
G&A	210	790	552	465	433	433	390	390	390	390
Total expectancy costs	958	4,969	2,946	465	433	433	390	390	390	390
Profit (Loss) before tax	(958 )	(4,969 )	21,454	26,673	11,184	14,222	15,581	15,725	15,869	11,912
Tax	–	–	3,854	6,668	2,796	3,555	3,895	3,931	3,967	2,978
Profit (Loss) after tax	(958 )	(4,969 )	17,600	20,004	8,388	10,666	11,686	11,794	11,902	8,934

*Source: BDO analysis.*

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**Kitov's IP Valuation**

**Revenues Expectancy Forecast**

***Drug Development processes and Revenues' Timeline***

The FDA'S drugs approval process is strict and obligating performance and completion of three clinical trials.

The following table presents the drugs development processes' timeline:

Development Stage	Length of Development Stage
Discovery	1
Patent Process Initiated	4-5
Pre-Clinical Trials	4-15
Phase I	1-2
Phase II	2-3
Phase III	3
Total Clinical Trials	6-8
Registration	1-4
Total	12-28

Source: [www.pfizer.com](http://www.pfizer.com), Kellogg and Charnes, 2000, Myers and Howe, 1997.

The date of launching the product on the market is likely to change significantly, and ranges over a relatively wide span of years. Accordingly, the Company's revenues from manufacturing and marketing the drug depend critically on the success of its clinical trials and on obtaining all the necessary permits.

As described in the market overview section, in light of the fact that the Company's KIT-302 components are known and approved for drug use, the necessary regulatory track for the approval of the product, basing on them in the FDA, is 505 (b) (2) track.

In this regulatory track, the Company can submit an application for product approval, which is based on the outcomes of the safety and efficacy tests done on the FCDP's components in the past, and therefore it needs to perform only a single Phase III trial and two additional minor trials.

As described in the Company's overview section, according to the Company's management's estimates, the Phase III clinical trial will begin in the fourth quarter of 2012 and will last 18 months, it will end in the first quarter of 2014. Parallel to this trial the Company will perform the CMC, as described in details in the Company's overview section.

In addition, according to the Company management's estimates in the fourth quarter of 2014, it was assumed that the Company will submit the KIT-302's NDA request, and in the fourth quarter of 2015 it will receive all regulatory registration and start to market the drug in the USA market.

Moreover, as described in the Company's overview section, the Company's management estimates that the positive results of these trials will strengthen the patent applications submitted by it, and that similarly for a new drug, if approved; it will provide the Company with 20 years of exclusivity. However, as of the Valuation Date there is no real evidence for such approval.

If KIT-302 isn't registered as a patent, and the Company filed the NDA for its drug's registration to the agencies before any other competitor, it will be given a 3 years of exclusivity in relation to its product. Moreover, if the Company succeeds in an additional minor trial, it will receive an additional 3 years of exclusivity.

Based on the fact that as of the Valuation Date there is no real evidence for patent approval, we did not refer to this possibility in our projection. According to the best knowledge of the Company's management, as of the Valuation Date there is no other company that develops a similar drug, and therefore it estimates that it will get the 3 years of exclusivity described above. In addition, the Company's management estimates that there is a high probability it will succeed in the additional minor trial required for receiving 3 additional years of exclusivity.

**Kitov's IP Valuation*****Revenues Expectancy Forecast***

The following table summarizes the KIT-302's development stages' and revenues acceptance's timeline:

**Development Stages**

Beg. of Phase III + CMC	Q4 2012
End of Phase III + CMC	Q1 2014
FDA Approval + Beg. of 3 Years of Exclusivity + Beg.of Sales	Q4 2015
Beg. of 3 Additional Years of Exclusivity	Q3 2018
End of Exclusivity	Q3 2021

*Source: The Company's management.*

***Size of Relevant Market***

As described in the Company's overview section, as of the Valuation Date, the Company intends to initially focus on the development of KIT-302, which is a FCDP, consisting of two existing effective drugs, combined together for one drug, aiming, on one hand, to treat the pain caused by both OA and HTN, and, on the other hand, to ameliorate the negative side effects of hypertension (HTN) caused from the OA treatment drugs. Accordingly, the Company's KIT-302's target market is the HTN and OA combined market.

As detailed in the market overview section, according to the CDC over 27 million people in the US suffer from some level of OA. According to discussion with Prof. Moshe Mittelman, this number include also mild cases of the disease treated by mild pain relievers such as Paracetamol and/or ointments such as Voltaren, while the relevant market for the Company's KIT-302 is those patients suffer from severe and chronic OA.

Accordingly and based on discussions with Prof. Moshe Mittelman, in order to estimate the HTN and OA combined market's size, it is better to use the HTN market size as a starting point, since this market size is easier to estimate and therefore more valid.



As detailed above, HTN is the most common chronic medical condition in the western world - with over 20% of the general population is suffering from it. According to Prof. Moshe Mittelman, the ratio between OA patients and HTN patients in the USA is approximately one fifth (20%). Moreover, according to the CDC and Prof. Moshe Mittelman, 50% of OA patients in the USA suffer from both diseases (OA and HTN).

According to Prof. Moshe Mittelman, the potential market size for the Company's KIT-302 is only 33% of the above calculated market (for more details see market overview section).

Accordingly, the above detailed assumptions were used in order to value the size of KIT-302's target market.

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**Kitov** Pharamceuticals Ltd. |

**Kitov's IP Valuation*****Revenues Expectancy Forecast******Size of Relevant Market (Cont.)***

The following table summarizes the calculation of KIT-302's target market size, as of the Valuation Date:

**KIT-302's Target Market Size**

USA Population as of the Valuation Date*		314,436,002
Number of American HTN Patients	20%	62,887,200
Number of American OA Patients	20%	12,577,440
Number of American Patients with HTN+OA	50%	6,288,720
Number of Potential Patients	33%	2,096,240

\* <http://www.census.gov/main/www/popclock.html>. Source: BDO analysis.

In the forecasted years we assumed this market to grow by the growth rate in the USA population (0.91%).

***The Company's Market Share***

We have assumed a 15% penetration rate of KIT-302 in the first year's market launch, gradually increasing to 30% in the fourth year and so on. It should be noted that we assumed relatively high penetration rates due to the fact that we assumed a relatively small target market for the Company's drug.

The following table presents the Company's accumulated potential patients in the Forecasted Period:

Q4 2012	2013	2014	2015	2016	2017	2018	2019	2020
---------	------	------	------	------	------	------	------	------

USA										
Accumulated potential patients each year	2,096,240	2,120,000	2,140,000	2,160,000	2,180,000	2,200,000	2,220,000	2,240,000	2,260,000	2,280,000
Penetration rate each year				15.0 %	20.0 %	25.0 %	30.0 %	30.0 %	30.0 %	30.0 %
Accumulated number of the Company's patients				324,000	436,000	550,000	666,000	672,000	672,000	672,000

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## **Kitov's IP Valuation**

### *Royalties Potential*

## **The Drug's Selling Price**

According to the Company's management and the Company's medical advisors, the selling price of KIT-302 will amount to approximately \$40 per monthly treatment (\$480 for an individual patient yearly), based on a dosage of one pill a day.

In order to base this estimation, we analyzed the VIMOVO's treatment price. As described in the market overview section, the Company doesn't refer to the VIMOVO as a direct competitor to the KIT-302. However, given the existing drugs in the market, this drug is the best reference to the Company's drug.

As detailed in the market overview section, the average cost of VIMOVO's monthly treatment in 2011 was 43\$. It should be noted that this price was adjusted by us. The reason for this adjustment is based on the fact that the VIMOVO treatment includes two pills a day while KIT-302 treatment will include one pill a day.

## **Royalties Rate**

The total royalties paid to a R&D company for a drug depends on a variety of factors, and primarily:

- The risk level of the anticipated development;
- Future development costs and the company's financial position;
- Potential of market targeted by the drug;
- Competition level and substitute products available in the market.

Furthermore, as customary in this type of transaction, there is a certain exchange ratio between the advance payment/lump sum paid to the company at the time of signing the agreement, and the royalty rate payable to the company from future revenues.

As described in the Company's overview section, the Company intends to cooperate with international companies for the purpose of granting them a sub-licence based on upfront payments, milestone payments and royalties, and/or marketing contracts, immediately after the development completion (Phase III).

Since, the Company's does not have any estimations concerning the amounts of the above mentioned payments, we based our estimations on the following sources.

In order to estimate the upfront payment and milestone payment amounts we based the payment amounts on VIMOVOs transaction with AstraZeneca as described in the following tables:

Dollars in millions	Upfront	Approval Milestones	Royalties On Sales	
VIMOVO Transaction	40	45	10	%

Source : <http://scr.zacks.com/Home/default.aspx>

Accordingly, we assumed that the Company will receive at the end of Phase III, and at the NDA Filing, an upfront payment of \$40 million and a millstone payment of \$ 45 million, respectively.

## **Kitov's IP Valuation**

## **Revenues Expectancy Forecast**

### ***Royalties Potential (Cont.)***

## **Royalties Rate**

In addition, we assumed the Company will get a 10% royalty rate out of sales, based on the above mention VIMOVO Transaction and based on additional data sources, as described in the following tables.

The following table presents the average royalties rate in Phase III deals, as published by Medius:

Stage	Royalties %
Pre-Clinical	0%-5%
Phase I	5%-10%
Phase II	8%-15%
Phase III	10%-20%
Launched Products	20%+

Source: [www.medi-us-associates.com](http://www.medi-us-associates.com)

## **Revenues Expectancy Forecast**

The following chart presents the frequency of royalty rates paid by pharmaceutical companies:

Source: Nigel Borshell and Adrian Dawkes, "Pharmaceutical royalties in licensing deals: No place for the 25 per cent rule of thumb".

[http://www.palgrave-journals.com/jcb/journal/v16/n1/fig\\_tab/jcb200913f1.html#figure-title](http://www.palgrave-journals.com/jcb/journal/v16/n1/fig_tab/jcb200913f1.html#figure-title)

The following chart sets out the royalty rates actually paid per individual product, split according to the development phase in which the agreement was signed:

Source: Nigel Borshell and Adrian Dawkes, "Pharmaceutical royalties in licensing deals: No place for the 25 per cent rule of thumb"

[. http://www.palgrave-journals.com/jcb/journal/v16/n1/fig\\_tab/jcb200913f1.html#figure-title](http://www.palgrave-journals.com/jcb/journal/v16/n1/fig_tab/jcb200913f1.html#figure-title)

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Kitov Pharmaceuticals Ltd. |

**Kitov's IP Valuation****Revenues Expectancy Forecast*****Royalties Potential (Cont.)*****Royalties Rate**

The following table presents the Company's potential royalties from the sales of KIT-302 in the USA in the Forecasted Period (Dollars in thousands):

Dollars in thousands	2015	2016	2017	2018	2019	2020	Q1-Q3 2021
Accumulated number of the Company's patients	324,000	436,000	550,000	666,000	672,000	678,000	684,000
Cost of drug per patient (\$ thousand)	0.480	0.480	0.480	0.480	0.480	0.480	0.480
Total revenues from drug sales	155,520	209,280	264,000	319,680	322,560	325,440	328,320
Company's royalty rates	10.0 %	10.0 %	10.0 %	10.0 %	10.0 %	10.0 %	10.0 %
Company's potential royalties - USA	3,888	20,928	26,400	31,968	32,256	32,544	24,624

\*The company's potential royalties at 2015 represents only the sales of Q4 2015.

*Source: BDO analysis.*

**Revenues Expectancy**

As aforementioned, the Company's revenues forecast comprised of revenues from covenants and revenues from royalties in the USA. Each of the mentioned categories was weighted by its accumulated probability to success. At



this manner, the predicted revenues from upfront payments were multiplied by the probability of success of Phase III, the predicted revenues from milestone payment were multiplied by the accumulated probability of success of Phase III and in the NDA Filing, and the predicted revenues from royalties were multiplied by the accumulated probability to success in Phase III clinical trial and in the NDA Filing, and to get marketing exclusivity (at 2015 and at 2018).

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**Kitov** Pharamceuticals Ltd. |

**Kitov's IP Valuation****Revenues Expectancy Forecast*****Revenues Expectancy (Cont.)***

We assessed the Company's success in the following drug development phases (Phase III and registration with the authorities) on the basis of DiMasi's small molecule drugs<sup>7</sup> research, as described in the following table:

## Small Molecule

stage	Probability to Success		Accumulated Probability	
Phase I	63	%	63	%
Phase II	38	%	24	%
Phase III	61	%	15	%
Filing	91	%	13	%

Source: DiMasi et Al. (2010).

It should be emphasized, that DiMasi odds relate to NCEs and not to FCDPs. Since FCDPs are based on generic already approved drugs, it is likely that the probability of success in each of the development stages of these drugs are higher. However, since no specific statistics were found relating to FCDPs' development success rates, it was decided to use DiMASI's probability rates to NCEs and to reflect the likelihood of higher probability rates through the specific risk premium taken in the WACC.

**Revenues Expectancy Forecast**

As described in the market overview section, in light of the fact that the Company's KIT-302 components are known and approved for drug use, the necessary regulatory track for the approval of the product basing on them in the FDA, is the 505 (b) (2) track. In this regulatory track, the Company can submit an application for product approval, which is based on the outcomes of the safety and efficacy tests done on the FCDP's components in the past, and therefore it

needs to perform only a single Phase III trial and two additional minor trials.

Accordingly, based on DiMasi's data research the Company's probability of success in each of the development stages and the accumulated probability are, as described in the following table:

Small Molecule

stage	Probability to Success		Accumulated Probability	
Phase III	61	%	61	%
Filing	91	%	55.5	%

Furthermore, besides the probabilities of success of the said phases, we estimated the Company's probability to receive marketing exclusivity. According to the best knowledge of the Company's management, as of the Valuation Date there is no other company that develops a similar drug, and therefore it estimates that it will get the 3 years of exclusivity described above (100% probability was estimated). In addition, the Company's management estimates that there is a high probability of it succeeding in the additional minor trial required for receiving 3 additional years of exclusivity (80% probability was estimated).

<sup>7</sup> There is a distinction between large molecule and small molecule. The Company's drug is a small molecule.

**Kitov's IP valuation****Revenues Expectancy Forecast*****Revenues Expectancy (Cont.)***

The following table presents the Company's revenues expectancy from KIT-302's sales in the USA in the Forecasted Period (Dollars in thousands):

Dollars in thousands	2014	2015	2016	2017	2018	2019	2020	Q1-Q3 2021
<b>Covenants</b>								
Covenants (\$ thousand)	40,000	45,000						
Probability of success	61.0 %	91.0 %						
Accumulated probability	61.0 %	55.5 %						
Revenues' expectancy - Covenants	24,400	24,980						
<b>Royalties</b>								
Company's potential royalties - USA		3,888	20,928	26,400	31,968	32,256	32,544	24,624
Probability of Exclusivity		100.0 %			90.0 %			
Accumulated probability		55.5 %	55.5 %	55.5 %	50.0 %	50.0 %	50.0 %	50.0 %
Revenues' expectancy - Royalties		2,158	11,617	14,655	15,971	16,115	16,259	12,302
Total Revenues' expectancy	24,400	27,138	11,617	14,655	15,971	16,115	16,259	12,302

*Source: BDO analysis.*

## **Kitov's IP Valuation**

## **Expenses Expectancy Forecast**

### ***Cost Phase III Clinical Trial***

According to the Company's management's estimations, the cost of Phase III clinical trial will amount to approximately \$7.5 million (approximately \$0.7 million in Q4 2012, approximately \$4.2million in 2013, and approximately \$2.1 million in Q1-Q3 2014), and will last 2 years.

Accordingly, the Company's predicted Phase III clinical trial costs were multiplied by 100%. Phase III clinical trial costs are costs which the Company must bear as it does not have to conduct Phase I and phase II clinical trials.

### ***Cost of NDA Filing***

According to the Company's management's estimation, the cost of NDA filing will amount to \$305 thousands, and the Company expected to bear them in the second quarter of 2014. The Company's predicted NDA filing costs were multiplied by the Company's probability to success in Phase III clinical trial.

### ***General and Administration Expenses***

According to the Company's management's estimation, the total general and administration expenses in the development period (Q4 2012- Q3 2014) will amount to approximately \$1.6 million, and from the second quarter of 2013 will amount to \$195 million per quarter.

It was assumed that the Company's general and administration expenses will total to \$195 thousands per quarter in the following projected years.

The predicted general and administration expenses were multiplied by the Company's accumulated probability of success in the development stages and to receive marketing exclusivity in accordance with the relevant reference in each of the forecasted years.

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**Kitov** Pharamceuticals Ltd. |

**Kitov's IP valuation****Expenses Expectancy Forecast**

The following table presents the Company's expenses expectancy on behalf of KIT-302's development in the Forecasted Period (Dollars in thousands):

Dollars in thousands	Q4 2012	2013	2014	2015	2016	2017	2018	2019	2020	Q1-Q3 2021
Expectancy Costs										
Probability Cost of Phase III	100.0 %	100.0%	100.0%							
Probability Cost of NDA Filing			61.0 %							
Probability G&A	100.0 %	100.0%	100.0%	61.0 %	55.5%	55.5%	50.0%	50.0%	50.0%	50.0 %
Cost of Phase III	748	4,179	2,089							
Cost of NDA Filing			305							
G&A	210	790	552	465	433	433	390	390	390	390
Total expectancy costs	958	4,969	2,946	465	433	433	390	390	390	390

Source: BDO analysis.

**Investment Forecast****Working Capital Investment**

The following table presents the Company's working capital estimation in the Forecasted Period (Dollars in thousands):

Dollars in thousands	2015	2016	2017	2018	2019	2020	2021
----------------------	------	------	------	------	------	------	------

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Royalties	2,158	11,617	14,655	15,971	16,115	16,259	12,302
Working Capital	1,419	1,910	2,409	2,625	2,649	2,673	2,696
Change in Working Capital	(1,419)	(491 )	(499 )	(216 )	(24 )	(24 )	(24 )

*Source: BDO analysis.*

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**Kitov** Pharamceuticals Ltd. |



## **Kitov's IP Valuation**

### **Investment Forecast**

#### ***Fixed Assets Investment***

In conformity with international standards, future negative cash flows that improve or increase the asset's performance level, must not be taken into account when estimating the asset's value in use, and positive cash flows deriving from such investments must be neutralized. While it is necessary, in the context of cash flows, to take cash outflows necessary for maintaining the level of future projected economic benefits likely to derive from the asset in its present situation, however, in this case, we do not anticipate a need for investment in structures and/or office equipment and/or computers etc.

#### ***Taxes***

According to the Company's management, as of the Valuation Date the Company has accumulated tax losses in the amount of approximately \$109 thousands. This amount was taken into account in the tax calculation. In the calculation of the after tax cash flows a 25% tax rate was taken into account, similar to the tax rate in Israel.

#### ***WACC***

When applying the Income Approach, the cash flows expected to be generated by a business are discounted to their present value equivalent using a rate of return that reflects the relative risk of the investment, as well as the time value of money. According to our estimation the discount rate totals to approximately 19%.

This return, known as the weighted average cost of capital (“**WACC**”) is calculated by weighting the required returns on interest-bearing debt and common equity capital in proportion to their estimated percentages in an expected industry capital structure.

The general formula for calculating the WACC is:

$$\text{WACC} = K_d (D\%) + K_e (E\%)$$

Where:

WACC= Weighted average rate of return on invested capital;

$K_d$ = After-tax rate of return on debt capital;

$D\%$ = Debt capital as a percentage of the sum of the debt, preferred and common equity capital (“Total Invested Capital”);

$K_e$ = Rate of return on common equity capital; and

$E\%$ = Common equity capital as a percentage of the Total Invested Capital.

CAPM has been empirically tested and is widely accepted for the purpose of estimating a company’s required return on capital. In applying the CAPM, the rate of return on capital is estimated as the current risk-free rate of return on Israeli Governmental bonds, plus a market risk premium expected over the risk-free rate of multiplied by the “**beta**” for the valued company. Beta is defined as a risk measure that reflects the sensitivity of a company’s stock (**or capital**) price to the movements of the stock market as a whole.

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**Kitov** Pharamceuticals Ltd. |

## Kitov's IP Valuation

### WACC

The CAPM rate of return on capital is calculated using the following formula:

$$K_e = R_f + \beta (R_m - R_f) + SCP + Sp \text{ Where;}$$

$K_e$  = Rate of return on capital (in this case, total invested capital);

$R_f$  = Risk free rate of return;

$\beta$  = Beta or systematic risk for this type of capital investment (in this case, asset beta);

=

In order to calculate the beta we based on Damodaran's data on company's operating in the drug market and on comparable companies operating in the drug market (Celgene, ONYX Pharmaceuticals Inc., AstraZeneca PLC, Bristol-Myers Squibb Company and Novartis AG) (Hereinafter: the "**Comparable Companies**").

$R_m$  – Market risk premium; the expected return on a broad portfolio of stocks in the market ( $R_m$ ) less the risk free rate ( $R_f$ );

SCP Small cap premium - Ibbotson valuation edition 2011 yearbook

SRP Specific Premium

Since most of biotechnology companies are unleveraged the debt weight was determined to be 0%.

Following are the parameters that served for the calculation of the Company's WACC as of September 30, 2012:

Parameter	Symbol	Value	Source
Beta		0.78	Damodaran and comparable companies
$R_f$	$R_f$	0.5 %	US Treasury Inflation Indexed Curve for 30 years ( <b>Source</b> : <i>Bloomberg</i> )

Risk Premium	Rm-Rf	6.0 %	US Risk Premium Damodaran
Additional Risk Small Company	SCP	11.8 %	Ibbotson 2012
Additional Specific risk	SRP	2.5 %	Specific Risk Premium due to uncertainty in recruitment of financing sources
Cost of Capital	Ke	19.4 %	$R_f + (R_m - R_f) + SRP$
WACC	WACC	19 %	$(1-T) * K_d + (E/V) * K_e$

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**Kitov** Pharamceuticals Ltd. |

**Kitov's IP Valuation****Cash Flows Forecast**

The following table presents the Company's predicted free cash flows in the Forecasted Period based on the assumptions detailed above (Dollars in thousands):

Dollars in thousands	Q4 2012	2013	2014	2015	2016	2017	2018	2019	2020	Q1-Q3 2021
Profit (Loss) after tax	(958 )	(4,969)	17,600	20,004	8,388	10,666	11,686	11,794	11,902	8,934
Change in Working Capital	–	–	–	(1,419 )	(491 )	(499 )	(216 )	(24 )	(24 )	(24 )
Free Cash Flow	(958 )	(4,969)	17,600	18,585	7,898	10,167	11,470	11,770	11,878	8,911
Total Capitalized Cash Flow	(937 )	(4,349)	12,899	11,405	4,058	4,374	4,132	3,550	3,000	2,105
Total Value	40,236									

Source: BDO analysis.

**The IP's Value**

The following table summarizes the results of the valuation:

**Dollar in thousands**

Total IP's Value, as of September 30, 2012 40,236

Source: BDO Analysis.

**Kitov's IP Valuation****Sensitivity Analysis**

The following table presents the sensitivity analysis for the Company's IP's value , according to the royalties rates and the discount rates (Dollars in thousands):

		WACC													
		16	%	17	%	18	%	19	%	20	%	21	%	22	%
	6 %	34,779		33,612		32,501		31,443		30,433		29,470		28,551	
	7 %	37,330		36,038		34,810		33,641		32,528		31,467		30,455	
	8 %	39,882		38,465		37,119		35,839		34,622		33,463		32,359	
	9 %	42,433		40,891		39,428		38,038		36,717		35,459		34,263	
	10%	44,984		43,318		41,737		40,236		38,811		37,456		36,167	
Royalties Rate	11%	47,536		45,744		44,046		42,435		40,905		39,452		38,071	
	12%	50,087		48,170		46,355		44,633		43,000		41,449		39,975	
	13%	52,638		50,597		48,664		46,832		45,094		43,445		41,879	
	14%	55,190		53,023		50,973		49,030		47,188		45,441		43,783	
	15%	57,741		55,450		53,281		51,228		49,283		47,438		45,687	
	16%	60,293		57,876		55,590		53,427		51,377		49,434		47,591	

Source: BDO analysis.

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Kitov Pharamceuticals Ltd. |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

XTL  
BIOPHARMACEUTICALS  
LTD.

Date: October 25, 2012 By: /s/ David Grossman  
Name: David Grossman  
Title: Chief Executive  
Officer