Mapi Pharma

Value-Added High-Barrier to Entry Pharmaceuticals

Q2 2015

Corporate Overview

Strategy	Building a vertically integrated, diversified, risk mitigated business model with high-barrier, high-added-value pharmaceuticals including depot injections
Growth Engines	Life Cycle Management (LCM) products for big markets, with limited competition, some under FDA 505(b)(2) or ANDA; as well as complex products and formulations
Experienced Team	Successful management team with vast business and R&D experience mostly from Teva Pharmaceuticals
Portfolio, Co-development	3 LCM Products, 13 APIs, 1 NCE; Co-development with a Big Pharma, 1 major collaboration with a leading global generic, 3 co-development and marketing agreements, global and China
IP & Clinical trials	Ongoing Phase II with GA Depot, additional 2 leading products are to start clinical trials. Granted 10 US patents, allowed 1 US patents, 1 EU patent, 20 patents in process
Financing	Series A completed, enables initiation of phase III with GA Depot. First significant revenue expected in 2017

Lead Product: Glatiramer Acetate Depot

- A monthly depot injection vs. the daily / thrice-weekly injection in the market today
- The next Copaxone® lifecycle management product
- Blockbuster potential as of 2019
- Regulatory and clinical strategy validated after pre-IND meeting w/FDA
- Risk-mitigated development compared to NCEs
- Engaged in Phase II clinical trial
- In preparations for Phase III
- Registration via FDA 505(b)(2)

Core Team

Ehud Marom, CEO & Chairman of the Board of Directors

Teva VP Tapi, head of the Copaxone global operation team

Makteshim (now ADAMA-ChemChina) CEO

Gamida Cell CEO

Peptor (DeveloGen) President

Nir Bernstein, CPA, CFO
Ampal Inc. VP-Accounting & Control
PwC Senior Manager

Uri Danon, Executive VP
Teva Projects manager including Copaxone in a solution in pre-filled syringes
Atox Bio Chairman & CEO **BioCancell** President & CEO

Dr. Shai Rubnov, VP R&D
NasVax Manager QA and regulatory affairs
Peptor (DeveloGen) Director of CMC

Alex Mogle, VP Corporate Development
Makhteshim-Agan Head of supply chain, assistant to the CEO, Company Secretary
NICE System BD Director DVR **Ministry of Finance**

Safi Landskroner, VP Business Development
Meuhedet Sick Fund Head of Procurement
Dexcel Pharma VP BD & RA
Neopharm VP BD **Therapix Biosciences** Director

Dr. David Leonov, Head of API Development
Teva Senior research positions
Makhteshim Chief Scientist responsible for the development of a wide scale R&D expansion strategy in India

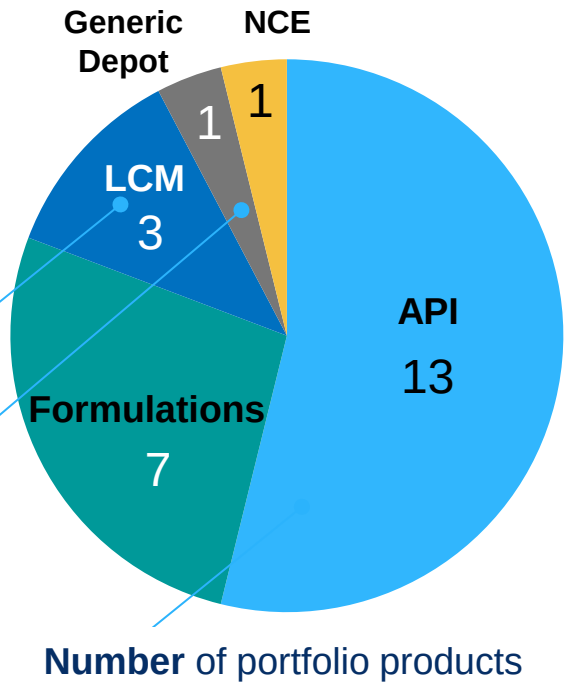
Dr. Yoram Sela, Head of Formulations
Teva Manager controlled-release unit
Karma-Pharm Founder **LycoRed (Makhtshim-Agan)**
Nesher Solutions VP R&D

Mitigated Risk and Growth Portfolio

Value-Added High-Barrier to Entry Pharmaceuticals

Product Category	Current Market*
Life Cycle Management (LCM)	$9 billion
Generic Depot	$1.3 billion
API + Formulations	$12.5 billion

* Based on Thomson Reuters Cortellis' website



Examples from our portfolio:

Life Cycle Management
GA Depot (MS)

Generic Depot
Risperidone LAI (Schizophrenia)

API & Formulation
First major co-development agreement signed

Pipeline: Life Cycle Management

Compound (Brand)	Indication	Pre-Clinical (2014 Branded Product Sales*)	Human PK	Phase 2	Phase 3 and Registration
Glatiramer Acetate Depot (Copaxone®)	MS	US$4.2B	Collaboration under negotiations	Ongoing	2018
Risperidone LAI (Risperdal® Consta®)	Schizophrenia	US$1.19B		First Regional Agreement Signed	
Pregabalin ER (Lyrica®)	Neuropathic Pain	US$5.2B		Two Regional Agreements Signed	
New Chemical Entity (NCE)	MS				

* 2014 sales based on Thomson Reuters Cortellis' website

Remarks:

- Not all regular development phases are applicable for 505(b)(2) regulatory filings
- Sales figures are of original product brand
- Glatiramer Acetate Depot patent granted in 2013
- Risperidone LAI received approval to initiate BE trial

Current Sales

Plans for 2015

Depot Long-Acting Formulations

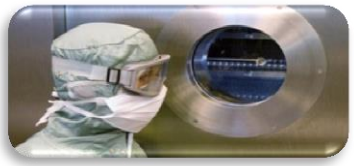
- Depot formulations are comprised of a biodegradable polymer that encapsulates the API and disintegrates over an extended period of time, releasing the API gradually
- Originally, oral products, such as Risperidone, Paliperidone, Olanzepine and Naltrexone, were converted into long-acting injections, once or twice per month
- Most of these drugs are central nervous system drugs, for which compliance and adherence to treatment protocols is of crucial importance to efficacy
- Our product-tailored technology provides extensive know-how and non-infringing generic solutions to the currently marketed long-acting drugs
- In-house know-how, dedicated depot R&D teams and production facilities (lab scale, pilot and for clinical trials) to implement variations of depot technologies

API + Excipients

Mix in Reactors

Centrifugation + Rinse

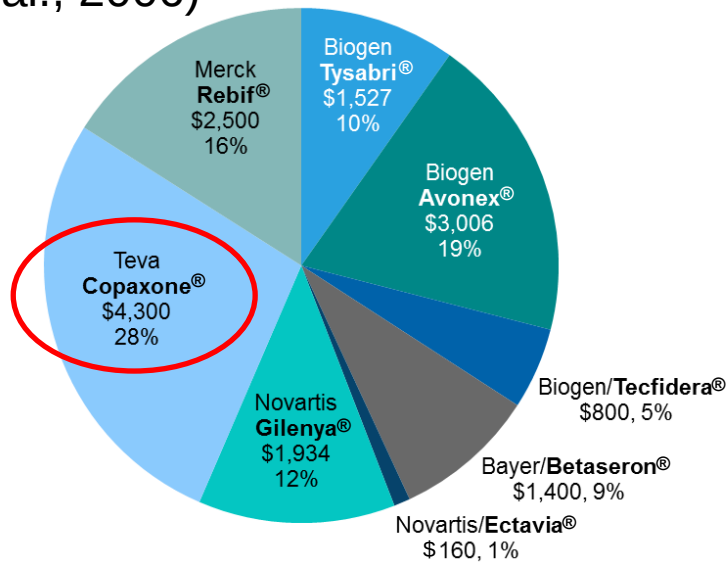
Lyophilization



Vials + WFI

Multiple Sclerosis (MS)

- 400,000 individuals in the US and 1.1-2.5 million individuals worldwide (Oleen-Burkey et al., 2011)
- Usually diagnosed between the ages of 20 and 40, with a mean age of 32 years. Women outnumber men by a ratio of almost 2 to 1 (clevelandclinicmeded.com)
- 34% (136,000) of the 400,000 diagnosed MS patients in the US, are firstly prescribed with Glatiramer Acetate (GA) (Margolis et al., 2011)
- The annual combined direct and indirect costs of MS in the US in 2004 have been estimated to be an average of $47,215 per diagnosed individual (estimated as $59,142 if converted to 2010 dollars) (Kobelt et al., 2006)
- The 2013 MS therapeutics market* is estimated at over $15 billion
- **GA Compliance today, estimated at 70% (Kleinman NL et al. J, Med Econ 2010), will increase dramatically with Mapi's GA Depot**



* 2013 sales based on Thomson Reuters Cortellis' website

Glatiramer Acetate – API/Formulation

- **Brand name:** Copaxone®, Teva
- **Composition:** random polymer of acetate salts of polypeptides L-glutamic acid, L-alanine, L-tyrosine and L-lysine
- **Indication:** reducing the frequency of relapses in RRMS patients
- **Administration:**
  - 20 mg subcutaneously, daily
  - 40 mg subcutaneously, thrice-weekly
- **Assumed mechanism of action:** immunomodulation of processes considered to be responsible for the pathogenesis of MS
- **Momenta's Glatopa:** a generic version was approved by the FDA on April 17, 2015

Overview of Mapi's GA Depot

GA in Mapi's PLGA formulation **based on all approved FDA compounds**

Allows **a monthly injection**, instead of current once daily and Teva's recently approved thrice weekly

US Patents 8,377,885 and 8,796,226 titled Depot Systems Comprising Glatiramer, **granted May 2013, until Dec. 2030**

In vivo activity

In vitro release profile indicates **linear release over 4 weeks**

Phase II ongoing

Increased patient compliance and convenience; reduced burden of treatment

GA Depot – General

- **Product:** Glatiramer acetate (GA) long-acting injection
- **Know-how:** Complete in-house GA know-how
- **Formulation:** based on GA-loaded PLGA microspheres, ~10 microns in size; releases 90% of GA within 30 days
- Microspheres are made of Poly (lactide-co-glycolide) (PLGA), a bio-degradable polyester, used in FDA-approved drugs: Lupron®, Risperdal® Consta® and Vivitrol®
- Microspheres encapsulate the GA; there is no chemical connection to GA (hence, GA is unchanged)
- Former studies by Prof. J.M. Rabey indicate effectiveness of using low doses of GA
- US Patent 8,377,885, titled “Depot systems comprising glatiramer or pharmacologically acceptable salt thereof”, granted in 2013, covers any GA Depot formulation from 1 week to 6 months

FDA Validated Clinical Trials & Regulatory Strategy

- **Regulatory pathway:** development of GA Depot under 505(b)(2)
- **FDA Pre-IND meeting on March 10th, 2015:** validated regulatory, R&D and clinical strategy, while confirming: minimal requirements for IND for Phase III, layout for a single pivotal Phase III and minimal requirements for NDA. CMC was prepared with Mapi's API; considering adding another supplier
- **Ongoing non-IND Phase II:** open label study to evaluate safety, tolerability, and efficacy of switching to GA Depot from Copaxone®
- **Planned Pivotal Phase III:** placebo-controlled study of GA Depot in patients with RRMS, for efficacy, safety and tolerability (n=920); in preparations to initiate the Phase III study in Q1/2016 (regulatory filings, CRO discussions and scale-up operations)

GA Depot Potential

- **Compliance superiority and reduced treatment burden:** over daily generics and Teva's thrice-weekly Copaxone®, may also enable first-line therapy status
- **Regulatory Path:** validated by the FDA, also, by Teva's approval of its 40 mg product with a single phase III pivotal trial (single dose); launch is expected by 2019
- **Patent Protection:** Mapi's granted patent for GA Depot extend to the end of 2030
- **Sustainability of Glatiramer Acetate Market:** Teva's successful switching from 20 mg to 40 mg (67%) and the largest market share of Copaxone® validates the sustained demand for Glatiramer Acetate
- **Physicians:** Benefits include monthly IM administration, boosting demand and assuring compliance
- **Further potential:** Enhanced efficacy of GA Depot enables testing in progressive forms of MS, where no other treatment is available, with vast medical need and commercial potential

Generic Products: API + FDF

API	Product	Mapi Patent	Sales 2013* ($M)	Patent exp./Data exc.	Medical Indication
Dronedarone HCl	Multaq (Sanofi)		362	2016	Atrial Fibrillation
Abiraterone Acetate	Zytiga (J&J)	Processes (PCT)	1,689	2016	Prostate Cancer
Glatiramer Acetate	Copaxone (Teva)		4,300	2014	RRMS
Darunavir **(Para. IV)**	Prezista (J&J)	Processes (US/EP Allowed) Polymorphs (PCT)	1,673	2017	HIV
Fingolimod HCl	Gilenya (Novartis)	Allowed US Patent	1,972	2017	RRMS
Lurasidone HCl	Latuda (DSP)	Processes (PCT)	397	2018	Schizophrenia
Febuxostat	Uloric (Takeda)	Processes (PCT) Polymorphs (PCT)	265	2019	Chronic Hyperuricemia
Deferasirox	Exjade (Novartis)	Processes (US Allowed) Polymorphs (PCT)	894	2019	Chronic Iron Overload
Indacaterol Maleate	Onbrez, Arcapta (Novartis)		193	2020	COPD
Perampanel **(Para. IV)**	Fycompa (Eisai)	Processes (US Prov.)	22	2021	Epilepsy
Tapentadol HCl	Nucynta, Palexia (J&J)	Granted US 8410176	246	2022	Acute pain
Dapagliflozin **(Para. IV)**	Forxiga (BMS & AstraZeneca)	CO-CRYSTALS (US Allowed)	21	2020	Type 2 Diabetes
Alogliptin Benzoate **(Para. IV)**	Nesina (Takeda)	Process (US Allowed), Polymorphs	519	2028	Diabetes

* 2013 Sales based on Thomson Reuters Cortellis' website

First collaboration over one product (confidential) with global generic with profit share of $100M

Formulation

(1) To be produced in Mapi's API plant in Neot-Hovav

(2) To License out to a partner, finalized pilot API production in preparation of DMF

(3) Para. IV: launching under Paragraph IV, if successful, provides market exclusivity of 180 days