



**Corporate Presentation** 

Issuer Free Writing Prospectus Filed Pursuant to Rule 433 Registration No. 333-199297 October 31, 2014



## **Forward-looking statements**

This presentation includes statements that are, or may be deemed, "forward-looking statements." In some cases these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," "potential," or in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. Such forward-looking statements appear in a number of places throughout this presentation and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the localized drug delivery markets ize and its growth potential, our position and potential in the localized drug delivery market, our product pipeline, the timing and cost of trials for our products or whether such trials will be conducted at all, completion and receiving favorable results for trials of our products, regulatory action with respect to our products, the use of proceeds from this offering, our projections for funds required for the development and commercialization four products, market adoption of our products by physicians and patients, and the timing, cost and other aspects of the commercialization and marketing of our products. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the control of PolyPid Ltd. ("PolyPid"), and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements.

Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) the adequacy of PolyPid's financial and other resources, particularly in light of its history of recurring loss as and the uncertainty regarding the adequacy of its liquidity to pursue its complete business objectives; (ii) PolyPid's ability to commercialize its pharmaceutical products; (iii) PolyPid's ability to obtain and maintain adequate protection of its intellectual property; (iv) PolyPid's ability to complete the development of its products; (vi) PolyPid's ability to find suitable co-development partners; (vi) PolyPid's ability to manufacture its products in commercial quantities, at an adequate quality or at an acceptable cost; (vii) PolyPid's ability to establish adequate sales, marketing and distribution channels; (viii) acceptance of PolyPid's products by healthcare profess ionab and patients; (ix) the possibility that PolyPid may face third party claims of intellectual property infringement; (x) PolyPid's ability to obtain or maintain regulatory approvable for its products in its target markets and the possibility of adverse regulatory or legal actions relating to its or their products; (xii) intense competition in PolyPid's industry, with competitors havings ubstantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than PolyPid; (xiii) potential product liability claims; (xiv) potential adverse federal, state and local government regulation, in the United States, Europe or Is rael and (xv) loss or retirement of key executives and research scientists; (xvi) PolyPid's projections and timeline estimates are based on its current best understanding which may change or deviate due to business, regulatory, clinical, market, financial and manufacturing changes.

You should carefully read the factors described in the "Risk Factors" section of the prospectus included in Amendment No. 1 to PolyPid's Registration Statement on Form F-1 filed with the Securities and Exchange Commission on October 31, 2014 to better understand the risks and uncertainties inherent in PolyPid's business and underlying any forward-looking statement.

PolyPid is presenting this information as of the date of the presentation and expressly disclaims any duty to update the information contained in this presentation. This presentation contains information from third-party sources, including data from studies conducted by others and market data and industry forecasts obtained from industry publications. Although PolyPid believes that such information is reliable, PolyPid has not independently verified any of this information and PolyPid does not guarantee the accuracy or completeness of this information.



## **Free Writing Prospectus Statement**

This presentation highlights basic information about us and the offering. Because it is a summary, it does not contain all of the information that you should consider before investing.

We have filed a registration statement (including a prospectus) with the SEC for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the prospectus in the registration statement (including the risk factors described therein) and other documents we have filed with the SEC for more complete information about us and the offering. You may get these documents for free by visiting EDGAR on SEC web site at <a href="www.sec.gov">www.sec.gov</a>. The preliminary prospectus, dated October 31, 2014, is available on the SEC web site at <a href="http://www.sec.gov/cgi-bin/browse-edgar?company=polypid&owner=exclude&action=getcompany">http://www.sec.gov/cgi-bin/browse-edgar?company=polypid&owner=exclude&action=getcompany</a>. Alternatively, we or any underwriter participating in the offering will arrange to send you the prospectus if you contact Aegis Capital Corp., Prospectus Department, 810 Seventh Avenue, 18th Floor, New York, NY 10019, telephone: 212-813-1010, e-mail: prospectus@aegiscap.com</a>



## **Initial Public Offering summary**

Issuer	PolyPid Ltd.
Exchange / symbol	NASDAQ Capital Market / PLPD
Offering Size	1.8M shares (100% primary)
Over-Allotment	15% or 273,000 shares (100% primary)
Price Range	\$10 - \$12
Indication of Interest from Insiders	Up to \$7 million
Use of Proceeds	<ul> <li>\$7.5 million for clinical studies and regulatory approvals for BonyPid-1000 &amp; 500 product candidates;</li> <li>\$2.5 million to advance research activities for PLEX and development activities of BonyPid-1000, 500 and D-PLEX product candidates; and</li> <li>\$2 million to establish in-house GMP backup manufacturing facilities and;</li> <li>Remainder for working capital and general corporate purposes</li> </ul>
Underwriters	Aegis Capital Corp. (sole bookrunner) MLV & Co./Chardan Capital Markets, LLC (co-mangers)



## PolyPid snapshot

Established: 2008

PLEX™ Technology: Local drug delivery matrix enabling highly effective and safe treatment for a period of up to several months

**Pipeline:** Focused on the development and commercialization of a multiple solutions for the prevention and treatment of infection

 First products for orthopedic and dental planned to enter pivotal clinical studies during 2015, to be submitted (CE) for clearance during 2016 Employees: 30

**Production:** Scale up GMP capabilities (CMO in Europe)

Patents: Over 35 patent applications submitted globally may provide multiple layers of protection to 2029 and beyond

 Three granted patents; two in the USA, one in China and one allowed in Israel





## PolyPid - unique investment opportunity



Experienced Global Strong IP PLEX™ **Impressive** Scalable Market & Management Technology -Clinical Data -Business Team Strategic based focused Safety & Model with Partnership pipeline performance Attractive Opportunities best-in-class **Economics** products



### Here with you today

#### Amir Weisberg - Chief Executive Officer

Leading PolyPid since 2010, Mr. Weisberg has 20 years of experience as an entrepreneur and CEO of start-up companies with two financial exits. Prior to PolyPid, Mr. Weisberg managed start-up companies in the Life Science sphere, from incubator stage to clinical trials, including leading financing rounds for these companies.

#### Noam Emanuel, Ph.D. - Chief Technology Officer

Dr. Emanuel has vast experience in biotechnology projects, including development of drug delivery systems and immunology. Dr. Emanuel has a number of approved patents in the field of drug delivery and diagnostics. Dr. Emanuel is a co-founder of PolyPid and served as its CEO during the company's first three years. Dr. Emanuel received his Ph.D. degree from the Faculty of Medicine at the Hebrew University of Jerusalem.

#### Dikla Czaczkes Akselbrad CPA, MBA - Chief Strategy Officer

Dikla Czaczkes Akselbrad joined PolyPid in July 2014. Prior to joining PolyPid, she spent over 12 years with Compugen the last 7 years of which as the Chief Financial Officer, where she played a leading role in numerous capital transactions giving raise to over \$130,000,000. Before joining Compugen, Ms. Czaczkes was CFO of Packet Technologies, and before that an audit manager at Ernst & Young Israel. Ms. Czaczkes holds an MBA in finance and a BA in accounting and economics, both from Tel Aviv University, and is a certified public accountant in Israel.

#### Advisory Board

#### Yechezkel Barenholz,

Head of the Laboratory of Membrane and Liposome Research at the Department of Biochemistry of the Hadassah Medical School at the Hebrew University of Jerusalem, co-inventor of Doxil™

#### Ramon Gustilo, MD

Professor of orthopedics at the University of Minnesota

#### Zvi Metzger, DMD

Professor of Endodontology and Associate Professor of Oral Biology at Tel Aviv University

#### Moshe Salai, MD

Head of the orthopedic division of the Tel-Aviv Sourasky Medical Center

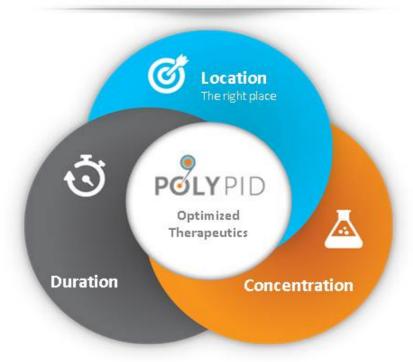
#### David Segal, MD

Former Chairman of, and Professor in the Orthopedic Surgery Department, Hadassah Medical Center



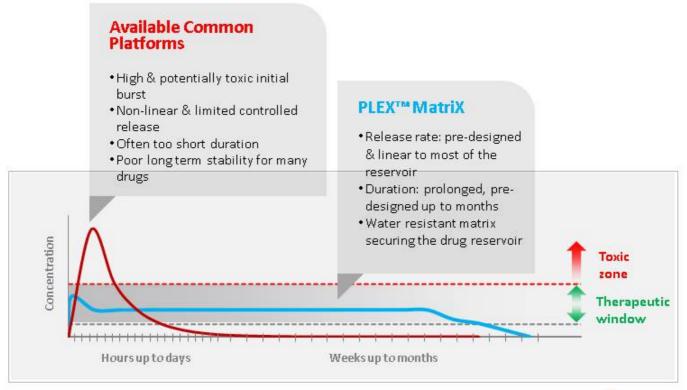
## **Optimized therapeutics for local delivery**

### Overcome systemic limitations



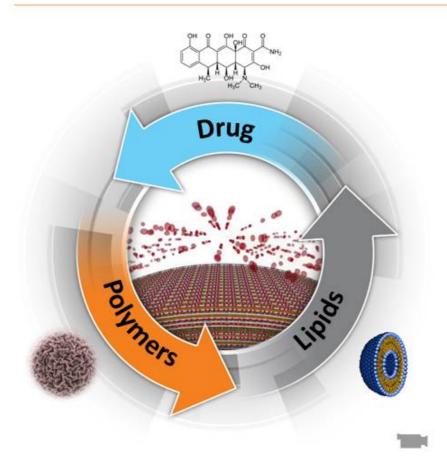


## PLEX™ technology setting new standards





## PLEX™: Polymer Lipid Encapsulation matriX

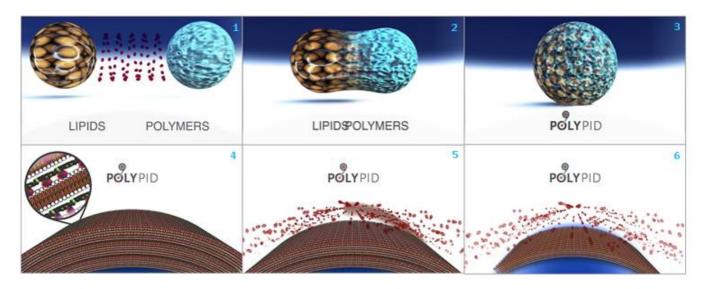


- No covalent bonds between the compounds or with the drug
  - Faster regulatory pathway
  - Commercially available compounds
  - Production under mild conditions





## Core platform technology



On a molecular level, polymers and lipid self-assembled into thousands of alternating layers that encapsulate the drug. Drug captured between the layers released over time by the gradual degradation of the layers





## PLEX™ platform - breadth of drug applications

#### Any size or physical characteristics



Small molecules
Antibiotics<sup>1</sup>

NSAID<sup>3</sup>, Anti-fungal<sup>3</sup>, Steroids<sup>2</sup>



**Peptides** 

Several tested; including anti microbial<sup>2</sup>



**Proteins** 

Antibodies<sup>3</sup> & Growth factors<sup>2</sup>



Nucleic acids based drugs

Plasmid DNA<sup>3</sup> & siRNA<sup>3</sup>

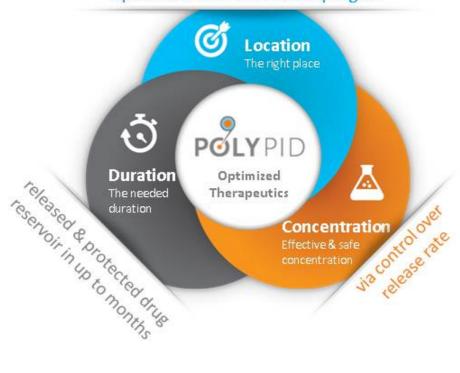
- · Over 20 different drugs types validated: Encapsulation and controlled release
- · Pre-clinical studies several different animal models:
  - Bone growth and recovery proteins, growth factors (BMP2)
  - · Anti-infection small molecules and peptides, bacterial contaminated bones, including resistant bacteria
  - · Anti-inflammation steroids
  - · Anti-cancer siRNA

¹clinical stage | ²in-vivo POC | ³in-vitro POC



## PLEX™ platform - optimized therapeutics for local delivery

## Overcome the limited penetration of systemic treatments into key organs





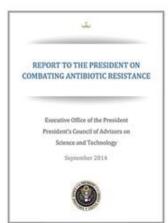


## PLEX™ is best positioned to fight infection



### Significant health economic burden:

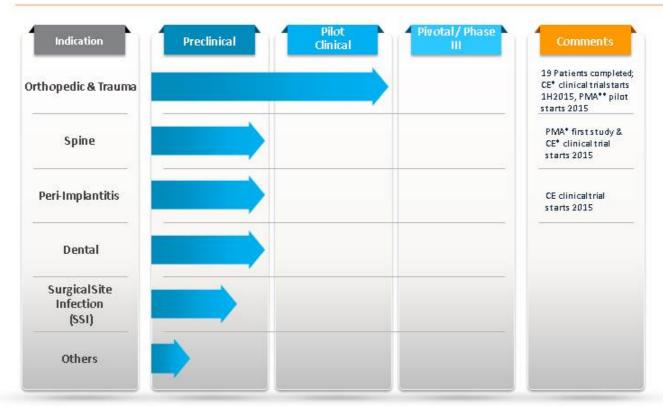
- Up to 15% of patients incur infection while hospitalized in spite of all of the anti bacteria regimes
- · An on-going battle
- . . . and it is getting worse antibiotic resistance



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## **Snapshot: Infection-focused portfolio**



<sup>\*</sup> CE route was confirmed as Medical Device Class III



<sup>\*\*</sup> PMA regulatory route pending FDA official confirmation





BonyPid-1000™ Product Overview



## BonyPid-1000™ answers an unmet need

#### The Need

Supports fast bone recovery

#### But...

Every open fracture is contaminated by bacteria

Many of the open fractures are already infected at the time of initial treatment and the risk of infection continues after surgery

#### **Unmet Need**

Protect bone from bacterial contamination to enable bone recovery

Every orthopedic surgery is prone to infection





# Open fracture: infection & amputation rates correlate with severity of open fractures

Gustilo Grade	1	11	IIIA	IIIB	IIIC
Infection Rate	0-2%	2-7%	10-25%	10-50%	25-50%
Amputation Rate		2.5%	5.6%	50%	







 $Hans-Christoph\,Pape,\,Roy\,Sanders,\,Joseph\,Borrell,\,Jr.\,The\,Poly-Traumatized\,Patient\,with\,Fractures.\,Springer\,Heidelberg,\,2011.\,Page\,309$ 





## **Current local treatment regiment in the USA**

- · Gentamicin loaded PMMA beads
- Short release of effective antibiotics few days
- Require a second operation for removal interfere with bone growth
- May contribute to bacterial Biofilm on top of the beads
- Not yet approved as beads by the FDA



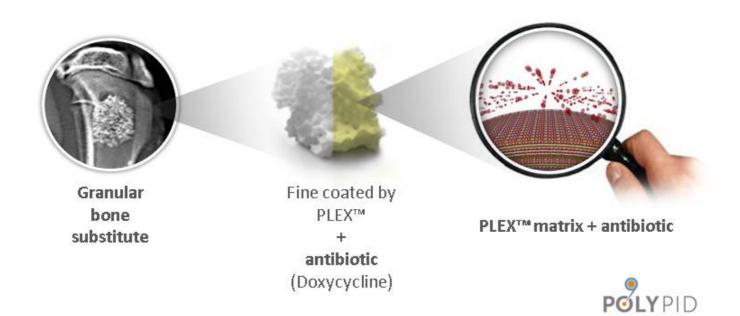






# BonePid-1000™: combining PLEX technology, bone substitute and antibiotics to enable local protection

BonyPid-1000™ coating components are well organized on a molecular level as a fine, sub-structure by self-assembly into PLEX™





## BonyPid-1000™ - Local vs. systemic drug delivery

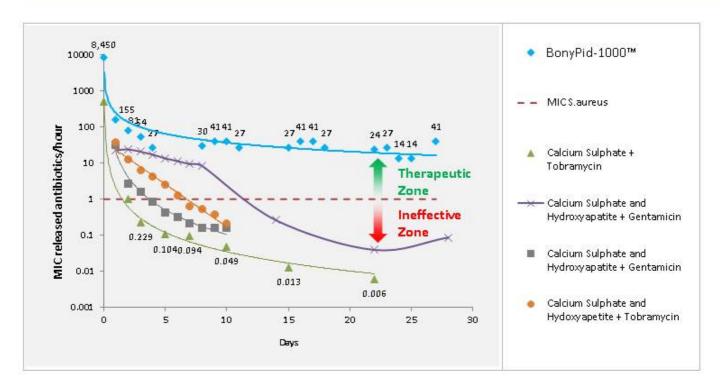
A low, localized 30-day dose is sufficient to achieve a significant therapeutic effect







# BonyPid-1000™ optimizes drug release (and beats competition)\*



<sup>\*</sup>Release measured in several MIC per hour (*in-witro*). Results adapted from competitor-published data MIC= Minimal Inhibitory Concentration. This reflects the lowest drug concentration that prevents bacterial (S.aureus) growth





## BonyPid-1000™ - no change in the method of use



- · Filling and reconstructing bone voids, defects or gaps
- · Implanted during the first surgery
- · Drug is released for 3-4 weeks

Simple use

BonyPid-1000™

Pour

Hydrate & Use

On top of Standard of Care

 BonyPid-1000™ is to be used in conjunction with standard of care in orthopedic surgeries

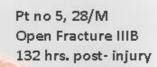


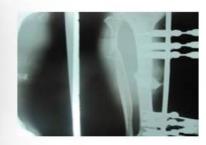
## Example: patient no. 14 - primary closure





# Example: patient no. 5 - Gustilo IIIB soleus flap & skin graft

















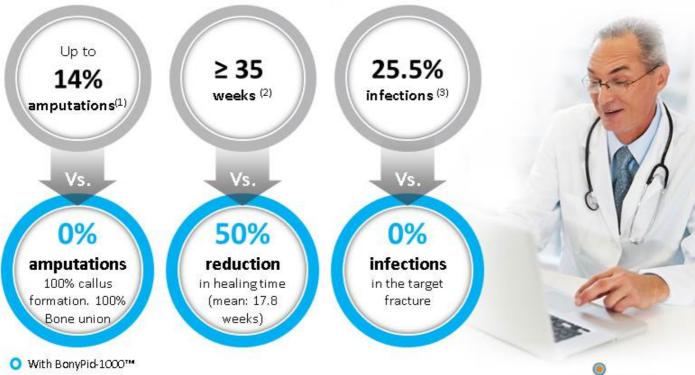






# BonyPid-1000™ clinical trial results summary 19 patients / 6-12 months follow-up

Validated in the most challenging bacteria-contaminated orthopedic indication



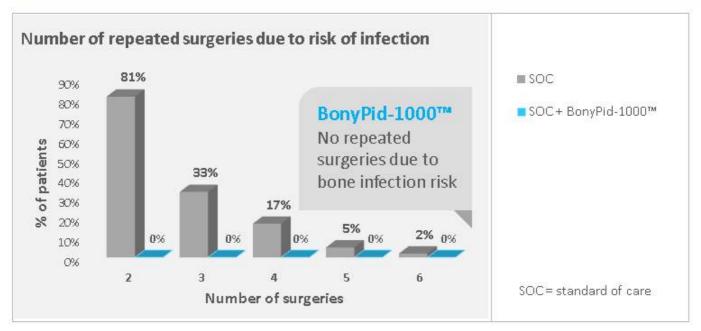
<sup>(1) &</sup>quot;Infection complications of type IIIT ibial fractures among combat casualties" Clin. Infect. Dis. (2007) 45 (4): 409-415 (2) ys. known literature







## BonyPid-1000™ clinical trial results summary - cont.



Improved clinical and patient outcome suggesting significant health economics impact





## Infection-focused portfolio: Next regulatory steps1

Indication	Regulatory Pathway	Clinical TriaF initiation	Pivotal Trial initiation	Clinical summary submission for Marketing Approval
<b>Orthopedic</b> BonyPId-1000™	EU Œ Mark	1H-2015	NA	2016
Spine/Open Fracture BonyPid-1000™	US PMA	2H-2015	H1-2017	2018
Dental US BonyPid-1000™  Peri-implantitis²	EU CE mark	1H-2015	NA	2016
	US PMA	2H-2015	2H-2016	2018
	EU CE Mark	1H-2015	NA	2017

<sup>4</sup> Estimates and dates may deviate due to business, regulatory, clinical, market, financial and manufacturing factors

<sup>2</sup> Mis - development and commercialization collaboration for the Peri-implantitis dental implants market (BonyPid-500™) OPTIMIZED THERAPEUTICS 28

<sup>&</sup>lt;sup>3</sup> Clinical Trial initiation refers to the submission of the files to the MOH



## Infection-focused portfolio: Next regulatory steps cont.

## Safety and performance of BonyPid-1000™ in Gustilo IIIA and IIIB tibial open fractures

**Design**: Prospective, Multinational, Multicenter, Randomized, Two arm, Open Label, Standard of Care Controlled, Blinded central reading center study

#### **Study Objectives:**

- a. To assess the safety of BonyPid-1000™ implantation
- b. To assess the performance of BonyPid-1000™ when implanted in severe open tibial bone fractures

**Planned sample size**: 64 subjects, 32 per group, planned to achieve at least 30 evaluable subjects per group

Follow up: 6 months





# PLEX™ - doxycycline antibacterial agents: Value proposition addresses significant market needs



### Orthopedic

## Trauma, spine, joint replacement

Fast route to EU market followed by spine indication for US

~2.7 million orthopedic surgical procedures annually in the US

#### Dental

### Sinus lifts, ridge augmentation, peri-implantitis

Fast dental route to EU market followed by FDA route

~3.9 million relevant dental applications annually in the US

### Surgical Site Infections

Huge prevention and treatment markets

Over 30 million relevant surgeries annually in the US



## **Collaboration strategy**

### **R&D** and licensing

License proprietary
PLEX™ technology
to biopharmaceutical
companies, enabling
them to encapsulate
their therapeutic
agents under upfront,
milestone and royaltybearing agreements



Market and distribute our products independently in target markets.

Engage partners to commercialize our pipeline in other geographic regions





## **Capitalization table**

0/31/2014	Shares Outstanding
referred Shares*	6,461,962
Ordinary shares	967,742
arrants on Preferred Shares*	114,530
nployees stock Options	1,505,376
ully diluted total	9,049,610







## PolyPid - unique investment opportunity



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Thank you www.PolyPid.com