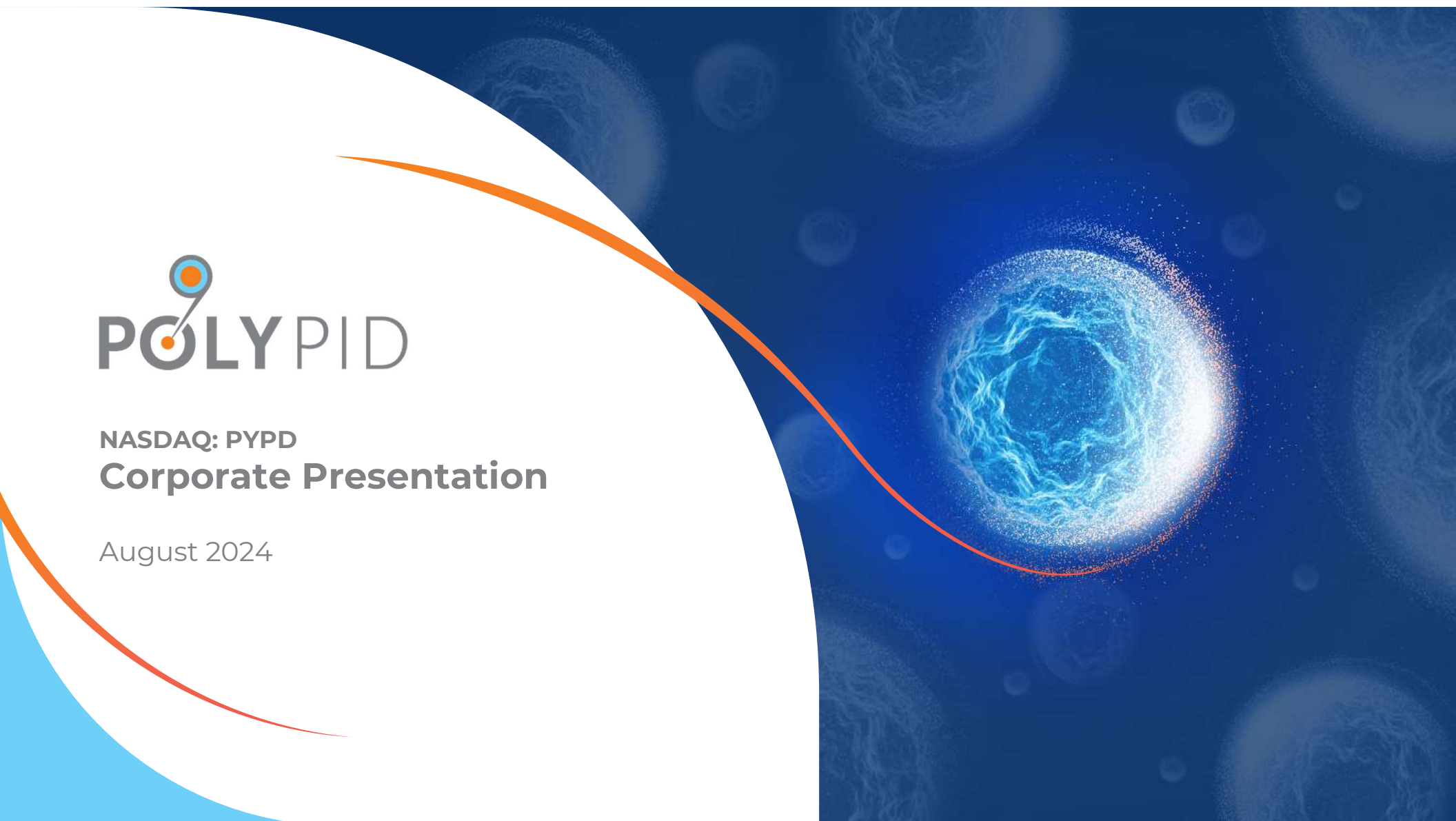




NASDAQ: PYPD  
**Corporate Presentation**

August 2024



# Cautionary Note Regarding Forward Looking Statements

This presentation of PolyPid Ltd. (the “Company”) contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act and other securities laws. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates” and similar expressions or variations of such words are intended to identify forward-looking statements. For example, the Company is using forward-looking statements when it discusses statements relating to our objectives, plans, strategies, the expected timing of trials, research, development, use of our platform technologies, technologies, products and product candidates, potential benefits and advantages of our products and product candidates, and all statements (other than statements of historical facts) that address activities, events or developments that the Company intends, expects, projects, believes, or anticipates will or may occur in the future, expected timing of completion of patient recruitment and top-line results of the SHIELD II study and the timing of the unblinded interim analysis thereof, expected indication for D-PLEX<sub>100</sub>, US and Europe addressable markets, the expectation to meet commercial demand for the first 4-5 years from launch, the planned NDA submission for D-PLEX<sub>100</sub> and the potential to receive additional funds if warrants are exercised. Forward-looking statements are not historical facts, and are based upon management’s current expectations, beliefs and projections, many of which, by their nature, are inherently

uncertain. Such expectations, beliefs and projections are expressed in good faith. However, there can be no assurance that management’s expectations, beliefs and projections will be achieved and actual results may differ materially from what is expressed in or indicated by the forward-looking statements. Forward-looking statements are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in the forward-looking statements. For a more detailed description of the risks and uncertainties affecting the Company, reference is made to the Company’s reports filed from time to time with the Securities and Exchange Commission (“SEC”), including, but not limited to, the risks detailed in the Company’s Annual Report on Form 20-F, filed with the SEC on March 6, 2024. Forward-looking statements speak only as of the date the statements are made. The Company assumes no obligation to update forward-looking statements to reflect actual results, subsequent events or circumstances, changes in assumptions or changes in other factors affecting forward-looking information except to the extent required by applicable securities laws. If the Company does update one or more forward-looking statements, no inference should be drawn that the Company will make additional updates with respect thereto or with respect to other forward-looking statements.

# PolyPid Overview

Late clinical  
stage biopharma  
company

Unique LOCAL  
Prolonged Delivery of  
APIs

Polymer-Lipid  
Encapsulation matrix  
(PLEX) Platform

Lead Product D-PLEX<sub>100</sub> in  
Phase 3 trial

OncoPLEX Next Big  
Opportunity for Solid  
Tumors

**176**

granted and  
pending patents<sup>(1)</sup>

**65**

employees<sup>(1)</sup>

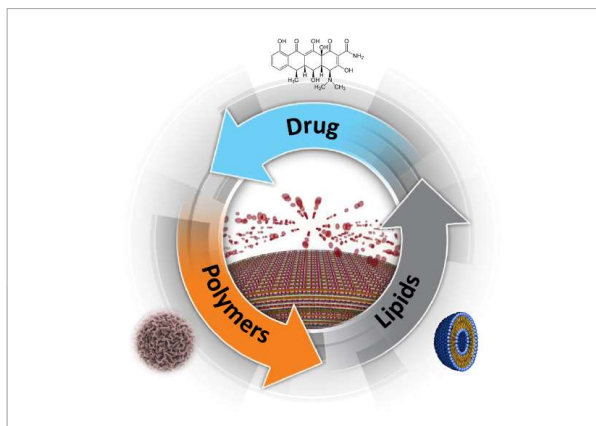
**HQs**

**Global:** Petach Tikva, Israel  
**US:** New Jersey

**NASDAQ: PYPD**

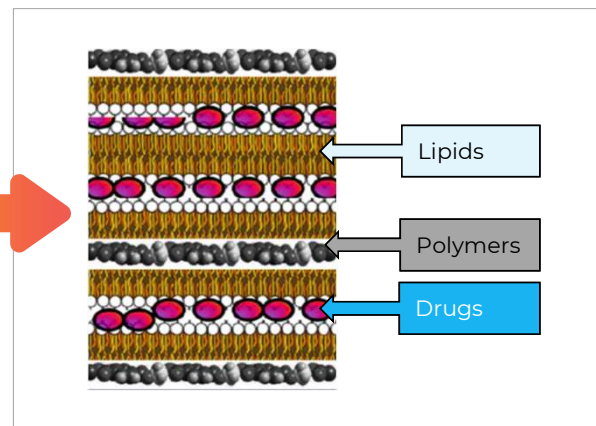
# Optimizing local drug delivery: Overview of the PLEX technology platform

Selected **Composition**  
Raw materials



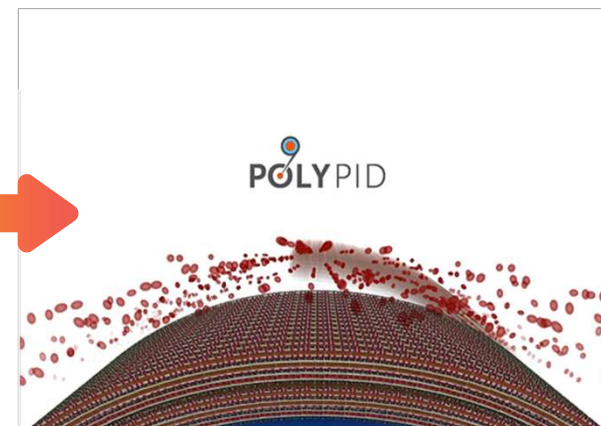
**Out of a vast number of potential combinations,** only a few will optimally fit a specific medical need

From the non-ordered - Liquid stage  
To **highly ordered matrix** - Solid stage



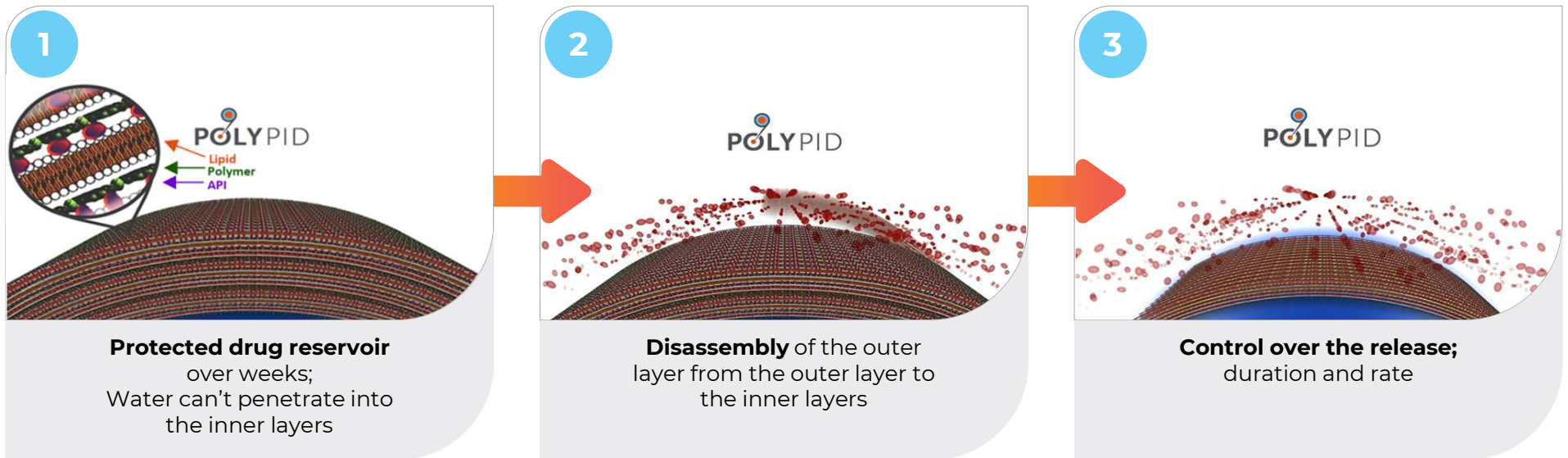
**Production –**  
Generating ordered matrix by **self-assembly**, based on weak forces

**Organized disassembly**  
Solid state > Liquid stage



**In vivo**  
Controlled & prolong  
drug release

# PLEX™ Technology – Organized disassembly of the outer layer - from Solid stage > Liquid stage



# Robust Pipeline with Multiple Near- and Longer-Term Inflection Points

Product candidate and indication	Preclinical	Phase 1	Phase 2	Phase 3	Key milestones
<b>D-PLEX<sub>100</sub> Prevention of Surgical Complications</b>  Prevention of SSI in Colorectal Abdominal  Prevention of SSI in Abdominal Surgery  Prevention of SSI in Orthopedic Surgery	SHIELD I pivotal study in abdominal colorectal surgery  SHIELD II abdominal colorectal surgeries with large incisions				SHIELD I study – completed  SHIELD II: • Trial resumed June 2023 • Topline expected by Q1 2025
				PK + Safety Study	2026
				Post-Approval Efficacy Study	2027/2028
<b>OncoPLEX</b>  Post Surgical Tumor Resection (Adjuvant)  Intratumoral Solid Tumors (Neoadjuvant)					Pre-IND meeting completed (FDA) for GBM  Pre-clinical stage

# D-PLEX<sub>100</sub> is a Potential First-in-class for the prevention of SSIs

Indication:

Prevention of abdominal incisional SSI

Doxycycline (broad spectrum antibiotic)

FDA 505(b)(2) regulatory pathway

Administered directly into the surgical site for prolonged 30 days release

~12M Surgeries addressable market in US

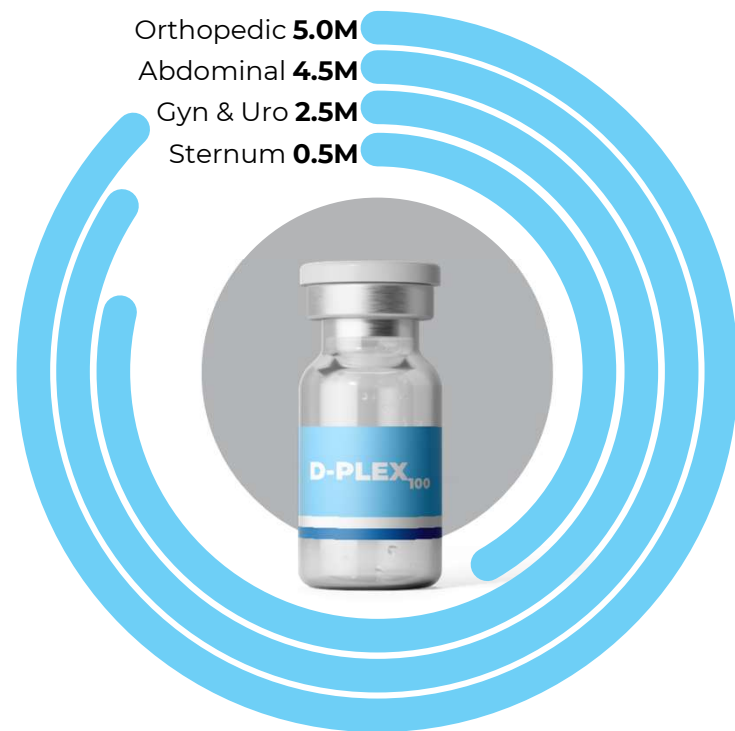
**~12M procedures**

Orthopedic **5.0M**

Abdominal **4.5M**

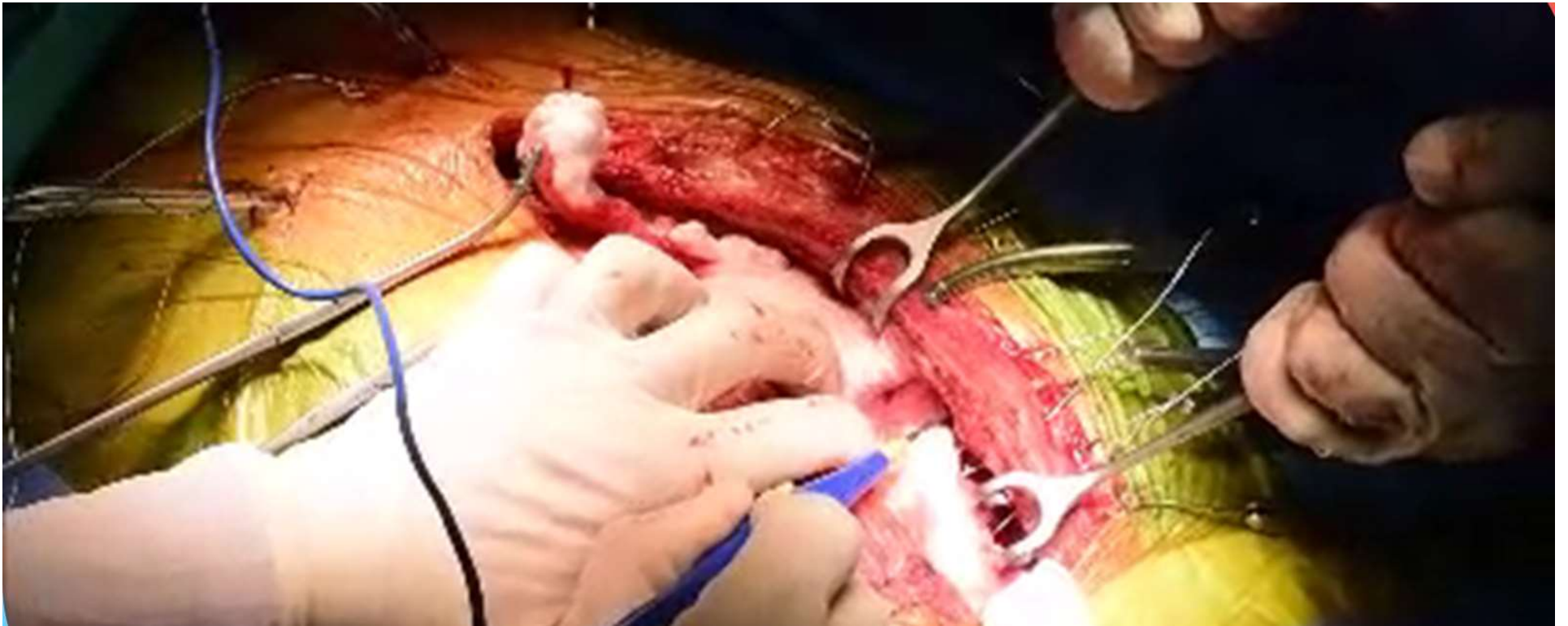
Gyn & Uro **2.5M**

Sternum **0.5M**





## Short Movie

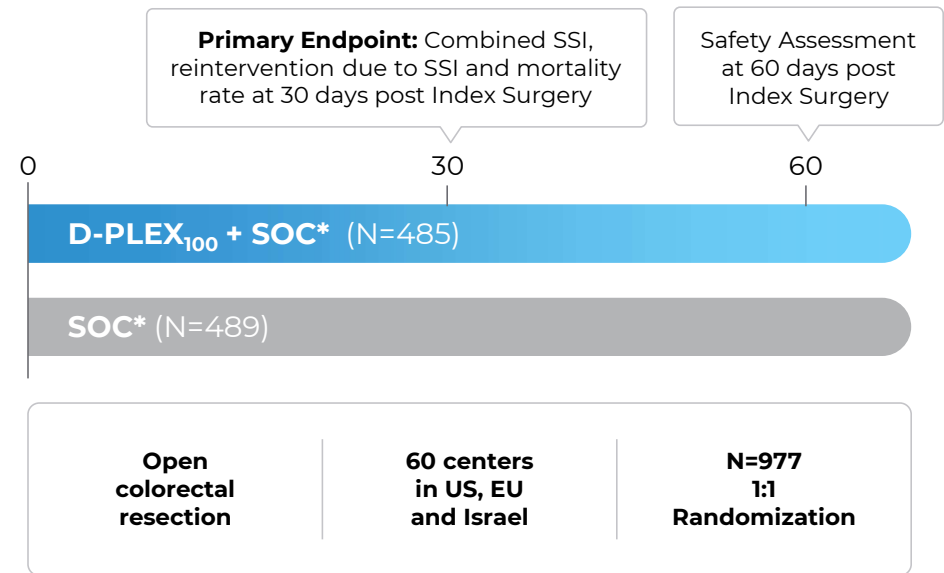




# SHIELD I Study was the Largest Phase 3 Study of Infection Prevention in Colorectal Surgery in Over a Decade

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

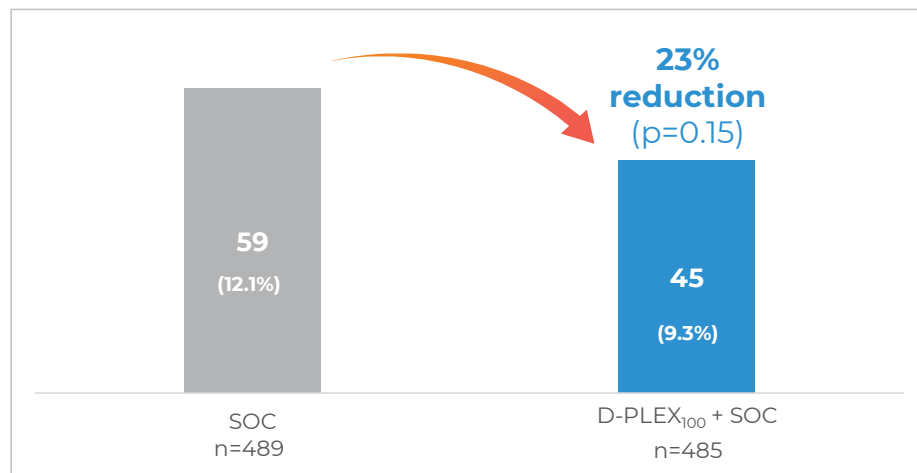
(prospective, multicenter, randomized, controlled, two arm, double-blind study)



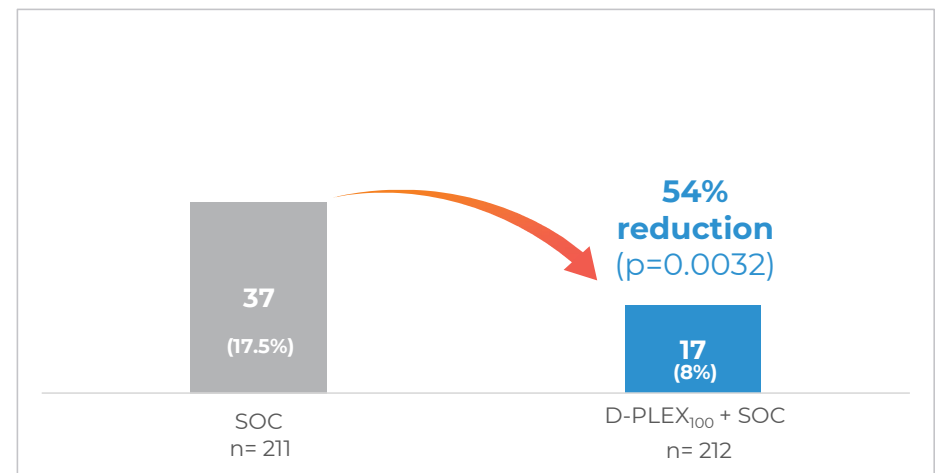
\*SOC - Standard of Care

# SHIELD I Topline Results

## All cohort (primary endpoint\*, ITT)



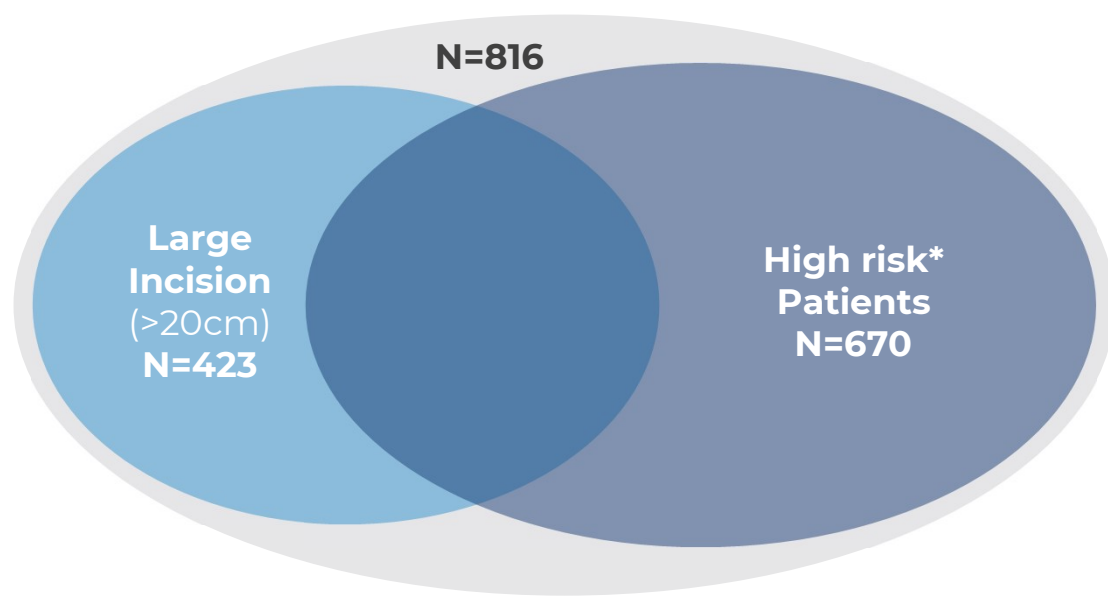
## Large incisions complex surgeries – pre-specified subgroup analysis (primary endpoint, incisions >20cm)



# SHIELD I: Deep Dive into the Large-Incision Subgroup

Parameter	D-PLEX (N=212)	Control (N=211)	Effect
<b>Primary endpoint</b>	<b>17 (8%)</b>	<b>37 (17.5%)</b>	<b>54%</b>
<b>Key Secondary Efficacy Endpoints</b>			
Infection rate during 30 days post abdominal surgery	9 (4.4%)	19 (9.7%)	55%
Number of subjects with at least 1 score of ASEPSIS >20	2 (1.0%)	5 (2.6%)	62%
<b>Additional Efficacy Endpoints</b>			
Incidence of <b>SSSI</b> rate during 30 days post surgery	9 (4.4%)	17 (8.7%)	49%
Incidence of DSSI rate during 30 days post surgery	0	2 (1.0%)	100%
<b>Mortality</b> rate within 30 days post abdominal surgery	6 (2.8%)	10 (4.7%)	40%
Time to adjudicated SSI during 30 days post index surgery (days)	8.0 (4, 28)	5.0 (1, 13)	NA
Number of subjects treated with IV Antibiotic as treatment for adjudicated SSI	1 (11.1%)	9 (47.4%)	77%
Number of subject with any <b>surgical re-interventions</b>	9 (4.4%)	19 (9.7%)	55%

# D-PLEX<sub>100</sub> Effect on in Patients with SSI Risk Factors\*



**816 Patients**

had a large incision and/or high-risk factors (comorbidities)

**37% Reduction**

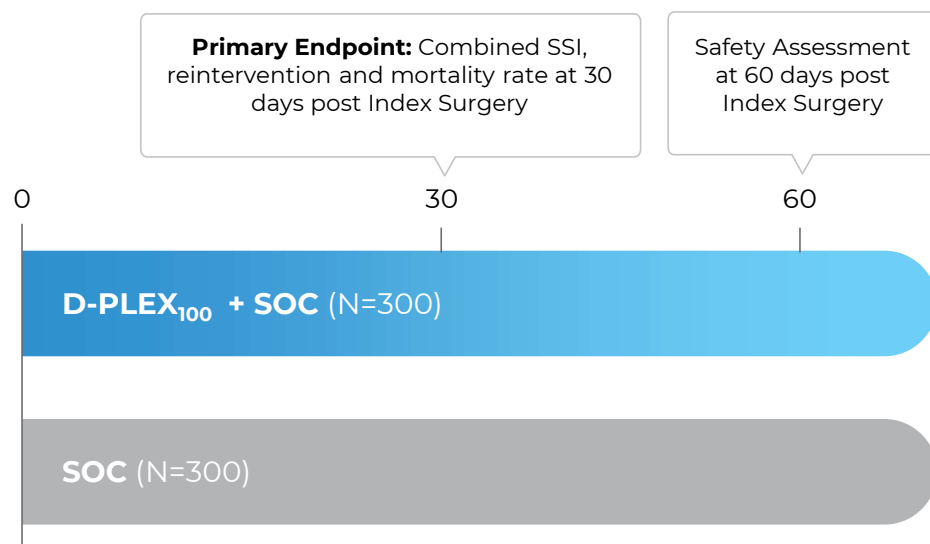
of the primary endpoint (p=0.0162)



# Study Design and Timeline

## SHIELD II

SSI PREVENTION WITH D-PLEX<sub>100</sub>



\*High- performing sites as it relates to recruitment, patient monitoring and good clinical practice

### Surgeries with large surgical incision

Expect total of 600 patients with interim review at 400 patients with an option to “stop for efficacy”

### Current timing assumptions

- Unblinded interim analysis: Q4 2024
- Topline results: Q1 2025

### Actions taken to de-risk SHIELD II

- Focused on population where SHIELD I was successful
- Not conducted within tight COVID-19 related restrictions
- Conservative statistical assumptions on SSI rates
- Implemented lessons-learned: performed detailed debriefing with the site PIs, kept only high-performing sites\*
- Strengthened clinical ops team

# Target Market at Launch is >7M Surgeries in US & Europe\*



**12M**

US total addressable market in-patient surgical procedures



**4.4M**

Abdominal Surgeries

**8M**

Europe total addressable market in-patient surgical procedure



**3M**

Abdominal Surgeries

**7,400K\*\***  
Core Target Surg. Procedures

\* Assuming additional safety and PK Study for US ; Expected Abdominal Indication in Europe based on SHIELD II phase 3 trial

\*\*Source IQVIA PM&I Global FlexView. Internal analysis



# Demonstrated Economic Benefits will be Essential for Market Access and Sales Uptake

## Direct cost

SSI costs ~\$25K/patient<sup>1</sup> on average

- Prolonged length of stay and higher readmission rates
- Re-operation in some cases (to debride and remove infected / necrotic tissues)

## Indirect cost

CMS 1-3% penalty on all the yearly Hospital Medicare reimbursement

## Reputational cost

Hospital SSI rates are public information and have direct influence on hospital ranking by CMS and U.S. News best hospitals ranking



1. Stone PW. Economic burden of healthcare-associated infections: an American perspective. Expert Rev Pharmacoecon Outcomes Res. 2009 Oct;9(5):417-22.

D-PLEX<sub>100</sub> is eligible  
for NTAP program  
**up to 75%**  
**reimbursement**  
of cost of drug



# Global Go-to-market Strategy

**Partnerships with leading pharma companies with established hospital-focused commercial capabilities and resources**

## Agreement highlights

Includes European Economic Area and UK

Potentially receive over \$115 million in upfront and milestone payments as well as royalties on net sales

\$2.7 million upfront payment paid upon signature of licensing agreement



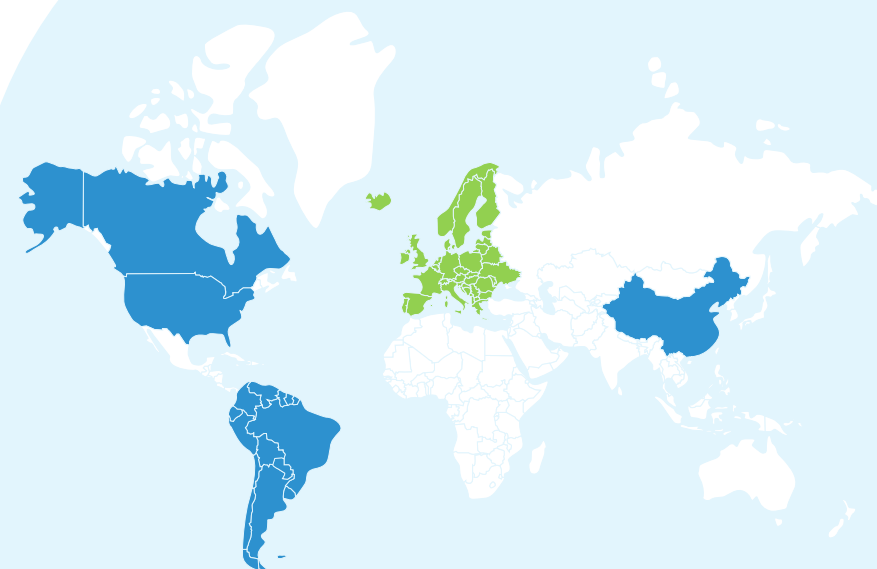
Focused on abdominal and cardiac indications

Signed licensing agreement includes transfer price, development and sales-related milestone payments and royalties

Development-related milestones for a total of up to \$25 million



\*Announced August 3rd, 2022



**Next-in-line**  
US, Canada, China and  
South America

- Partnered territories with Advanz Pharma
- Next-in-line

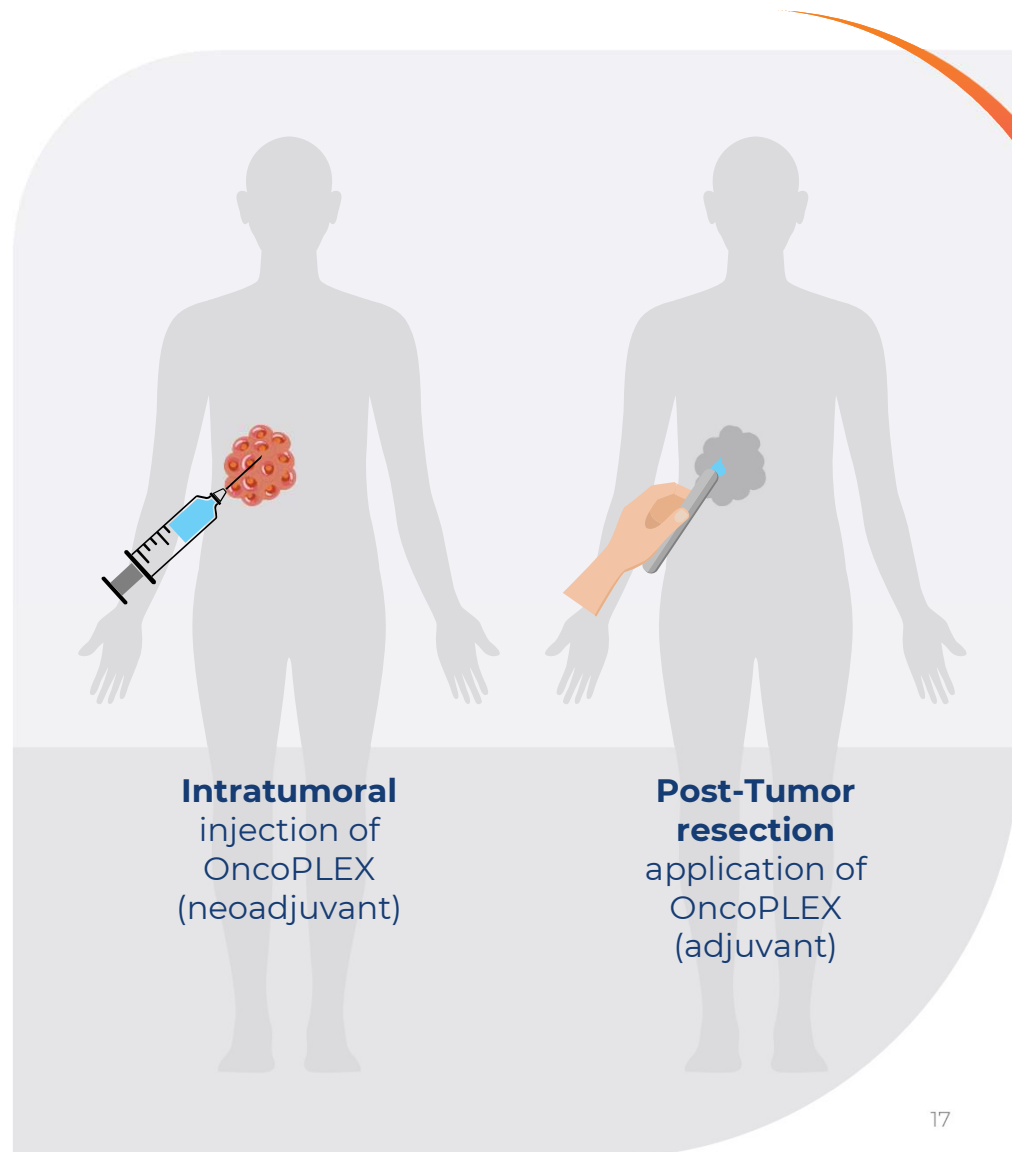
# OncoPLEX - The Next Big Opportunity @ PolyPid

New approach for solid tumors - every year, 1.6 million new cases of solid tumors in the U.S. alone

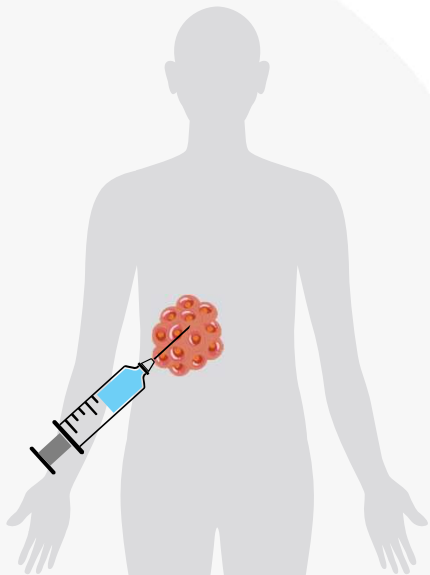
Prolonged 3wks release of docetaxel: intratumoral (neoadjuvant) and post surgical resection of the tumor (adjuvant)

Evaluated successfully in various animal models

Pre-IND meeting (FDA) completed for GBM

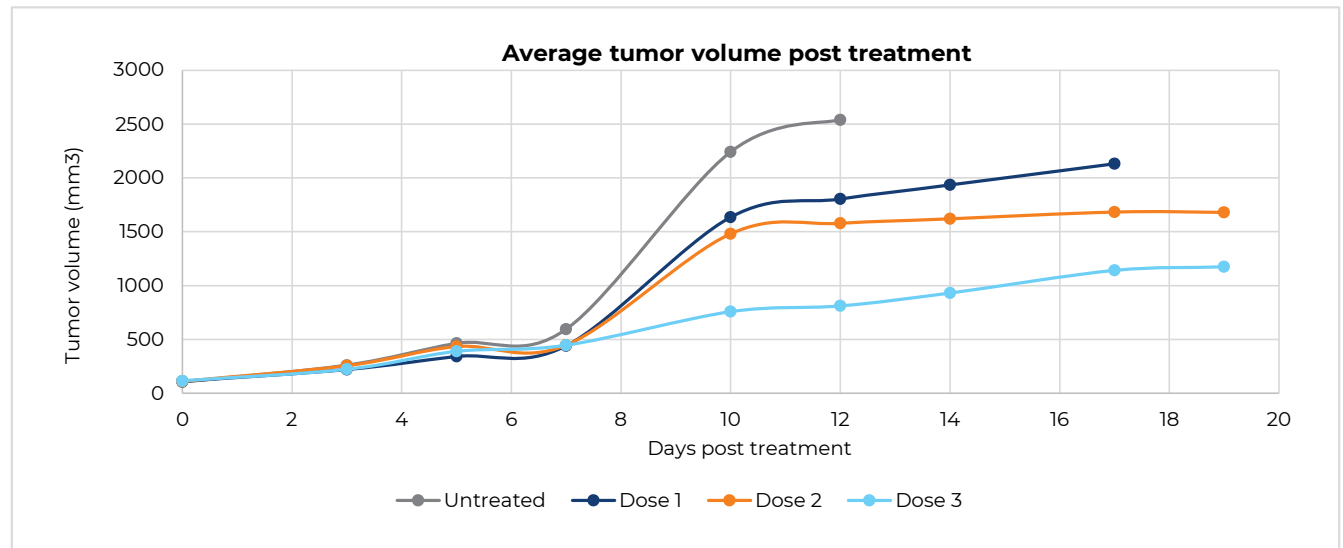


# Single Intratumoral Injection of OncoPLEX reduced tumor growth



**B16 murine melanoma:  
Dose response**

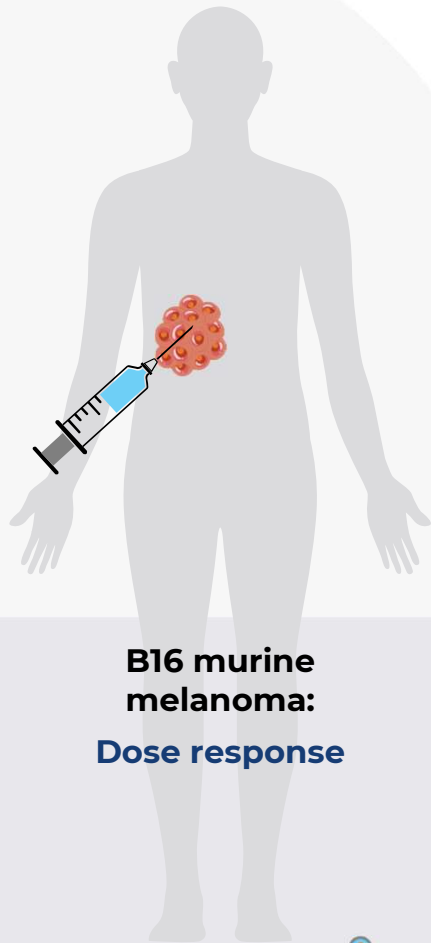
**POLYPID**



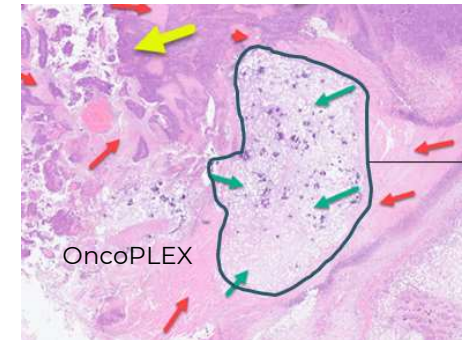
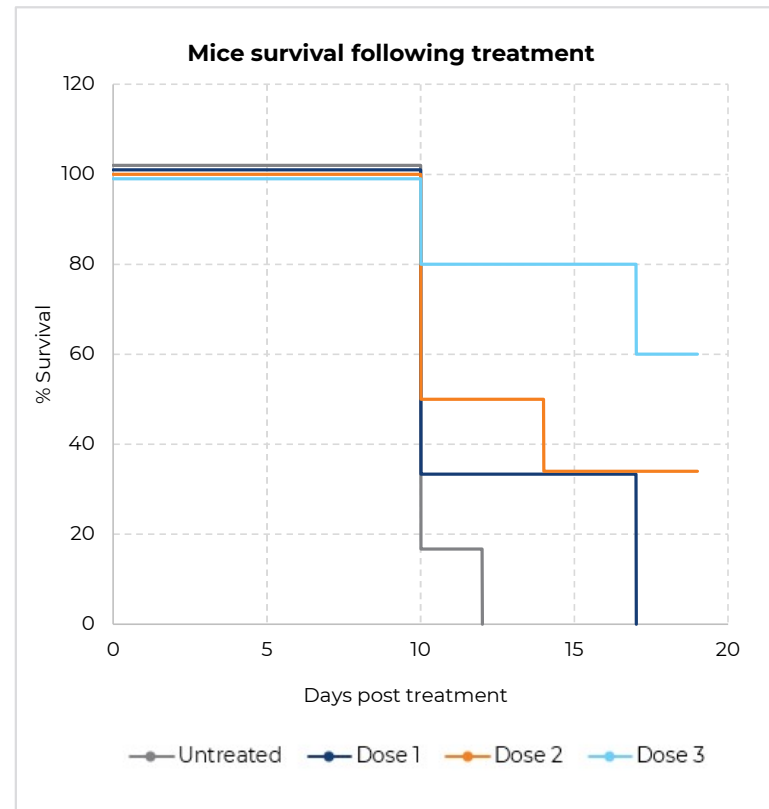
## Key Takeaways

- OncoPLEX spheres remain anchored to the injection site over the entire period
- The prolonged and constant release mechanism allows the released drug to generate an effective microenvironment far from the injection site

## 60% Survival at Day 19 for the Most Effective Dose



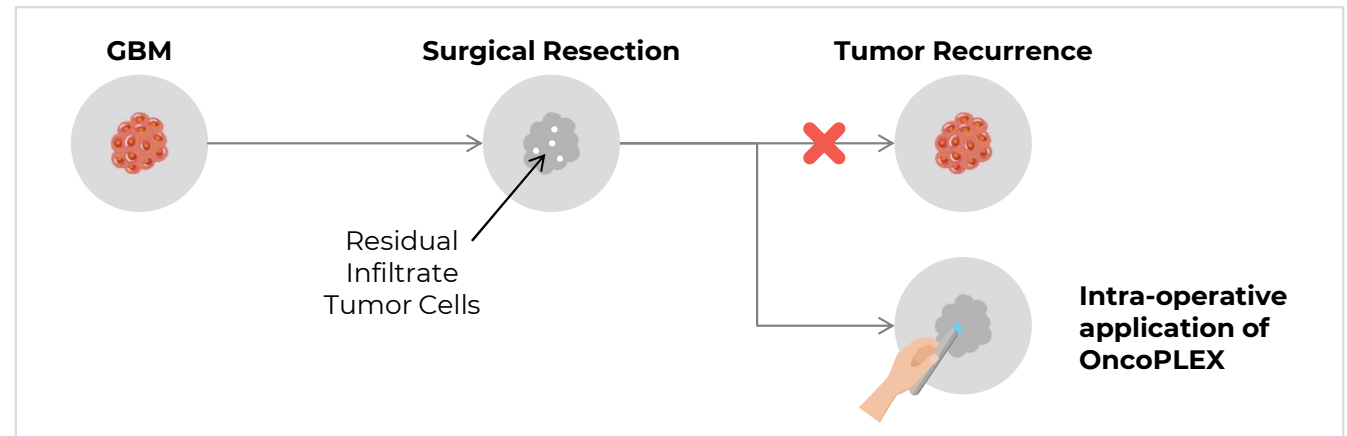
POLYPID



OncoPLEX Focal Deposits are mostly Surrounded by **Necrotic Tumor Tissues and Inflammation**

# Post-Surgical Resection in GBM & Other Solid Tumors

- Prolonged 3wks. local release of Docetaxel directly in the tumor resection pocket
- Evaluated successfully in various animal models
- 98% tumor growth inhibition (day 41) in resected GBM tumor mouse model compared to the untreated control ( $p < 0.001$ )
- 60% survival (day 41) in resected GBM tumor mouse model vs 20% for the systemic treated mice ( $p = 0.0165$ )
- 75% overall tumor free survival in resected colon carcinoma tumor mouse model compared to 25% for the systemic docetaxel arm
- Pre-IND meeting in GBM completed (FDA)





# State-of-the-Art Manufacturing Facility

PolyPid was granted Manufacturer Authorization and Good Manufacturing Practice – **GMP - certification** by Israel's MoH and EU qualified person for its state-of-the-art ~18,000 square feet (~1,700 m<sup>2</sup>) manufacturing facility.

## Investment

machinery, qualifications and validations

## Supply capacity

expected to meet commercial demand for the first 4-5 years from launch



# Financials

<b>Nasdaq IPO</b>	June 2020
<b>Last financing</b>	PIPE August 2024
<b>Ticker</b>	PYPD
<b>52-week range<sup>1</sup></b>	\$2.95-\$11.10
<b>Average Daily Volume (3M)<sup>1</sup></b>	6.1K
<b>Market cap<sup>1</sup></b>	\$25.8 M
<b>Cash (not including proceeds from August PIPE)<sup>2</sup></b>	\$9.8 M



1. As of August 14 2024  
2. As of June 30, 2024

## Top Holders

(Participated in last financing)



## Analyst coverage



Balaji Prasad



Roy Buchanan



Raghuram Selvaraju

# Key Accomplishments

Raised over \$27 million from existing and new life science-focused investors\*

Signed a commercialization agreement for Europe With Advanz Pharma

Completed the largest Phase 3 trial in prevention of SSI in colorectal resection in over a decade

Advanced the development of OncoPLEX including pre-IND studies

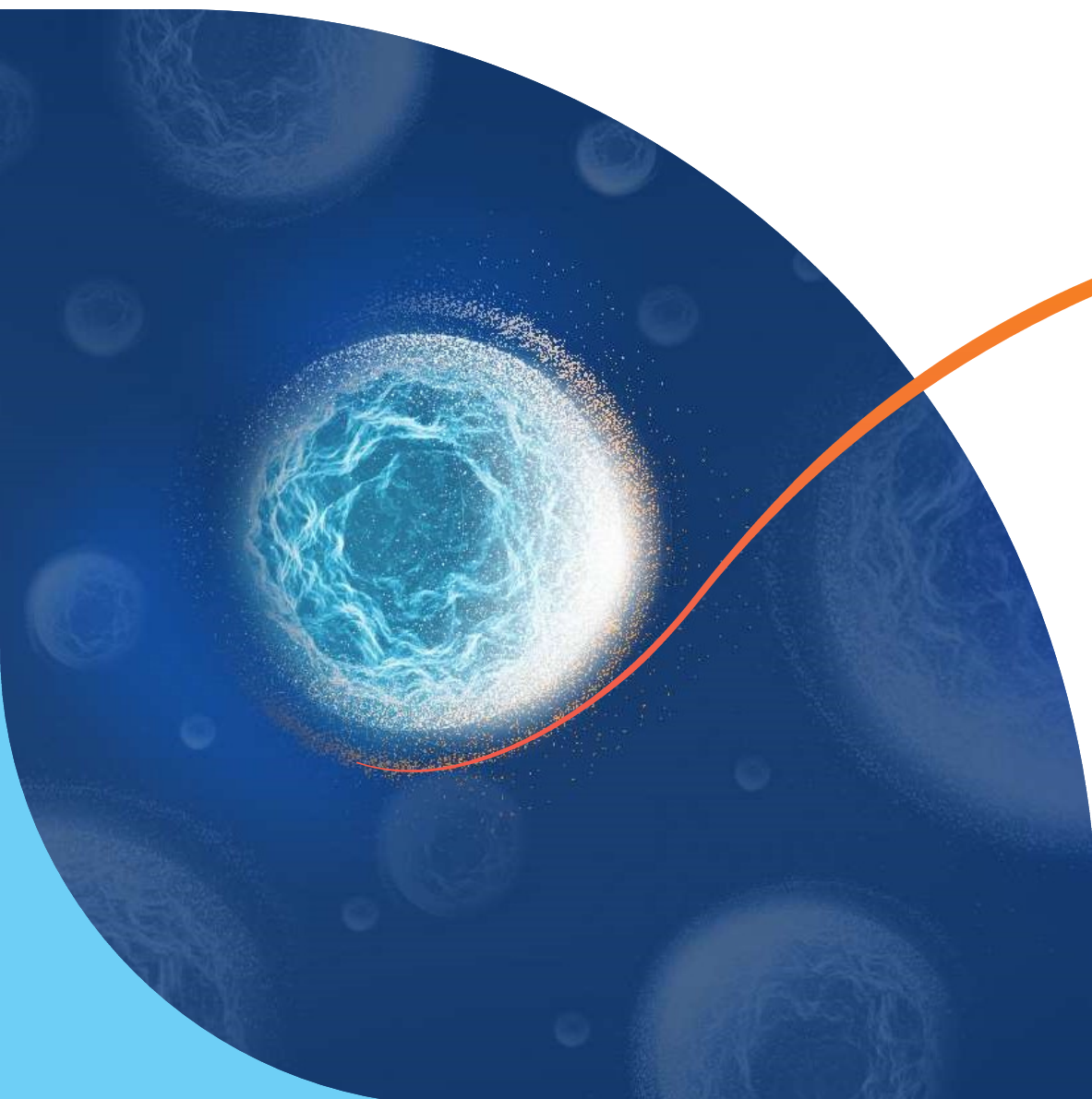
Initiated a second Phase 3 for prevention of SSI in abdominal colorectal resection with large incisions – top line expected by 2H-2024

Completed process validation for D-PLEX<sub>100</sub> and passed cGMP inspection – manufacturing facility ready for EU launch



\*Pricing of \$6.2 Million Underwritten Public Offering of Ordinary Shares and Concurrent \$4.4 Million Private Placement in March 2023 and Private Placement for \$16 Million in Jan 2024





**THANK YOU**

[Polypid.com](http://Polypid.com)

# PLEX based product typical presentation



## Solid spheres

Micron range in diameter

## Dry format (powder) and sterile

Ready to use

## Each particle contains

the PLEX formulation & the Pre-Encapsulated API/APIs

## The PLEX formulation

is predesigned to achieve the needed release characteristics

## The dry powder can be

prepared for administration by either:

**Hydration into a paste**, to be applied locally into the wound/tumor bed during the surgery

**Injected ( $\geq 21G$ ) as a paste**, or as a dry powder – Once or multiple applications





# Recognizes the Potential Value of D-PLEX<sub>100</sub> in SSI



## 3 Fast Track Designations

More frequent meetings with the FDA to discuss the development plan

Eligible for accelerated approval and priority review, if relevant criteria are met

Rolling Review

## 3 Qualified Infectious Disease Product (QIDP) Designations

All the benefits of Fast Track

Additional 5-years of market exclusivity

Improved CMS add-on payment, increase of the NTAP from 50% to 75%

## Breakthrough Therapy Designation

All the benefits of Fast Track

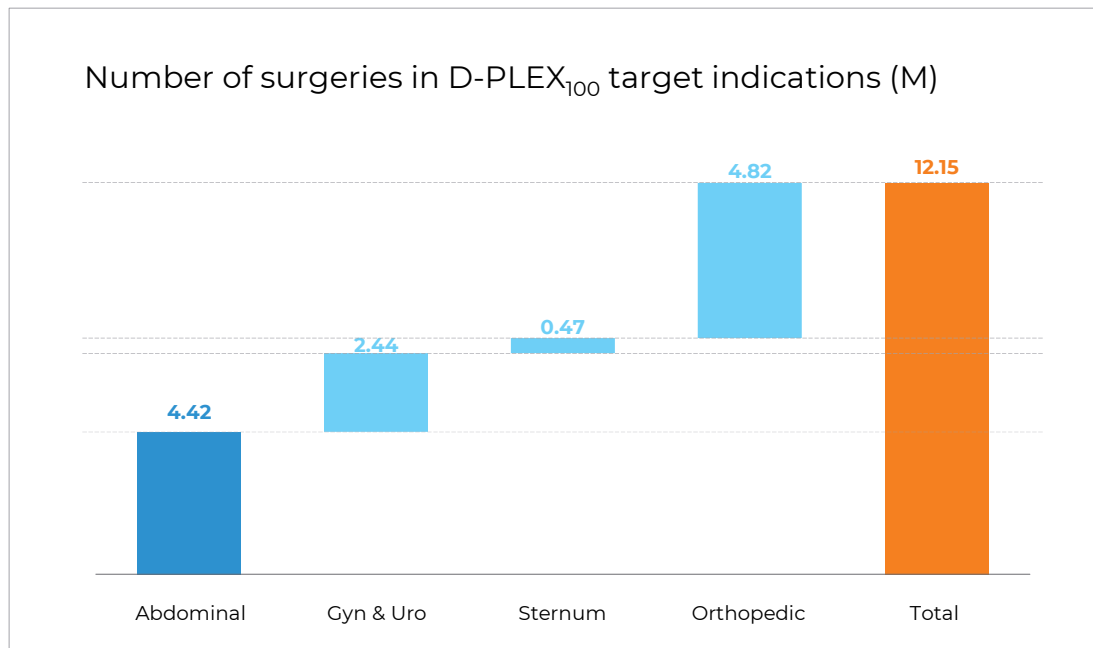
Intensive guidance from FDA on an efficient drug development program

Organizational commitment from FDA involving senior managers



# Total US Addressable Market

US TAM for D-PLEX<sub>100</sub> is Over  
**12.2M Procedures**



Source: IQVIA PM&I Global FlexView. Internal analysis



## Main drivers of surgery volumes

### Abdominal surgeries

- Herniorrhaphies – 2.1M / year
- Cholecystectomies – 616K / year
- Colorectal resection – 544K / year

### Gynecology & Urology surgeries

- Hysterectomies – 660K / year
- Oophorectomies – 1.1M / year

### Orthopedic surgeries

- Joint replacement – 1.8M / year
- Long bone fraction – 2M / year
- Spine procedures – 1M / year