



Mapi Pharma

Corporate Overview – Oct. 2021

VALUE-ADDED HIGH BARRIER-TO-ENTRY
PHARMACEUTICALS

Investment Highlights



Founded in 2010 with a mission to develop improved depot extended-release versions of innovative and existing commercially successful pharmaceuticals



Fully integrated with API and sterile injections formulation and fill/finish production facilities



Lead product is a long acting Glatiramer Acetate (Copaxone®) Depot for treating MS

- Phase 3 trial - Last Patient In for large pivotal trial reached in May 2021
- NDA submission expected in Q4 2022, seeking marketing approval for RRMS indication
- Commercialization of RRMS indication by Viatris (Mylan)
- On-going Phase II for PPMS indication



Promising pipeline of 505(b)(2) products as well as complex depot sterile injectable generic formulations for diabetes, Parkinson's disease, schizophrenia



Well-established product-specific partnerships with leading global pharmaceutical companies for both worldwide and country specific markets

Mapi Pharma

Today

Lead Product: In **Phase III** with GA Depot for RRMS, ~1,000 patients

GA Depot Marketing Partner: Agreement with Viatriis (Mylan/Pfizer's Upjohn division) for the RRMS indication. Equity investment, upfront \$20 million, commercialization milestones \$500 million and high teens royalties

Infrastructure: Fully integrated GMP-approved facilities for API and Finished Dosage Form aseptic injections

Products focus: Long-acting depot injectables and controlled release 505(b)(2) products

Indication Focus: Neurology and Depot products

Major Global partnerships: GA Depot (long-acting Copaxone®) licensed to Viatriis (Mylan) in April 2018 and Fingolimod (GILENYA®)

Sales of Fingolimod in Israel/PA, Latin America & Europe

In Two Years

Lead Products: GA Depot approved for RRMS and launched in the US, commercialization by Viatriis

GA Depot **Phase 3 PPMS** results with new collaboration agreement for \$4 billion market EU opportunity

Pregabalin ER launched in the EU with a partner


Sales: Supplying GA Depot for RRMS to Viatriis, for PPMS



Pipeline: Advanced 505(b)(2) pipeline for pain, schizophrenia and diabetes in clinical stages

Clinical Programs: Depot QQ product in clinical development for Schizophrenia and GLP-1

Commercial Products: Several complex generic products in commercialization

Pipeline Key Products

505 (b) (2) Pathway Compound (Brand)	Indication	R&D / IP	Human PK	Phase II	Phase III and Registration
GA Depot (Copaxone®)	RRMS		Global Licensing		2022 
GA Depot (Copaxone®)	PPMS		Promising open study results		Phase III 2022
Pregabalin ER (Lyrica®)	Neuropathic Pain		Seeking Partner		2021
GLP-1 Depot (various products)	Diabetes / PD		Regional Agreement		

ANDA Pathway Compound (Brand)	Indication	R&D / IP	Human PK	Registration	Marketing
Fingolimod (Gilenya®)	RRMS		Rafa IL/Regional Marketing Agreements	Approved IL May 2017	Sales & Marketing IL/LA/EU 2019-2020
Apremilast (Otezla®)	Psoriasis		Rafa IL	Approved IL 2021	
gCopaxone (Copaxone®)	RRMS			ANDA 2022	
Paliperidone (Invega Sustenna®)	Schizophrenia		Regional Agreement	Phase II	
Paliperidone (Invega Trinza®)	Schizophrenia				
Aripiprazole (Ability Maintena®)	Schizophrenia				
Mapi Pharma	Legend:				

API Plant



Location

Israel's designated industrial chemical park, Neot Hovav

Facility

Currently dedicated to the production of Glatiramer Acetate for Depot and Generic GA. Equipped for manufacturing lyophilized API as well as powders. Scale-up for future commercial stages is on-going.

Status

GMP Approved facilities - both API (Neot Hovav) and Labs (Ness Ziona)

QA Audit conducted by Mylan and GMP approved by the Israeli Ministry of Health, May 2019

“Preferred Enterprise” granted governmental cash grants of 20% (may increase by 4%) as a subsidy to cover capital expenditures in designated areas

Entitled to a reduced tax rate of 7.5% (compared to a 24% corporate income tax rate)

Sterile Finished Dosage Forms (FDF) Facility



Location

Har Hotzvim, Bio Park, Jerusalem

Status

Ongoing Depot production for Phase III clinical trials, scale-up for increased capacity is under-way

Equipped for manufacturing lyophilized powders for reconstitution in vials and prefilled syringes as well as tablets.

Commissioning a dedicated FDF Facility for Depot production (~50,000 square foot)

GMP approval by Mylan (Viatris) and Israeli MOH, May 2019

Expansion of facility to enable GA Depot commercial supply approved and partially funded by GOI

Sterile Finished Dosage Forms (FDF) Facility



GA Depot – MS Market \$24 Billion Market

Developing GA Depot as a premium drug to Copaxone® for MS patients with improved compliance, convenience and clinical outcome

<p>PLGA microspheres ~10-micron GA-loaded</p>	<p>On-going Phase II (7 Years), development under 505(b)(2)</p>	<p>Improved: Quality of Life, safety by fewer AEs and tolerability and efficacy</p>
<p>Strong U.S. patent protection until 2030; three new patent applications under process to extend to 2037</p>	<p>Compliance maximized to ~100%, injection by nurse at patient's home or clinic</p>	<p>Phase 3 RRMS, On-going, single pivotal Phase III synopsis approved by FDA</p>
<p>GA Depot 40mg IM, once Every 4 weeks Patients and neurologists prefer a once-monthly injection</p>	<p>Good efficacy Excellent NEDA of 90% observed in Phase II (4 years data)</p>	<p>Phase 2 PPMS on-going, all patients show stable EDSS or improved EDSS</p>

Source: Dr. Carlo Tornatore | New York, February 13, 2018, https://www.youtube.com/watch?v=5_UuFQrm2Nc

GA Depot for RRMS: Global Licensing Agreement with Viatriis



Equity investments: \$40M



High teens royalties from sales



Upfront payment: \$20M



Co-marketing option



Development milestones



New indications retained by Mapi



Sales milestones



Product manufactured and supplied by Mapi.
Launch stock financed by Viatriis in 2021.



Responsibility:

- IP and R&D
- Management of Clinical studies Phase II / III
- NDA (FDA) Registration
- Clinical / Commercial Product Supply

Responsibility:

- Marketing
- Registration in other territories after USA

Liraglutide LAI (GLP-1) Depot

- Liraglutide is an analog with 97% homology to human glucagon-like peptide-1 (GLP-1) for the therapy of type 2 diabetes, hypoglycemia, obesity and in pre-clinical for PD, Alzheimer's
- 2 innovative Liraglutide LAI prototypes were developed by Mapi, both demonstrated efficacy in diabetes model up to 28 days, efficacy in Parkinson's disease model up to 28 days due to Liraglutide's neuroprotective effects
- Product intended for NDA/505(b)(2) regulatory pathway
- Pilot scale-up is being studied in the R&D lab
- IP protection for Mapi's Liraglutide Depot covering 1 week to 1 in six months

Market opportunity:

Current formulation reached USD 4.5 billion in 2019, expected to reach over USD 6.8 billion in 2027, growing at a CAGR of over 9.5%

New Depot expected to quickly reach blockbuster status



Pregabalin ER Capsules (once daily)

- Extended Release Pregabalin developed by Mapi for the Chinese market with an EU-GMP approved partner, ROW rights retained by Mapi Pharma
- IP protected technology (WO 2018015946), when approved until 2037
- CMC and Preclinical studies completed (PK study on dogs)
- Bioavailability (BA) Phase I trial (head-to-head Lyrica IR) – completed
- Bioequivalence (BE) trial Phase I (vs. Lyrica CR) – ongoing
- EU Phase III trial – Looking for partners

Market opportunity:

Lyrica CR not registered by Pfizer in the EU

EU annual Pregabalin market: USD \$1 billion

Conservative Market Share estimate: 10%
totaling \$100 million in annual revenue



GLP-1 Depot for Diabetes & Parkinson's Disease



Diabetes:

- Demonstrated efficacy in diabetes model up to 28 days
- PK study in mice demonstrated continued release up to day 14
- Both animal study and in vitro release tested

Parkinson's Disease:

- Neuroprotective effects of GLP-1 receptor activation.
- GLP-1 reduces apoptosis signaling and enhances the release of other growth factors such as BDNF and NGF in the brain.
- Animal study (MPTP induced Parkinson's disease)
- Efficacy demonstrated by evaluating the mice performance on various PD simulating tests (Rotaroad, Catalepsy or rigidity), Open field observations
- Significantly improved various parameters of MPTP induced Parkinson's disease:
 - Rotarod motor sensory performance test up to day 28
 - Catalepsy test, up to day 12
 - Open field observations – rearing and mobility
 - No effect was noted over gait, posture and arousal levels.

Strong Financial Position

- **Investors:** Viatris, Generali Insurance company, aMoon Fund, Shavit Capital, Jingxin Nhwa
- Substantial Founder and Insider ownership
- Raised over \$165 million to date, of which \$55 million in up-front payments and non-dilutive funding
- Most recent post money valuation \$400 million
- Supply Agreement was signed with Viatris in June 2021 with advanced payments that cover the launch supply
- Large on-going Phase III trial for GA Depot
- Current income from generic product sales, milestones and royalties



Ehud Marom, Founder, CEO & Chairman



Founder of Mapi Pharma and has served as CEO and Chairman since inception

Over 40 years of senior management and operational experience in the life sciences industry

Vice President of two divisions at Teva Pharmaceutical Industries Ltd. (1992 to 1995)

Launched Copaxone® and was the head of the Copaxone global operation team and headed the global operations of Teva Pharmaceutical's chemical division

President of Peptor Ltd.(2000 to 2002), served as where he led the pharmaceutical development of the innovative diabetes product, DiaPep

CEO of Gamida-Cell Ltd. (2002 to 2004), a stem cell development company

CEO of Makhteshim, a company with annual sales of \$1 billion, and the world's leader in branded off-patent crop protection solutions. Acquired by ChemChina for \$2.4 billion in October 2011, the largest ever deal between a Chinese company and an Israeli company.

Currently serves on the BOD of Pharma Two B (is the founder and previously served as Chairman) and is CEO and Chairman of Stem Cell Medicine Ltd.

B.Sc. in chemical engineering with honors, from the Technion, Israel

