Kitov Pharmaceuticals Ltd.

Development Regulatory Inspired Late Stage Drug

October 2013

Forward-looking statements

This presentation contains forward-looking statements as defined by the Securities Law, 1968, which are based on the Company's expectations with regard to its development potential and on information and documents received by the Company from professional sources that are relevant to the Company's development plan.

Some or all of these expectations may not be achieved, or may be achieved in a manner different from expected. The information referred to includes forecasts, objectives, and estimates that relate to future events or matters whose materialization is uncertain and not in the control of the Company ("forward-looking statements").

Company Overview

- Traded on the Tel-Aviv Stock Exchange (TASE:KTOV), market cap: NIS 65M*
- Kitov is developing **Combination Drugs** - a drug that integrates two existing, effective drugs into one unit in order to **decrease the deleterious side** effect in one of the drugs by providing a second drug that deals with the side effect of the first
- The Company is currently focusing on developing 2 combination drugs – **KIT-301** and **KIT -302**, that are intended to provide pain relief to patients suffering from Osteoarthritis (OA) - **without the risk involved in blood pressure elevation**, a side effect of existing drugs that deal with this type of pain
- The Company's first product - KIT-302, in an advanced regulatory stage **with written approval from the FDA** to start a Phase III clinical trial with a rapid development track. KIT-302 is intended to substantially reduce the risk of high blood pressure, stroke, heart attack, and death that exists in leading market drugs; presentation of a New Drug Application (NDA) to the FDA for the Company's leading drug is expected to take place in 2015

* As of October 7, 2013

Company Overview

- The Company's **relative advantage** significantly increases the chances for KIT-302 to succeed in its Phase III clinical trial and to rapidly reach the market:
  - KIT-302 is composed of **two existing drugs that are already approved for marketing**
  - **Relief provided by the FDA** in terms of regulatory requirements allows for the immediate start of the single Pivotal Phase III clinical trial
  - Relatively **low technological risk**
  - Relatively **low cost**
- Experienced drug development, regulatory, and biotech management team. The Company's Chairman of the Board, and Chief Medical Officer, Dr. Paul Waymack has held **drug review positions in the FDA**

The Team

Executive


Dr. Paul Waymack

Paul Waymack, M.D., Sc.D.; Chairman of the Board, Chief Medical Officer - Former academic transplant surgeon and former FDA medical officer. Over 15 years of experience in drug development as a consultant to major pharmaceutical companies

Isaac Israel; CEO - Biotechnology entrepreneur and executive, founding CEO of BeeContact Ltd. (TASE:BCNT)

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

Non Executive


Prof. Hochberg

Professor Mark Hochberg - Internationally known rheumatologist and advisor to the FDA, extensive background in the development of non steroidal drugs, with a special emphasis on avoiding cardiovascular complications resulting from the use of non-steroidals

William Berlin, PhD; - Former FDA chemist, with over 15 years experience in drug development and consulting to multi-national and emerging biotech and pharmaceuticals companies

Osteoarthritis and Hypertension

- **Osteoarthritis** (OA) affects the joints causing the loss of cartilage, decreased mobility, and significant pain in the joints
- OA is the most common joint problem, with people becoming more susceptible to OA as they age
- **27 million people in the U.S**. suffer from OA
- Many drugs are effective for treating medical conditions such as pain, however – these drugs are known significantly to increase blood pressure
- Hypertension is known as the "silent killer". Every increase of **even one point** increases the risk of **heart attack, stroke, and death**

Osteoarthritis and Hypertension

- Drugs that treat pain (NSAID's) carry a **"Black Box" warning** in the U.S. of increased cardiovascular risks:

> **Cardiovascular Risk**
>
> - CELEBREX may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs may have a similar risk. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. (See **WARNINGS** and **CLINICAL TRIALS**).
>
> - CELEBREX is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery (see **WARNINGS**).

- In the U.S. **13.5 million people** suffer from OA **and** hypertension (HTN)
- Approximately **50%** of these patients **do not receive pain relief medication** (NSAID) due to the **fear of elevated blood pressure**
- The global market for drugs that treat pain from OA (NSAID's and COX -2) is approximately **$13 billion annually**

*The Links Among NSAID's, BP and CV Events in Patients With OA. www.medscape.com
**NICOX 2009 Annual Report Page 11

About Combination Drugs

- A combination drug integrates **two existing, effective drugs** into one unit
- The objective of the integration is to **decrease the deleterious side effect** in one of the drugs by providing a second drug that deals with the side effect of the first
- The cost of developing a combination drug is materially lower than developing a new drug
- Low risk – the component drugs are in use after having established their **efficacy and safety** in the market
- Major marketing advantage for a combination drug vs. its individual components

Combination Drugs - Pipeline

Expected NDA Submission to FDA	Combination	Indication	Product
2015	Celecoxib + Anti-HTN	Osteoarthritis	**KIT-302**
Approximately 2 years from the start of the Phase III clinical trial	Naproxen + Anti-HTN	Osteoarthritis	**KIT-301**

* Assuming adequate funding to proceed with clinical and chemistry development in parallel

kitov PHARMACEUTICALS

KIT-302 Combination Drug - Advantages

Advantage vs. Current Treatment

- Relative Advantage - integration of existing drugs approved for marketing
- Patients demonstrate very good compliance in taking pain medications - **because it hurts**
- Patients notoriously do not take prescribed HTN medications because HTN has no symptoms: **it doesn't hurt**
- Kitov provides a solution that does not exist in the market today:

- **Treatment of a severe medical condition** (HTN)
- **Convenience** of taking one pill instead of two
- **Lower cost** for one drug as opposed to two drugs

Patient Advantages

- **Treatment of a severe medical condition (HTN)**
- **Reduction of physician's legal exposure**

Physician Advantages

Advantage vs. Current Treatment

- Reduction of legal exposure: new (March 2011) FDA policy states that a drug that lowers blood pressure will be permitted to carry the following in its labeling:

> DRUGNAME is a [name of pharmacologic class] indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

- Following FDA approval of KIT-302, physicians' choice in treating OA pain will be:

✘ **NSAID** - pain relief drug with its "black box" warning with regard to the risk of heart attack, stroke, and death

OR

✓ **KIT-302** - with its labeling noting **improvement in blood pressure** and **the lowering of the risk** of heart attack, stroke and death

A physician who prescribes an NSAID for a patient suffering from HTN could be exposed to claims of malpractice

Regulatory easing granted by FDA

- Significant Regulatory Relief:
  - ✓ Immediate Phase III clinical trial
  - ✓ Resulting low technological risk
  - ✓ Resulting low costs
- Based on written correspondence and SPA (Special Protocol Assessment) **approved and signed by the FDA**:
  - ✓ **Only one** Phase 3 clinical trial required + 2 minor trials - no need for non-clinical trials (animal trials) or additional efficacy or safety trials [505(b)2 track]
  - ✓ Company is authorized to use the KIT-302 regulatory relief for Kitov's other drugs
  - ✓ Can use existing drug supplies for the pivotal clinical trials with **no need to wait for the formulation of the single combination tablet**

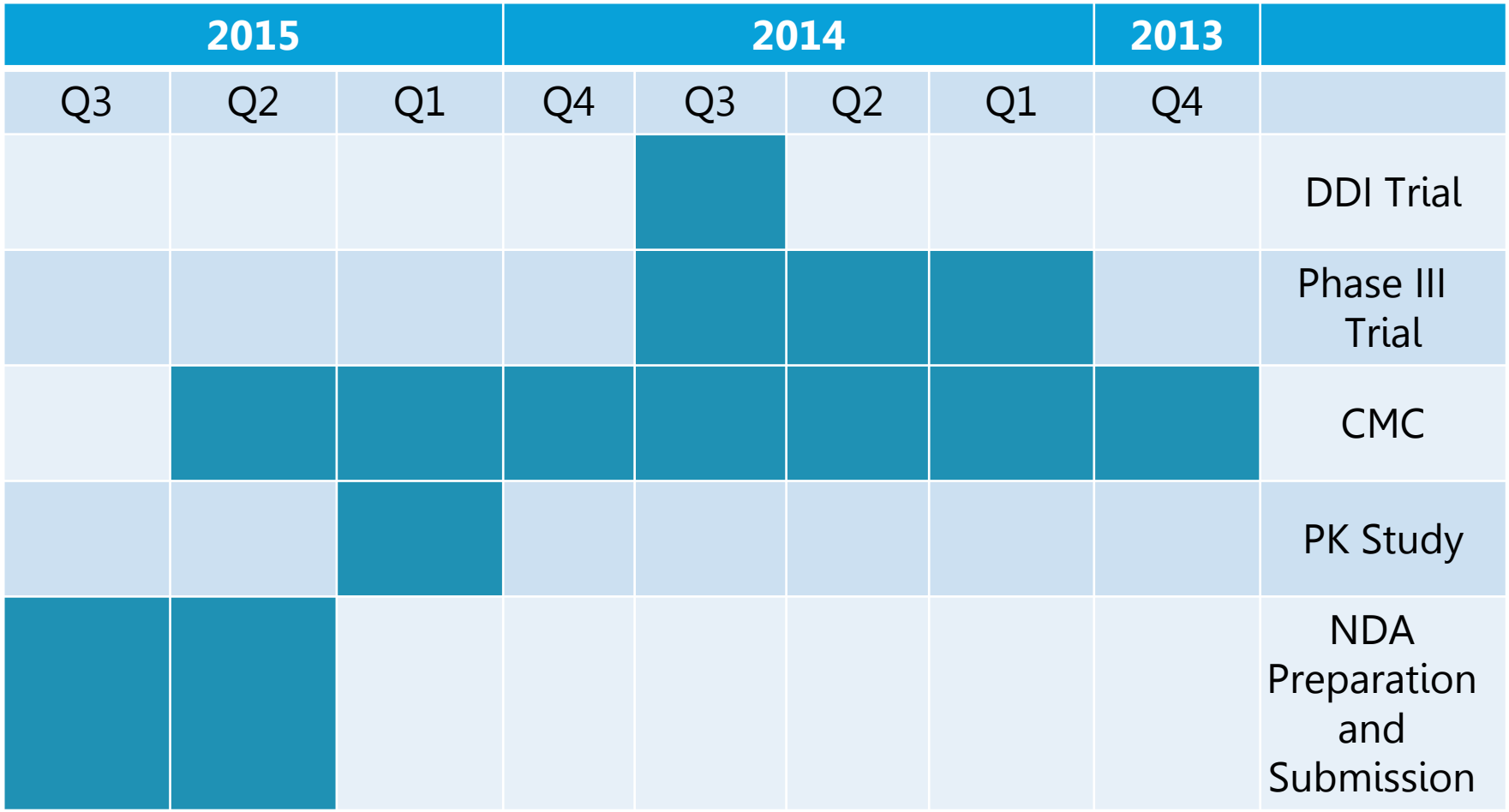
Regulatory easing granted by FDA

Required clinical development in order to obtain FDA marketing approval:

- **One Phase III HTN clinical trial**
  - ✓ Four groups of 30-50 patients each over 2 weeks (placebo, Celecoxib, Anti-HTN, KIT-302)
  - ✓ The trial requires demonstrating only half or more of the reduction in blood pressure seen with the antihypertensive drug without the addition of celecoxib
  - ✓ Cost of the trial – only about $2 million
- **Two minor trials – only <u>after</u> completion of the Phase III trial**
  - ✓ 18 healthy individuals in order to test Drug-Drug Interaction between the two active ingredients in KIT-302
  - ✓ 24 healthy individuals in order to test levels of the drug substances (Celecoxib and the Anti-HTN) in blood for the new KIT-302 combination

Implementing FDA requirements will be simple and relatively inexpensive - with relatively low risk

KIT-302 - Two Years to NDA filling



*Assuming adequate funding to proceed with clinical and chemistry development in parallel

Intellectual Property

- ✓ Pharmaceutical Formulations And Methods Of Use Which Combine NSAID Compounds With Anti-Hypertensive Compounds (PCT- priority date: 2008)
- ✓ Methods For Ameliorating Drug Induced Elevations In Blood Pressure Via Adjunctive Use Of At Least One Anti-Hypertensive (PCT- priority date: 2011)

Phase III Study - Milestones

Status	Due Date	Milestone
✓ Done	September 2013	Obtain ABPM statistical plan
✓ Done	September 2013	Begin manufacture of drug supply for pivotal study
✓ Done	September 2013	Contract for the required inspection of manufacturing site
	Q4 2013	Submit pivotal protocol to FDA
	Q4 2013	Sign contract with CRO
	Q1 2014	Submit a Clinical Trial application in EU
	Q1 2014	Sign contract with investigators
	Q1 2014	Obtain human ethics committee approval for study
	Q1-Q2 2014	Start recruiting patients

*Assuming adequate funding to proceed with clinical development. The above timetable is subject to possible delays that could not be fully controlled by the company. This information includes a forward-looking statement as defined by the Securities Law, 1968

Phase III - Status

- Agreement reached with contract manufacturer, **Sterling Pharma** of the United States
- Manufacturing of drug product for Phase III trial: Commenced October 2013
- Stability data for the drug to be used in the Phase III study will be available Q1 2014

- Agreement reached with the contract research organization **DABL**
- DABL is the world's leader in ambulatory blood pressure monitoring (ABPM) in clinical trials
- Has prepared the statistical analysis plan for the ABPM in the Phase III stud
- Will supply the ABPM for the Phase III study
- Will train the investigators in the ABPM use
- Will electronically download all ABPM data from all patients, and statistically analyze the data

Business Model

- Kitov's unique business and regulatory model significantly increases the chances for KIT-302 to succeed in the Phase III clinical trial and to rapidly reach the market
- Upon completion of the development of the combination drugs, the Company will consider entering into agreements with strategic partners for the manufacturing and marketing of the products:
  - ✓ Marketing agreements
  - ✓ Licensing agreements

- **Vimovo – Deal analysis:**
  - Combination drug developed by Pozen; commercialized by Astra Zeneca
  - Combination of Naproxen and Azomprozel for the treatment of gastro side effects, whose importance is significantly less than the cardiovascular risk, which will be dealt with by KIT-302
  - Drug was approved in 2009
  - Vimovo sales in 2012 of about $60 million, increase of 24% compared to 2011

AstraZeneca Vimovo® (naproxen/esomeprazole magnesium) 375/20-500/20 mg delayed-release tablets POZEN® Transforming medicine. Transforming lives.

Business Strategy

- Build a product pipeline through the acquisition of additional drug rights that meet Kitov's business model criteria:
  - ✓ Late stage of development
  - ✓ Low to moderate risk
  - ✓ Kitov's team can provide significant added value in working with FDA
- Dual list on NASDAQ through Level II ADRs

Kitov Pharma will work towards internal and external growth to become a leading pharmaceutical company with a varied portfolio of late-stage products

Why Kitov Pharmaceuticals?

- ✓ KIT-302 provides a solution to an unmet medial need
- ✓ KIT-302 has the benefits of combination drugs:
  - Phase III clinical results in approximately **one year**
  - Significant increase in chance for success
  - Short time to market
  - Low development cost
- ✓ KIT-302 has regulatory benefits due to significant relief from the FDA:
  - Lowering of risk and cost
  - Short time to market
  - Advantages in marketing the drug to patients
- ✓ KIT-302 is a serious alternative to drugs currently in the market

Kitov Pharmaceuticals - Unique and Sophisticated Regulatory Inspired Late Stage Drug Development

Thank you,
Kitov Pharmaceuticals Ltd.

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