



INVESTOR PRESENTATION

JUNE 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** EVP & 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



**Taunia Markvicka, PharmD** 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 rate 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>



**57**

employees<sup>(2)</sup>

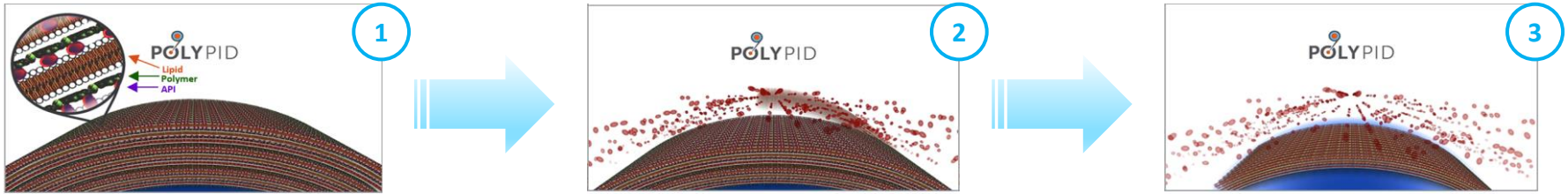


**HQs**

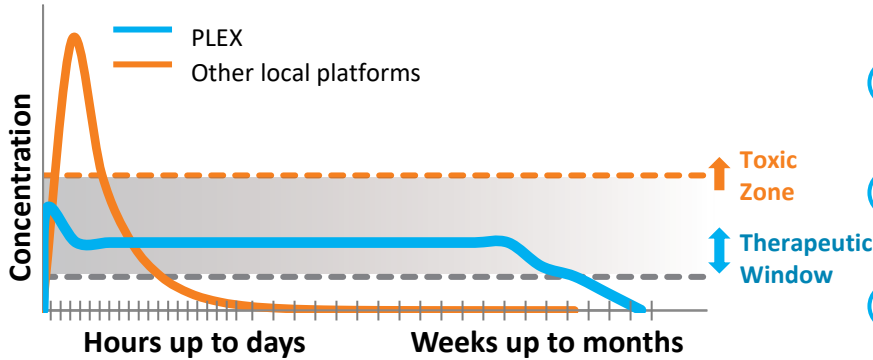
Global: Petach Tikva, Israel  
US: Summit, NJ



# 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

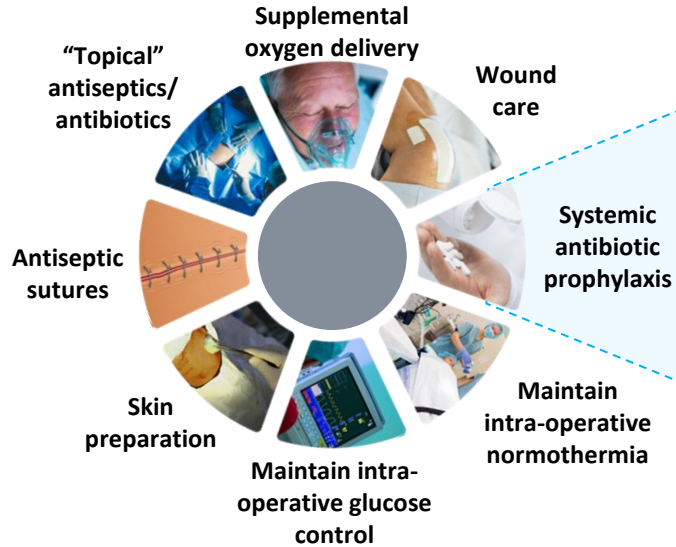


- 1 PLEX technology consists of **several thousand layers of polymers and lipids** that physically **embed and protect an active drug** between each layer
- 2 Drugs stored between the PLEX layers are **released over time** in a controlled manner by the gradual disintegration of the outer layers when 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

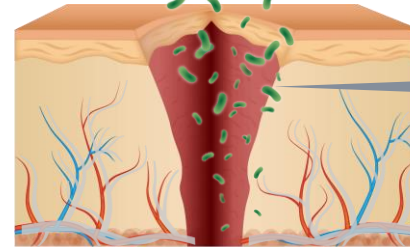
## The Current Paradigm



## 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 into 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

**Medtronic**  
 TYRX Absorbable  
 Antibacterial Envelope

**Johnson & Johnson**  
**ETHICON**

**Smith-Nephew**  
 PICO<sup>®</sup> 7

**3M**  
 Acelyty  
 prevena

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

**POLYPID**

Source: American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update. Ban et al. J Am CollSurg 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



# The Burden of Surgical Site Infections

## Up to 30%

Estimated SSI rate of patients undergoing colorectal surgery<sup>1,2</sup>



## 7-11 days

Additional post-operative hospital days for patients with SSIs<sup>3</sup>



## 20%

SSI rate of all health care-associated infections in US hospitals<sup>3</sup>



## 2-11x

Increased risk of death for SSI patient (up to 40% mortality after deep sternal infection)<sup>1</sup>



## \$11k-26k

Cost of treatment per infection directly attributable to SSIs



US

## \$10bn

EU

## ~€11bn

Estimated SSI-related incremental annual hospital costs in the US and EU<sup>4,5</sup>



## A Globally Recognized Problem

### SSI GUIDELINES:

*What's New and What's Not*



***“The human and financial costs of treating surgical site infections (SSIs) are increasing. The number of surgical procedures performed in the United States continues to rise, and surgical patients are initially seen with increasingly complex comorbidities.”***



## World Health Organization

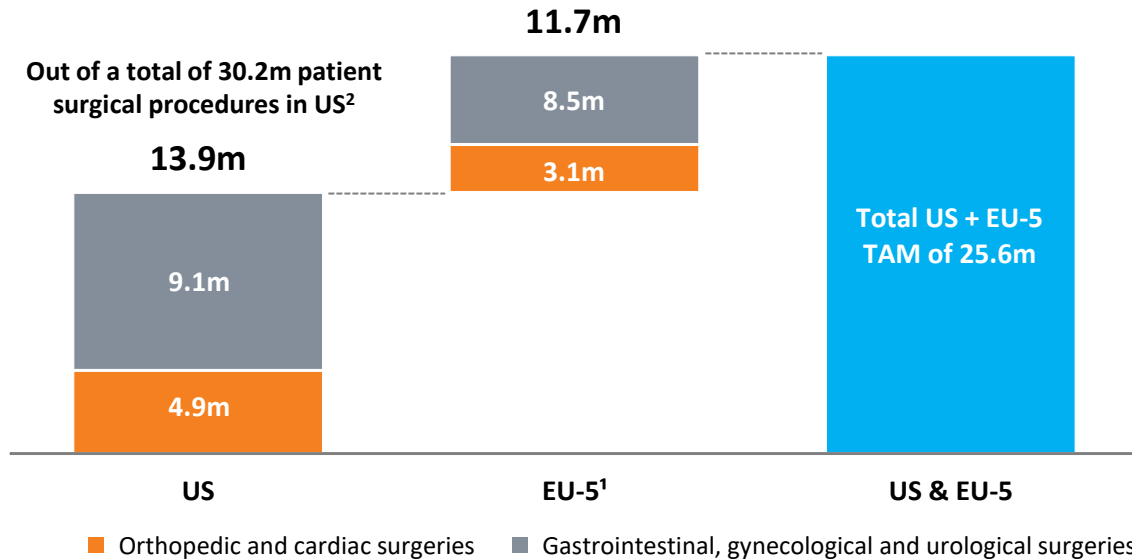
***“The prevention of SSIs is complex and requires the integration of a range of preventive measures before, during, and after surgery. No international guidelines are available...the prevention of SSIs is a priority for patient safety.”***<sup>6</sup>



<sup>1</sup> Devericki et al. *Strategies to Prevent Surgical Site Infections in Acute Care Hospitals: 2014 Update, Infection Control and Hospital Epidemiology*, 2014. <sup>2</sup> Estimated figures likely underestimated as ~50% of SSIs become evident only after a patient has been discharged. <sup>3</sup> *Financial Impact of Surgical Site Infections on Hospitals*. John Shepard et al. *JAMA Surg*. 2013;148(10):907-914. <https://www.evidencebasedpractice.com/2013/12/13/907-914/doi-show-reveal#:~:q=surgical-site-infection>. <sup>4</sup> *Surgical site infection – a European perspective of incidence and economic burden*. Leaper D et al. *Int Wound J*. 2004 Dec;1(4):247-73. <sup>5</sup> ~€11bn represents the midpoint of the range discussed in WHO Global guidelines on the prevention of surgical site infection. Nov 2016: 29. <sup>6</sup> *New WHO recommendations on intraoperative and postoperative measures for surgical site infection prevention: an evidence-based global perspective*. Benedetto Allegranzi et al. *Lancet Infect Dis*. 2016 Dec;16(12):e288-e303.

# 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



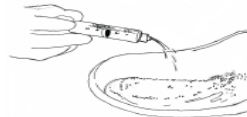
Antibiotic drug reservoir



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



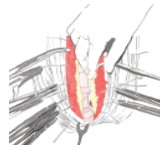
1. Pour



2. Hydrate



3. Mix



4. Apply



SURGICAL SITE INFECTION



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

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

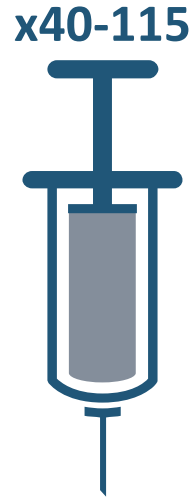
- ✓ Administered **directly in the surgical site**
- ✓ Local delivery that generates a therapeutically effective concentration of antibiotic over **prolonged duration (4 weeks)**
- ✓ **Simple administration** that requires no additional training

# 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

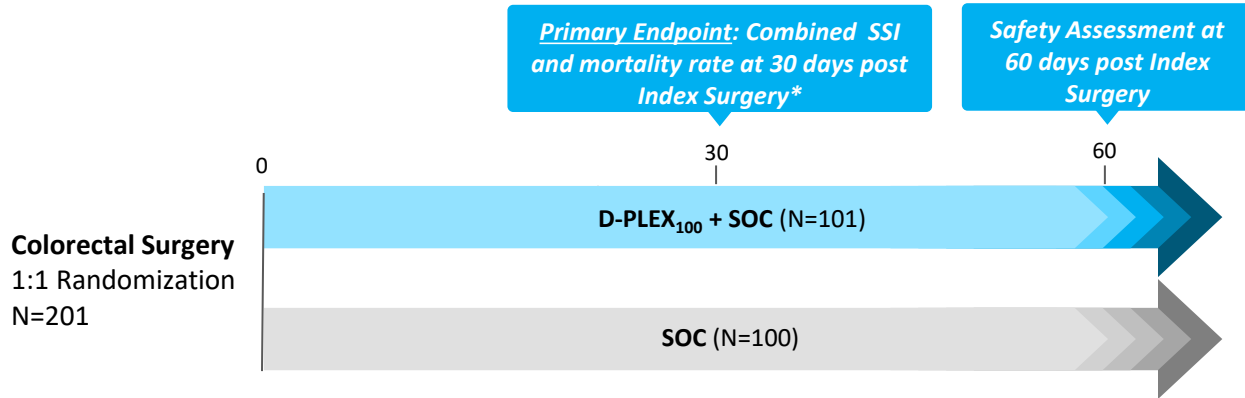
POLYPID

# Phase 2: D-PLEX<sub>100</sub> for the Prevention of SSIs in Post 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)



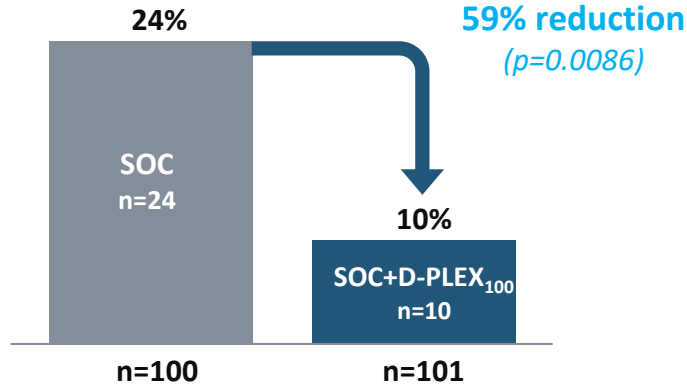
### Key secondary efficacy endpoints

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

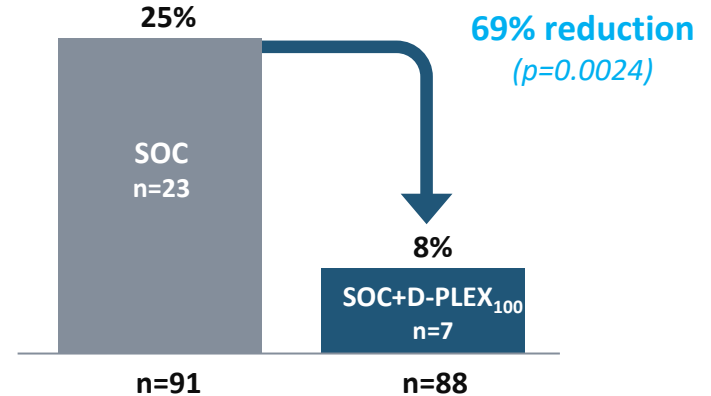


# Positive Phase 2 Results in Abdominal Surgery

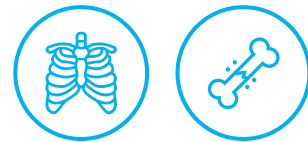
## Primary Endpoint\* ITT Analysis



## Primary Endpoint - Per Protocol Analysis

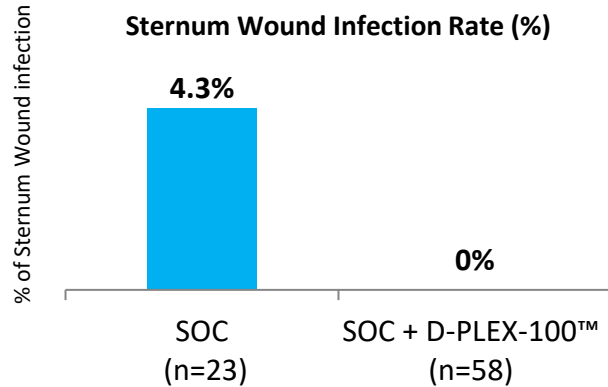


- 5 deaths observed in the SoC treatment arm, as compared to zero observed in the D-PLEX<sub>100</sub> +SOC treatment arm within the first 60 days post-surgery ( $p=0.0290$ )
- Generally well tolerated, with no confirmed drug-related SAEs and no increase in wound healing impairment at the incision site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



# D-PLEX in Sternal / Bone Surgeries

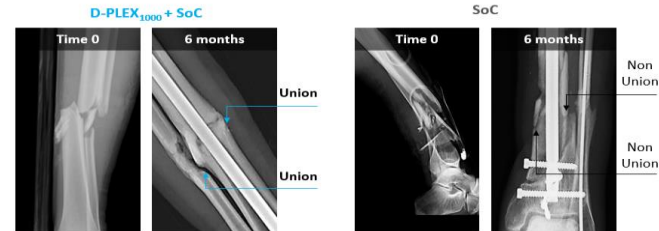
## D-PLEX<sub>100</sub>: P1b / 2 Open Heart Surgery Results<sup>1</sup>



**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

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

**5**  
completed  
clinical trials

**c.400**  
patient data set

**Supportive**  
clinical data

- Phase 3**
- First abdominal surgery Phase 3 study expected to start in early Q3, 2020
  - Ongoing Phase 3 in Open Heart Surgery (Sternum)

## Phase 3 Trial in Bone Tissue (Sternum) Underway



### SHIELD


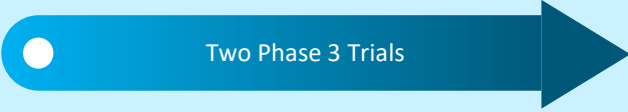
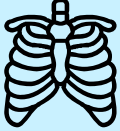



Surgical site Hospital acquired  
Infection prEvention with  
Local D-plex

Study	Design
Sternum (open-heart surgery) Phase 3 Study	• 1,284 – 1,600 patients ; 45 centers in US, EU and IL

## Phase 3 Trials in Soft Tissue (Abdominal) Planned

Study	Design
1 <sup>st</sup> Abdominal surgery Phase 3 study	• 616 - 900 patients ; 60 centers in US, EU and IL
2 <sup>nd</sup> Abdominal surgery Phase 3 study	• 900 – 1,400 patients ; 60 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 soft tissue (abdominal)</p>					<ul style="list-style-type: none"> <li>Phase 2 Results released in Oct. 2019</li> <li>IND Submitted in May 2020</li> <li>Top-Line Results from First Phase 3 Trial Expected by End of 2021</li> </ul>
 <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>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
  - Cholecystectomies
  - Appendectomies

### Selected Gynecological / Urological Surgeries

Hysterectomies ; Salpingo-Oophorectomies & Oophorectomies ;  
Breast Reconstruction ; 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) and EU qualified person 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 the life sciences space



**Tania Markvicka, PharmD** Chief Operation Officer US

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



**Dikla Czaczkes Akselbrad** EVP & 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** EVP & 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
- Over 20 years regulatory experience in a range of global life sciences 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