PYPD Earnings Call Transcript

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Operator: Greetings, and welcome to PolyPid Ltd.'s Third Quarter 2025 Conference Call. At this time, participants are in a listen-only mode. As a reminder, this call is recorded. I would now like to introduce your host for today's conference, Yehuda Leibler from ARX Investor Relations. Mr. Leibler, you may begin.
Yehuda Leibler: Thank you all for participating in PolyPid Ltd.'s third quarter 2025 earnings conference call. Joining me on the call today will be Dikla Czaczkes Akselbrad, Chief Executive Officer of PolyPid Ltd., Jonny Missulawin, PolyPid Ltd.'s Chief Financial Officer, and Ori Warshavsky, Chief Operating Officer US of PolyPid Ltd. Earlier today, PolyPid Ltd. released its financial results for the three months ended September 30, 2025. A copy of the press release is available in the Investors section on the company's website at www.polypid.com. I would like to remind you that on this call, management will make forward-looking statements within the meaning of the federal securities laws. For example, management is making forward-looking statements when it discusses anticipated timing of the pre-new drug application or NDA meeting of the US Food and Drug Administration or FDA, the planned NDA submission, DPLEX 100, the expected submission of the European marketing authorization application, the potential regulatory and commercial pathways for DPLEX 100, including leveraging its fast track and breakthrough therapy designations, the company's ongoing partnership discussions, market adoption, reimbursement assumptions, company's commercial manufacturing readiness, US market access study, utilization of DPLEX 100, regulatory inspection readiness, and the expected cash runway to fund operations well into 2026. Forward-looking statements are subject to numerous risks and uncertainties, many of which are beyond the company's control, including the risks described from time to time in its SEC filings. The company's results may differ materially from those projections. These statements involve material risks and uncertainties that could cause actual results or events to materially differ. Accordingly, you should not place undue reliance on these statements. I encourage you to review the company's filings with the SEC, including, without limitation, the company's annual report on Form 20-F, filed on February 26, 2025, which identifies specific factors that may cause actual results or events to differ materially from those described in the forward-looking statements. PolyPid Ltd. disclaims any intention or obligation, except as required by law, to update or revise any financial projection or forward-looking statements, whether because of new information, future events, or otherwise. This conference call contains time-sensitive information and speaks only as of the live broadcast today, November 12, 2025. With the completion of those remarks, it is my pleasure to turn the call over to Dikla Czaczkes Akselbrad, CEO of PolyPid Ltd. Dikla?
Dikla Czaczkes Akselbrad: Thank you, Yehuda. On behalf of our team at PolyPid Ltd., I would like to welcome everyone to our third quarter 2025 earnings conference call. The past quarter was significant for PolyPid Ltd. as we progress with our objective to bring DPLEX 100, our late-stage product candidate for the prevention of surgical site infection, to the market. We are pleased to report that our pre-NDA meeting with the FDA is scheduled for early December and is expected to be held as an in-person meeting at the FDA office. This important meeting is designed to align with the agency on the data package format and requirements for our NDA submission, representing a key milestone. We remain on track to submit the NDA for DPLEX 100 in early 2026, leveraging both our Fast Track and Breakthrough Therapy designations. In parallel, we are preparing for submission of the European

Marketing Authorization Application, which is expected to follow the NDA. During the quarter, we successfully completed the Israeli Ministry of Health Good Manufacturing Practice (GMP) inspection, marking our fourth consecutive successful inspection and an important step forward in achieving commercial readiness for DPLEX 100. The successful completion of this inspection ensures we can manufacture commercial product for the European market once DPLEX 100 is approved in Europe, as well as serve as a real-life test of our readiness for an FDA inspection of our facility, which we expect will follow the NDA submission. We continue to advance our strategic discussions with potential US partners with an established hospital sales infrastructure, building also on the strong momentum of our positive Phase III trial results. And now, in the second quarter, this discussion has progressed during the third quarter. We also recently completed a new US market study based on the presentation of the SHIELD II results. The study provided important validation of DPLEX 100's commercial potential. The results were very encouraging, confirming strong interest from both surgeons and hospital pharmacy directors. Taken together, the third quarter marked continued progress across all fronts: regulatory, commercial, and manufacturing. As we move steadily towards the next phase of positive growth pipeline, including our innovative in oncology, obesity, and diabetes. With that, I will now turn the call over to Ori Warshavsky, our Chief Operating Officer, US, who will provide additional insights on the market access study findings and our commercial readiness efforts.

Ori Warshavsky: Thank you, Dikla. As Dikla noted, this quarter was pivotal in strengthening our commercial readiness for DPLEX 100. The completion of the GMP inspection and our ongoing work with hospital stakeholders brings us closer to launch readiness. Last month, our medical team participated and presented data in two major US medical conferences: the 2025 American College of Surgeons Clinical Congress, which gathers surgeons from multiple disciplines across the US and internationally, and IDWeek, the key annual conference for infectious disease specialists. The response from both surgeons and infectious disease specialists was remarkably consistent. Both groups expressed the need for innovation and new tools to prevent SSI and were impressed by the SHIELD II trial design and the 58% reduction in surgical site infection demonstrated by DPLEX 100. As Dikla mentioned, we also recently completed a new US market access study that included both surgeons and hospital pharmacy directors from leading academic and community hospitals who are contributing members or heads of the pharmacy and therapeutic committee, also known as the P&T; Committee, review process at their respective hospitals. The results were very encouraging and in line with our expectations in terms of both clinical perception and commercial potential. I would like to share a few key highlights from the study. Among surgeons, DPLEX 100 was viewed as more valuable than currently available SSI prevention measures, primarily due to its strong efficacy, safety profile, and ease of use in the operating room. Most surgeons indicated that their hospitals are likely to add DPLEX 100 to formulary at launch, with 80% saying they are extremely likely to use it for their next eligible patients once available, and an average expected utilization of approximately six out of every ten eligible cases, particularly for high-risk patients undergoing colorectal or abdominal surgeries or those with comorbidities like obesity or diabetes. Hospital pharmacy directors echoed this enthusiasm. Based on the clinical profile, 70% reported a high likelihood to add and stock DPLEX 100. When asked if a new technology add-on payment or NTAP designation, which provides extra reimbursement to hospitals, would change their response, pharmacy directors anticipated that the formulary coverage would be even higher, and the overall hospital adoption outlook would look even more favorable. DPLEX 100 was widely seen as a promising new SSI prevention agent addressing a significant unmet need. Altogether, we believe these results are a significant vote of confidence and tangible support for both the clinical and economic potential of DPLEX 100. With that, I will now turn the call over to Jonny Missulawin, our Chief Financial Officer, to review our financial performance.

Jonny Missulawin: Thank you, Ori. Turning to our financial results for the third quarter of 2025, research and development expenses totaled $5.3 million, down from $6.2 million in the third quarter of 2024 and $6 million in the same quarter last year. This decrease reflects the completion of the SHIELD II Phase III trial. General and administrative expenses came in at $1.8 million compared to $1.2 million in the third quarter of 2024, while marketing and business development expenses were $400,000, up from $200,000 in the same period last year. The net loss for the quarter was $7.5 million or $0.37 per share, an improvement from the net loss of $7.8 million or $1.22 per share in 2024. Looking at the nine months

ended September 30, 2025, R&D; expenses totaled $17.6 million compared to $15.8 million in the prior year period. G&A; expenses increased to $5.4 million from $3.3 million last year, and marketing and business development expenses rose to $1.4 million from $700,000 last year. The increase in G&A; and marketing and business development expenses were primarily due to non-cash expenses related to performance-based options or PSUs, following the successful SHIELD II Phase III trial, which triggered the vesting of the PSUs. Net loss for the nine-month period was $25.7 million or $1.72 per share, compared to $20.5 million or $3.82 per share for the same period in 2024. From a balance sheet perspective, as of September 30, 2025, PolyPid Ltd. had $18.8 million in cash, cash equivalents, and short-term deposits, up from $15.6 million at year-end 2024. We continue to expect that our current cash balance will fund operations well into 2026. Notably, during the quarter, we made significant progress reducing our debt by decreasing current maturities from $6.5 million to $2.4 million. We remain focused on maintaining financial discipline while advancing our key strategic initiatives towards NDA submission and commercial readiness. With that, we will now open the call to your questions. Operator?

Operator: Thank you. If you wish to ask a question, you need to press 11 on your telephone and wait for your name to be announced. To withdraw your question, please press 11. We will take our first question. Your first question comes from the line of Chase Knickerbocker from Craig Hallum. Please go ahead. Your line is open.

Chase Knickerbocker: Good morning. Thanks for taking the questions. Maybe just first on the Israeli Ministry of Health's successful inspection. Could you maybe just walk us through any findings that you did see there? And I would just like to know, kind of to get your thoughts on your general confidence heading into that likely FDA inspection next year, now that you have had multiple successful inspections from several regulatory bodies. I mean, just kind of walk us through your confidence in any additional items that you do need to address before the FDA inspection or anything else that they would look for that would not be a part of these prior inspections.

Dikla Czaczkes Akselbrad: Good morning, Chase. Thank you. So, yes, we have passed this Ministry of Health inspection. Actually, this was the fourth consecutive inspection that we had. The Israeli Ministry of Health is recognized by the European authorities, so this also serves as commercial validation for the European authorities. And once we get the approval, we can start selling. As in every GMP inspection, obviously, there are always comments and things that are suggested for improvement. This has been and is an ongoing focus of ours to always improve our facility, always improve our QC laboratory, and the way that we are managing this process. There was not anything specific that I can point out that we got a comment on in a specific area. It was an ongoing discussion. Nothing that is critical, obviously, otherwise, we would not have passed. But we are very confident in our ability to pass. We have people here with overall years of experience working in GMP facilities in aseptic facilities, but, you know, to be honest, having confidence in this aspect. And from that, there is a list of things that the team is working on to make sure that we pass this at first. And this is a real important effort for us. So we are highly confident, but, you know, this is an ongoing effort. We have to maintain this high standard all along, not just for the inspection, but also afterwards for the actual commercial manufacturing.

Chase Knickerbocker: Got it. Helpful. Thanks. Maybe just ahead of that FDA, the pre-NDA meeting in December. Any specific items that you can call out that are particularly crucial to reach alignment with the agency ahead of the NDA filing that you would call out for investors?

Dikla Czaczkes Akselbrad: So we expect to review the data package, the submission format, the label, and our goal is to get agreement with the current clinical CMC data support NDA filing and clarity on any remaining requests before the rolling submission. A successful meeting will set the stage for an early 2026 submission, obviously, with priority review potential and their designation. So there is nothing specific, just the regular clearance that you would want to get from the FDA for an NDA.

Chase Knickerbocker: Got it. And then just last for me. Now that you have been able to do quite a bit more survey work and speak with relevant stakeholders in the market, any additional thoughts on pricing as we look forward?

Ori Warshavsky: Yeah, I can take that one. So we have done over the last month or so, we had quite a lot of touchpoints with stakeholders both formally through market research and less formally in the conferences, and really across the board, very strong interest in the product. From the point of view that

there is a need, there is a need for innovation, there is a need for something new to reduce the infection rates from where they are. We tested, I mentioned before, we tested both the willingness to prescribe, the willingness to put the product on formulary, whether it is on formulary and stocked or not stocked, and the impact on NTAP. And across the board, it sounds like premium pricing is something that we can reach. I do not want to give specific numbers because we are in discussion with partners, and this is all part of the activities that are ongoing on the partnership front. But from the prices that we tested before and we have seen, we see now that we can stretch that even higher. There is room and willingness to use this. There is a very strong understanding of the impact of SSI, what it does from just the direct cost of length of stay, but also I heard recently of surgeons that have in their annual review and in the kind of bonus payment, in fact, is or reduction in infection is part of it. So there is really a nice driver there, which will allow us to stretch higher the pricing piece.

Chase Knickerbocker: Got it. Thank you.

Dikla Czaczkes Akselbrad: Thank you, Chase.

Operator: Thank you. We will take our next question. Your next question comes from the line of Brandon Folkes from H.C. Wainwright. Please go ahead. Your line is open.

Brandon Folkes: Hi. Thanks for taking my questions and congrats on the progress. Maybe just sort of at a high level, post the partnership, how quickly do you expect to grow the PolyPid Ltd. pipeline? With you manufacturing DPLEX, can you just help us think through the evolution of PolyPid Ltd. in 2026 and 2027 through being a manufacturing partner, but then also redeploying capital into the pipeline going forward? And maybe just one more from me. In terms of the FDA filing in early 2026, anything that you need or any sort of answers coming out of that pre-NDA meeting that could extend that timeline? Just sort of how are you feeling about that meeting and sort of anything that may come out of that versus that guidance. Thank you.

Dikla Czaczkes Akselbrad: Thank you, Brandon. So I will start with your second question. In terms of our readiness for submission and where we stand, all the modules are ready for submission. The CMC and the nonclinical module are finalized, and the clinical module is being completed. We will incorporate, obviously, any FDA feedback after the December meeting and then start the rolling submission early 2026. We do not expect anything in particular. I can tell you that in the last year or so, we had a handful of correspondence with the FDA on specific aspects that we wanted to clear, specific that we wanted to make sure that we are on the right path. But, obviously, having the meeting early December and us wanting to submit in early 2026, there will be some things that will need to be incorporated based on the feedback and the meeting, but we do not expect this to be substantial. We will obviously update once we get the FDA minutes on the actual meeting, whatever we can update at this point. But there is nothing that we expect on that. As to your question on I would even broaden it a little bit, our vision for PolyPid Ltd. and our vision for the DPLEX platform. The way we see it, obviously, a US partner on the abdominal indication is very important. But our platform and our SHIELD II is a validation to our approach and to our ability to bring product in that format. We have our younger program, which will need to accelerate on this, and we have already been working on them, whether it is in the oncology space or in the obesity, diabetes space, but we also see DPLEX growing farther behind the abdominal indication. And that is also something that is a potential growth.

Operator: Thank you. Once again, if you wish to ask a question, please press 1. We will take our next question. Your next question comes from the line of Bupalan Pachaiyappan from ROTH Capital. Please go ahead. Your line is open.

Bupalan Pachaiyappan: Good morning, everyone, and thanks for taking our questions. So firstly, with respect to market research, you guys just described, it is pretty exciting. And I just need some additional thoughts on that. So firstly, can you talk to us about the sample size of your market research study? And then in that, specifically, the percentage of those who participated in the research, they were involved in the decision-making process. And within that market research question, I also wanted to know whether you had an option to sort of assess the preliminary thoughts on utilizing DPLEX 100 in the gynecology and urology area. Can you hear me?

Ori Warshavsky: Yes, we can hear you. Go ahead, Bupalan.

Bupalan Pachaiyappan: Yeah. And then what pricing point would make them comfortable to utilize DPLEX 100 in the US formulary? That is the first question.

Ori Warshavsky: Yeah. So all good questions. So in terms of the study itself, first, it is a qualitative study. The study was split into two. There were 10 surgeons, general surgeons, colorectal and gynecology surgeons. That is one. And then there were 10 pharmacy directors, both from standalone hospitals and network hospitals. Everyone who participated in this study was either running the P&T; process or a contributing member to the process. So that was by design. The purpose of the study was to have people who are on a formulary. And then you were asking about the second part again. I lost my thought.

Dikla Czaczkes Akselbrad: Maybe before that, I would just add, Bupalan, that this is not our first market access study. We have done several in the past, and besides for the pricing that we saw a higher price in this and a premium in reference to the NTAP, all were much in line. Now it is very detailed. It is actually we use the actual data that we saw in SHIELD II. Obviously, everything is blinded. They did not know the actual product, but it was very detailed in terms of referring to the specific product and the specific result that we had in SHIELD II.

Bupalan Pachaiyappan: Alright. That is very helpful. And then second, I understand you are advancing your partnership discussions in the US. And this may be some sort of hypothetical questions or sort of I am just thinking out loud. So I wanted to know, let us just say there is a global firm that wanted to commercialize DPLEX 100 in the US as well as in the Ex-US regions. And, obviously, on existing arrangement with Advance Pharma, so I wanted to know if this existing arrangement would, in any way, provide some sort of barriers or impediments to forge a partnership with a global player? And will there be any sort of, like, a buyback clause with the Advance Pharma agreement?

Dikla Czaczkes Akselbrad: So, no, there is nothing in the Advance agreement. Advance is our exclusive partner for Europe, but nothing out of that is part of this arrangement. US, Canada, all the rest of the world, it is not covered by this arrangement. If one of the partners, if it is a global partner, they would want to include Europe as part of the discussion. We will need to see if this is feasible. But it is not something that we plan on pursuing at this stage.

Bupalan Pachaiyappan: Alright. Great. And one final question from us. Obviously, DPLEX 100 will be manufactured in Israel. And as you are well aware, there is a push within the US for domestic manufacturing. And, also, its connection with most favored nation pricing. So maybe can you talk to us about potential challenges or barriers that PolyPid Ltd. needs to overcome to commercialize DPLEX 100 in the US? Thank you.

Dikla Czaczkes Akselbrad: So, yeah, first, I should mention that our current facility, and we have indicated this along the years, is not our end goal facility. It will not be sufficient for the peak sales. This facility is built in a way that it should be sufficient for the first five years of commercial launch. And we have already started planning and evaluating what should be our next facility or expanded facility, and we are taking into consideration. So the trend in the US around local manufacturing is something that we are taking into consideration. We are thinking about the expansion of the facility.

Bupalan Pachaiyappan: Alright. Congratulations again. Thanks for your time.

Operator: Thank you. There seems to be no further questions. I will now hand back to Dikla for closing remarks.

Dikla Czaczkes Akselbrad: Thank you for joining PolyPid Ltd.'s third quarter 2025 Earnings Conference Call. This has been a highly productive period as we execute on our regulatory strategy and move closer to our goal of bringing DPLEX 100 to patients and clinicians worldwide. With our pre-NDA meeting scheduled for early December, and our NDA submission on track for early 2026, we are confident in our path forward. At the same time, we are making important progress in partnership discussions and commercial partnerships while advancing our manufacturing readiness to support a successful launch upon approval. We look forward to sharing further updates on our regulatory and commercial milestones in the months ahead. As always, we thank our team members, partners, and shareholders for their ongoing support and commitment to our mission. Operator, you may now close the call.

Operator: This concludes today's conference call. Thank you for participating. You may now disconnect.