



INVESTOR PRESENTATION

FEBRUARY 2020



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# PolyPid: Experienced Team



**Amir Weisberg** Chief Executive Officer

- Chief Executive Officer of PolyPid since 2010
- Over 20 years of entrepreneurial and leadership experience within life sciences space



**Dikla Czaczkes Akselbrad** Chief Financial Officer

- Joined PolyPid in 2014
- Previously CFO at Compugen (NASDAQ: CGEN)
- BA in Accounting and Economics and an MBA in Finance, both from Tel Aviv University, and is a Certified Public Accountant in Israel



**Tania Markvicka** Chief Operation Officer US

- Joined PolyPid in 2019
- Over 25 years of pharma experience and previously CCO at Symbiomix and Pacira (NASDAQ: PCRX)



# PolyPid Overview

**PolyPid is a Phase 3 clinical-stage biopharmaceutical company focused on developing targeted, locally administered and prolonged release therapeutics to address diseases with high unmet medical needs**

## **Polymer-Lipid Encapsulation matrix (PLEX) Platform**

Our proprietary matrix of several thousand layers of polymers and lipids that physically embed an active drug and enable a customizable, predetermined release role of up to several months

## **Lead Product**

D-PLEX<sub>100</sub> is currently in Phase 3 development for the prevention of surgical site infections (SSIs) following abdominal (soft tissue) or post-cardiac sternal (bone) surgeries

**79**

issued patents<sup>(1)</sup>



**55**

employees<sup>(2)</sup>

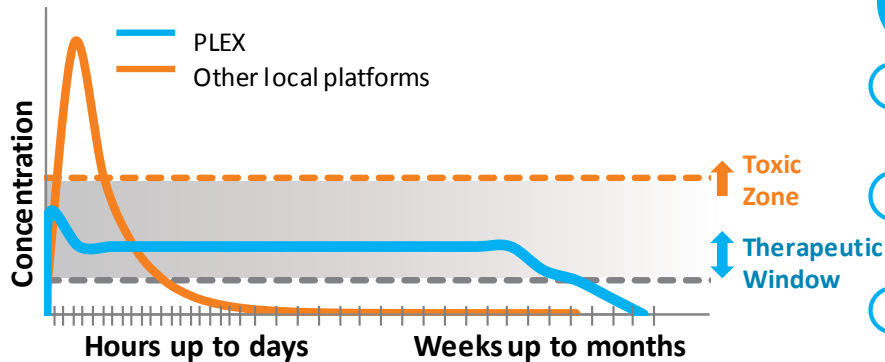
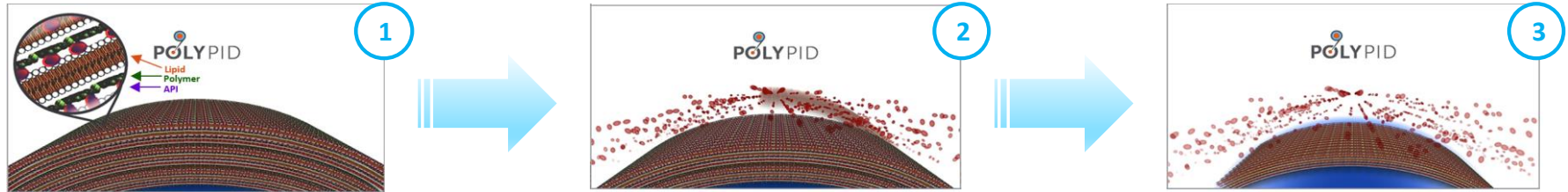


**HQs**

Global: Petach Tikva, Israel  
US: Summit, NJ



# Our Solution: PLEX Technology



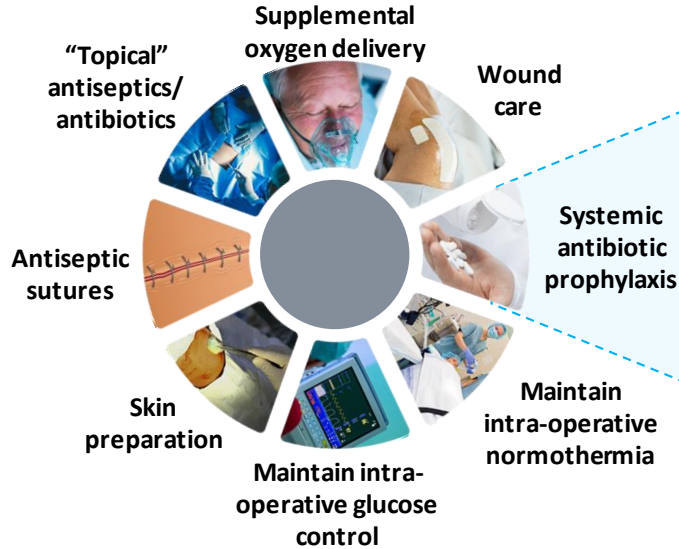
PLEX technology is designed to enable localized and prolonged drug delivery with significantly lower amounts of drug required compared to systemic administration

- 1 PLEX technology consists of **several thousand layers of polymers and lipids** that physically **embed and protect an active drug** between each layer
- 2 Drugs stored between the PLEX layers are **released over time** by the gradual disintegration of the outer layers when they are hydrated
- 3 The **PLEX matrix protects the stored drug** from the natural enzymes and biochemicals in the body that could potentially change or alter the drug

*PLEX technology is designed to be paired with a wide variety of marketed drugs or product candidates to deliver drugs to precise sites in the body at predetermined release rates ranging from several days to several months*

# Our Initial Focus: Enhancing Post-Operative SSI Prevention

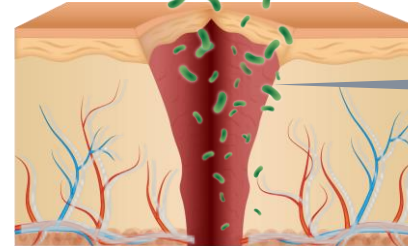
## The Current Paradigm



## Systemic Antibiotics Are Not Enough

- Systemic antibiotic prophylaxis (IV, Oral) ½ - 1-hour before the surgery is generally used to prevent SSIs
- But because of the surgical incision, the antibiotic penetration in the surgical wound is significantly limited (due to blood flow interruption) <sup>1,2\*</sup>

*In SSIs, the surgical incision becomes contaminated by bacteria*



**Our solution:**  
Direct local  
antibiotic  
administration at  
the site

## Selected Key Players



*The Goal: effective antibiotic concentrations over prolonged period within the surgical site*



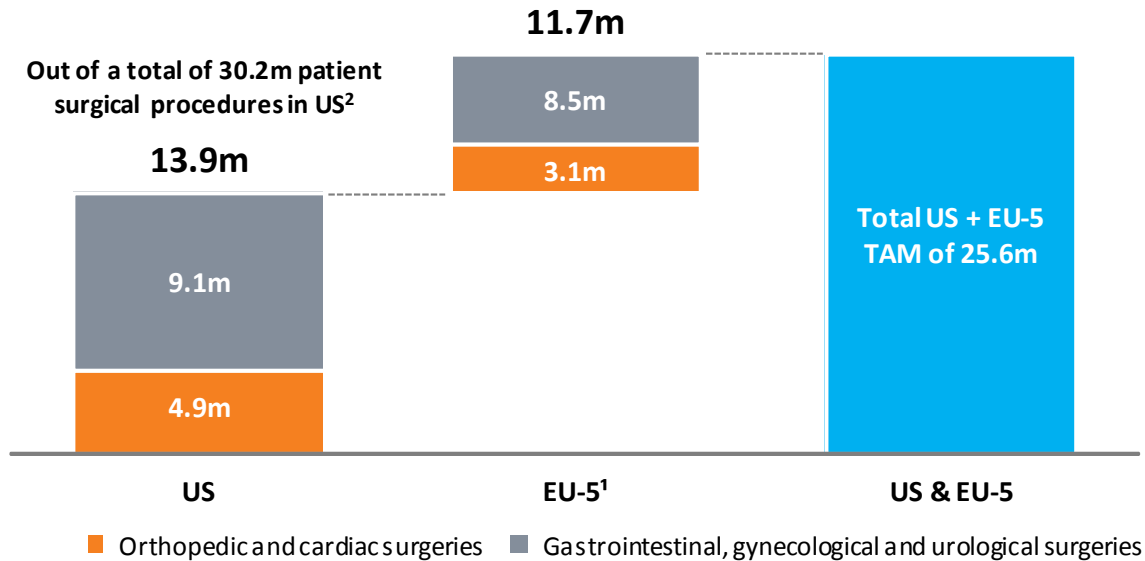
Source: American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update. Ban et al. J Am Coll Surg Vol. 224, No. 1, January 2017 ; New WHO recommendations on intraoperative and postoperative measures for surgical site infection prevention: an evidence-based global perspective - Benedetta Allegranzi et al. The Lancet Infectious Diseases, Vol. 16, No. 12

\*In CABG, left internal mammary artery (LIMA) harvesting further decrease antibiotic penetration ; Furthermore, Tissue perfusion is impaired in patients with diabetes or atherosclerosis, who are common in CABG / cardiac Surgery. 1 Cefazolin and linezolid penetration into sternal cancellous bone during coronary artery bypass grafting . Martin Andreas et al. European Journal of Cardio-Thoracic Surgery 48 (2015) 758-764 ; 2 Direct sternal administration of Vancomycin and Gentamicin during closure prevents wound infection. Andreas M. et al. Interactive CardioVascular and Thoracic Surgery (2017) 1-5



# SSIs Represent a Large Commercial and Clinical Opportunity

## Total Addressable Market in US and EU: Major Open Surgeries<sup>(3)</sup>



## Highlights

- Large addressable market
- Unmet medical need
- Growth opportunity
- Pharmacoeconomic benefit



# D-PLEX<sub>100</sub> is Potentially Transformative for the Prevention of SSIs



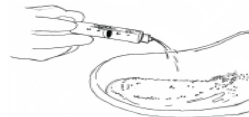
Antibiotic drug reservoir



PLEX<sup>TM</sup> matrix + antibiotic



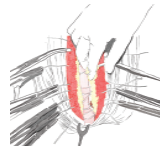
1. Pour



2. Hydrate



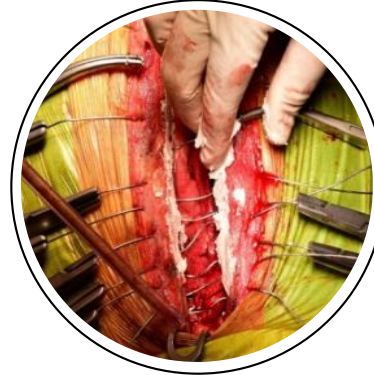
3. Mix



4. Apply



SURGICAL SITE INFECTION



Example of surgeon spreading the D-PLEX<sub>100</sub> paste in an open-heart surgery

## D-PLEX<sub>100</sub>: locally-administered doxycycline

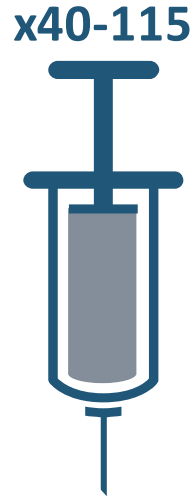
- ✓ Administered **directly in the surgical site**
- ✓ Local delivery of therapeutically effective concentration of antibiotic over **prolonged duration** (4 weeks)
- ✓ **Simple administration** that requires no additional training

# A Small Single Dose of D-PLEX<sub>100</sub> is Sufficient for High Local Concentrations for Several Weeks

POLYPID

Local delivery  
of doxycycline

55-164 mg



Systemic formulation  
of doxycycline

60 pills = 6,000 mg



D-PLEX<sub>100</sub> is designed to provide prolonged delivery following single administration and subsequent high local concentrations and has the potential to supersede existing antibiotic delivery systems, and may offer advantages over systemic treatments in the prevention of SSIs, including against many antibiotic-resistant bacterial strains

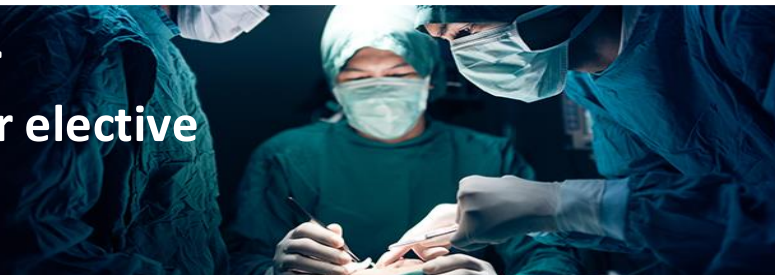
POLYPID

# Phase 2: D-PLEX<sub>100</sub> for the Prevention of SSIs in Post-Op Abdominal (Soft Tissue) Surgeries



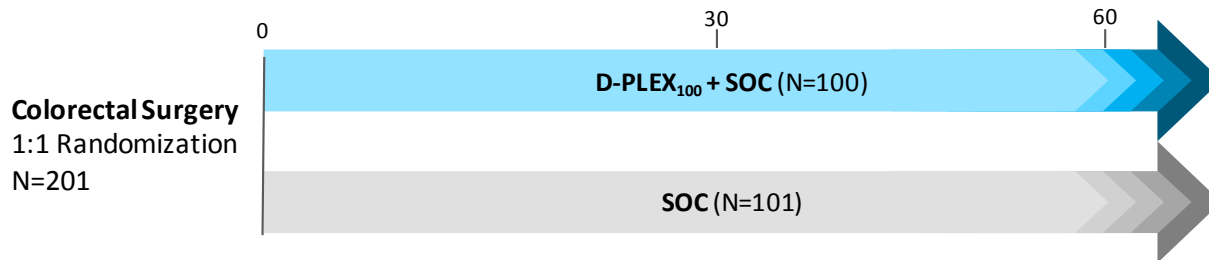
## Assess efficacy and safety of D-PLEX<sub>100</sub> for prevention of deep and incisional SSI after elective abdominal colon surgery

(prospective, multicenter, randomized, controlled, two arm study)



*Primary Endpoint: Combined SSI and mortality rate at 30 days post Index Surgery\**

*Safety Assessment at 60 days post Index Surgery*



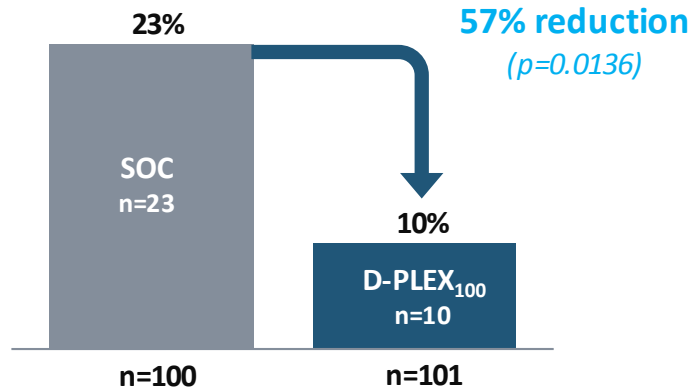
### Key secondary efficacy endpoints

- Number of hospitalization days post colorectal surgery due to SSI
- Average ASEPIS assessment score during 30 days post-surgery
- Number of surgical interventions due to SSI

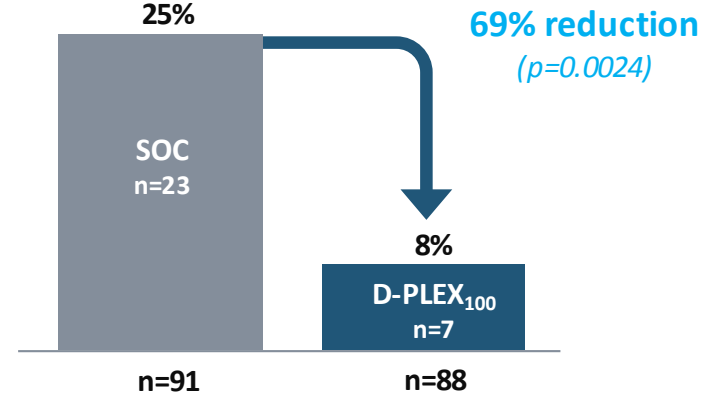


# Positive Phase 2 Results in Abdominal Surgery

## Primary Endpoint\* ITT Analysis



## Primary Endpoint - Per Protocol Analysis

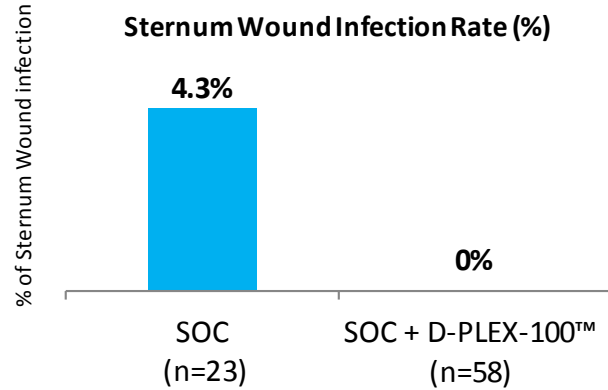


- 5 deaths observed in the SoC treatment arm, as compared to zero observed in the D-PLEX<sub>100</sub> treatment arm within the first 60 days post-surgery ( $p=0.0290$ )
- Generally well tolerated, with no confirmed drug-related SAEs and no increase in wound healing impairment at the incision site as compared to control



# D-PLEX in Post-Op Sternal (Bone) Surgeries

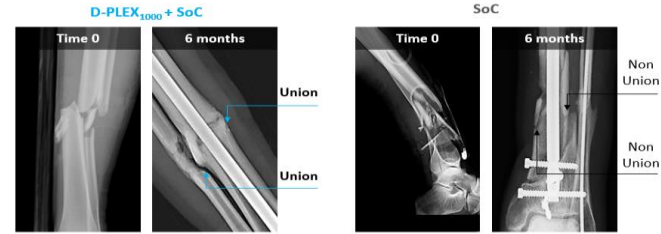
## D-PLEX<sub>100</sub>: P1b / 2 Open Heart Surgery Results<sup>1</sup>



**No Sternal Wound Infection in 58 Treated patients**  
 (Based on recent literature, we would have expected ~3-5 patients with SWIs in the D-PLEX<sub>100</sub> treatment group and 1-2 patients in the SoC control group)<sup>6-10</sup>

## D-PLEX<sub>1000</sub>: Open-Tibia Fractures<sup>11</sup>

	D-PLEX <sub>1000</sub> + SoC	SoC
Deep bone infections <sup>2</sup> / non-union <sup>3</sup> rate (%)	0% (0/24)	11.1% (3/27)



**No deep bone infections after 6 months across 24 treated patients, in comparison with reported incidences in the literature ranging between 7% to 19%<sup>4-5</sup>**

No treatment related SAEs

<sup>1</sup> Based on 3 months follow-up interim report; <sup>2</sup> One event; <sup>3</sup> Two events where another surgery and implantation of bone graft was needed; <sup>4</sup> Prodromidis et al. The 6-Hour Rule for Surgical Debridement of Open Tibial Fractures: A Systematic Review and Meta-Analysis of Infection and Nonunion Rates. 2016; <sup>5</sup> Poletti FL et al. Current Concepts and Principles in Open Tibial Fractures - Part II Management and Controversies. 2017. <sup>6</sup> Adding vancomycin to perioperative prophylaxis decreases deep sternal wound infections in high-risk cardiac surgery patients. Reneke S. et al. European Journal of Cardio-Thoracic Surgery (2017) 1-5 <sup>7</sup> Direct sternal administration of Vancomycin and Gentamicin during closure prevents wound infection. Andreas M. et al. Interactive Cardiovascular and Thoracic Surgery (2017) 1-5 <sup>8</sup> Prevention of surgical site sternal infections in cardiac surgery: a two-centre prospective randomized controlled study. Schimmer C et al. European Journal of Cardio-Thoracic Surgery (2016) 1-6. <sup>9</sup> Based on 3 months follow-up interim report. <sup>10</sup> Surgical Site Infections Volume-Outcome Relationship and Year-to-Year Stability of Performance Rankings. Calderwood MS. et al. Med Care 2017;55: 79-85; <sup>11</sup> Predecessor product candidate to D-PLEX100.

# Multiple Trials Completed and One Potentially Pivotal Phase 3 Trial Underway

**5**

clinical trials

**c.400**

patient data set

**Supportive**

clinical data

**Phase 3**

Potentially pivotal phase 3, FPI in Sternum as of February 2020, with abdominal study subject to FDA dialogue

## Potentially Pivotal Phase 3 Trial



**SHIELD**

Surgical site Hospital acquired Infection prevention with Local D-plex

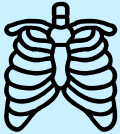




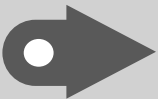
**Trial**

Sternum (open-heart surgery)

**Design**

• 1,284 – 1,600 patients; 45 centers in US, EU and IL

# Pipeline Summary

Product candidate and indication	Preclinical	Phase 1	Phase 2	Phase 3	Key milestones
 <p><b>D-PLEX<sub>100</sub></b> Prevention of SSI in bone tissue (sternum)</p>					<ul style="list-style-type: none"> <li>• First Patient Enrolled in Feb 2020<sup>(1)</sup></li> </ul>
 <p><b>D-PLEX<sub>100</sub></b> Prevention of SSI in soft tissue (abdominal)</p>					<ul style="list-style-type: none"> <li>• Phase 1b/2 results published Oct. 2019<sup>(1)</sup></li> </ul>
 <p><b>PLEX<sub>ONCO</sub></b> Intertumoral therapy</p>					<ul style="list-style-type: none"> <li>• Preclinical Stage</li> </ul>

*Unencumbered, late-stage pipeline with near-term value inflection*

# Regulatory and Commercial Strategies for D-PLEX<sub>100</sub>



- **Two Qualified Infectious Disease Product (QIDP) designations from the FDA.**
  - QIDP status provides total of eight years\* of market exclusivity for D-PLEX<sub>100</sub> upon FDA approval.
- **Investigational New Drug (IND) Application cleared by the FDA in November 2018.**
- **FDA Fast Track status received in November 2018.**



## **NTAP**

CMS add-on payment has been improved for QIDP designed antibiotics used under IPPS: increase of the NTAP from 50% to 75%

## **Outpatient Code**

J-Code support additional reimbursement in the outpatient setting (both CMS & Commercial Payers)

## **DISARM Act**

If approved, the new legislation would allow Medicare add-on payment to inpatient hospitals that use a qualifying DISARM antibiotic to treat a serious or life-threatening infection.

*Subject to feedback from the FDA, we intend to pursue a broad label for D-PLEX<sub>100</sub> for the prevention of SSIs*



# D-PLEX<sub>100</sub> Could Provide Clinical Benefit in Broad Surgical Population



## Soft Tissues

### General Surgeries

- Open Abdominal/GI/Colorectal Surgeries
  - Stomach & Intestinal
  - Herniorrhaphies
  - Colorectal
  - Gallbladder & Biliary
  - Appendectomies
  - Cholecystectomies
- Selected Abdominal Laparoscopic Surgeries

### Selected Gynecological / Urological Surgeries

Hysterectomies ; Salpingo-Oophorectomies & Oophorectomies ; Destructive Operations ; Prostatectomies ; Nephrectomies



## Bone Tissues

### Cardiac

- Open-Heart Surgeries (CABG, valve repair / replacement, heart / lung transplant, congenital defect repair)

### Orthopedic

- Fractures
- Hip Arthroplasties (primary + Revision)
- Knee Arthroplasties (primary + Revision)
- Spine Fusions (Cervical, Thoracic and Lumbar)

*US market represents c.14M major surgeries<sup>1,2</sup>*

# State-of-the-Art Manufacturing Facility



PolyPid was granted Manufacturer Authorization and Good Manufacturing Practice (GMP) certification by Israel's Ministry of Health (IMOH) for its state-of-the-art ~10,500 square feet GMP manufacturing facility



# Strong and Experienced Leadership



**Amir Weisberg** Chief Executive Officer

- Chief Executive Officer of PolyPid since 2010
- Over 20 years of entrepreneurial and leadership experience within life sciences space



**Taunia Markvicka** Chief Operation Officer US

- Joined PolyPid in 2019
- Over 25 years of pharma experience and previously CCO at Symbiomix and Pacira



**Dikla Czaczkes Akselbrad** Chief Financial Officer

- Joined PolyPid in 2014
- Previously CFO of Compugen
- BA in Accounting and Economics and an MBA in Finance, both from Tel Aviv University, and is a Certified Public Accountant in Israel



**Shaul Mukhtar PhD** Chief Operating Officer

- Joined PolyPid in 2019
- Previously SVP, Chief Operating Officer and Regional R&D Manager, Teva Japan & South Korea



**Noam Emanuel PhD** Chief Scientific Officer

- Co-founder of PolyPid and served as its CEO during the company's first three years
- Extensive expertise covering immunotherapy, vaccines, immunodiagnostics and drug-delivery
- PhD from the Faculty of Medicine at the Hebrew University of Jerusalem



**Dalit Hazan** VP R&D and Regulatory Affairs

- Joined PolyPid in 2016
- 20 years regulatory experience in a range of global life science companies

## Summary

POLYPID is poised  
for potential near-  
term value creation



- Pursuing expedited development pathway
- Large and growing target market
- Broad applicability of PLEX technology
- Near-term value inflection points
- Strong management team