PYPD Earnings Call Transcript

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Quarter: 2

Operator: Greetings, and welcome to PolyPid's Second Quarter 2025 Conference Call. [Operator Instructions] As a reminder, this call is recorded. And I would now like to introduce your host for today's conference, Yehuda Leibler from ARX Capital Markets. Mr. Leibler, you may begin.
Yehuda Leibler: Thank you all for participating in PolyPid's Second Quarter 2025 Earnings Conference Call. Joining me on the call today will be Dikla Czaczkes Akselbrad, Chief Executive Officer of PolyPid; Jonny Missulawin, PolyPid's Chief Financial Officer; and Ori Warshavsky, Chief Operating Officer, U.S. of PolyPid. Earlier today, PolyPid released its financial results for the 3 months ended June 30, 2025. A copy of the press release is available in the Investors section on the company's website available at www.polypid.com. I'd like to remind you that on this call, management will make forward-looking statements within the meaning of the federal securities law. For example, management is making forward- looking statements when it discusses D-PLEX100's potential benefits, including its potential to address a significant unmet medical need and to substantially reduce the burden of surgical site infections, improve patient outcomes and generate meaningful health care cost savings, the expected regulatory submissions and their timing, the aim of GLP-1 program and its potential to address significant unmet medical needs in the treatment of metabolic diseases, the company's expected cash runway and the potential partnership opportunities for D-PLEX100. 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 these 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 its 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 disclaims any intention or obligation, except as required by law, to update or revise any financial projections 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, August 13, 2025. With the completion of those prepared remarks, it is my pleasure to turn the call over to Dikla Czaczkes Akselbrad, CEO of PolyPid. Dikla?
Dikla Czaczkes Akselbrad: Thank you, Yehuda. On behalf of our team at PolyPid, I would like to welcome everyone to our second quarter 2025 earnings conference call. The second quarter of 2025 was truly transformational for PolyPid, marked by the successful results of our SHIELD II Phase III trial, which demonstrated significant clinical benefits of D-PLEX100 in preventing surgical site infections, or SSI, in abdominal colorectal surgeries. As announced in June 2025, the study showed a statistically significant reduction of 38% with a p- value below 0.005 in the primary endpoint, which, as a reminder, is the combination of deep and superficial SSI, all-cause mortality and surgical reintervention. In addition, we demonstrated a robust 58% reduction in the rate of surgical site infections in patients treated with D-PLEX100 versus standard of care with a p-value below 0.005, including a significant reduction in deep surgical site infection with 5 cases of deep SSIs representing approximately 14% out of all SSIs in the standard of care arm versus 0 in D-PLEX100 arm with a p-value below 0.05. Importantly, we also saw in the study a clear and statistically significant 62% reduction of patients with

an ASEPSIS score over 20. The ASEPSIS score reflects the severity of the wound infection appearance and the clinical consequences of the infection. So D- PLEX100 not only markedly decreased the rate of superficial and deep SSIs, but even when SSIs occurred in the D-PLEX100 arm, they were less severe and caused less medical burden such as prolonged hospitalization or use of IV antibiotics. This robust result validated our conviction in D-PLEX100 potential to address a significant unmet medical need and have generated substantial interest from potential commercial partners. We are extremely encouraged by the enthusiastic reception from health care professionals, lead surgeons in different types of surgeries as well as thought leaders in the field of surgical site infections, all recognize D-PLEX100 potential to substantially reduce the burden of surgical site infections, improve patient outcomes and generate meaningful health care cost savings. In addition, further analysis of the Phase III SHIELD II trial safety data revealed a good safety profile with no difference in serious treatment-emergent adverse events between patients treated with D-PLEX100 versus standard of care. This safety profile further supports the D-PLEX100 potential as a well-tolerated prophylactic treatment option for patients undergoing major abdominal surgeries. Following the positive Phase III data, we are on track with our new drug application or NDA preparation. Our next steps include a pre-NDA meeting with the FDA planned by the end of this year, leveraging our Fast Track and Breakthrough Therapy designations to facilitate regulatory review. We anticipate submitting the NDA to the FDA in early 2026 and marketing authorization application or MAA submission in Europe shortly thereafter. Shifting gears, we recently made significant progress on our GLP-1 program, which leverages the company's extensive long-term experience. This initiative aims to deliver approximately 60 days no-burst GLP-1 receptor agonist peptide for improved patient compliance and enhanced therapeutic outcomes in the rapidly growing weight loss and diabetes market. We have formally unveiled this program early in the current quarter, and we believe it represents an exciting opportunity to expand our therapeutic footprint into the fast-growing metabolic disease market. Following the end of the quarter, yesterday, we announced the appointment of Dr. Nurit Tweezer-Zaks, M.D., M.B.A., as Chief Medical Officer of the company, transitioning from her role on PolyPid's Board of Directors. Dr. Tweezer-Zaks brings extensive medical R&D; and business development expertise to this executive position, strengthening the company's leadership team as it advances towards NDA submission and commercial preparations following the positive Phase III SHIELD II results. From a financial perspective, we have significantly strengthened our balance sheet through a successful warrant exercise inducement transaction, extending our cash runway well into 2026. With that, I will now turn the call over to Ori, our COO in U.S., to provide more details on our commercial preparations and partnering efforts for D-PLEX100. Ori?

Ori Warshavsky: Thank you, Dikla. Following the successful completion of the Phase III SHIELD II trial positive efficacy data, we have intensified our commercial preparation activities in partnership discussions. We believe that the positive Phase III results have validated the substantial market opportunity for D-PLEX100. To reiterate, based on our [indiscernible] data, we believe the total addressable market for D-PLEX100 in the U.S. is just over 12 million total surgeries annually, with approximately 4.4 million of those being abdominal surgeries and an additional 2.1 million abdominal procedures, principally in gynecology and urology. The 58% reduction in SSI demonstrated in our Phase III trial is particularly significant when considering the substantial costs associated with SSI. As a reminder, SSIs are estimated to U.S. health care system up to $10 billion annually, extend hospital length of stay by 9.7 days on average and increase hospitalization by more than $20,000 per patient admission. D-PLEX100's potential ability to significantly reduce these infection rates represents a compelling value proposition for health care systems, payers and most importantly, for patients. With respect to our partnership strategy, we continue to believe that identifying a U.S. partner with a dedicated hospital-focused sales force and significant resources will enable D-PLEX100 to maximize sales potential in the U.S. Following the positive Phase III data announcement, we have seen increased interest from potential partners, and we are currently evaluating opportunities. We will, of course, provide updates on these discussions as appropriate. For the European market, as we mentioned previously, we already have an exclusive licensing agreement in place with Advance Pharma to commercialize D-PLEX100 across European countries. And we are actively working together to plan and implement prelaunch activities to maximize D-PLEX100 and anticipated launch in

Europe. And with that, I will now turn the call over to our CFO, Jonny, to review our financial results. Jonny?

Jonny Missulawin: Thank you, Ori. We are pleased to report our financial results for the second quarter of 2025, which reflects our continued investments in advancing our pipeline while maintaining fiscal discipline. Starting with our balance sheet. As of June 30, 2025, the company had cash and cash equivalents of $17.4 million and short-term deposits of $12 million for a total of $29.5 million. This represents a significant improvement from our cash position of $15.6 million as of December 31, 2024. The increase was primarily driven by the successful warrant exercise inducement transaction that Dikla mentioned earlier. We expect that our current cash balance will be sufficient to fund operations well into 2026. Now turning to our income statement for the 3 months ended June 30, 2025. Research and development expenses were $6.2 million, compared to $4.8 million in the same period of 2024. The increase was primarily due to activities related to the completion of the SHIELD II Phase III trial and preparation for regulatory submissions. General and administrative expenses were $2.5 million, compared to $1.1 million for the same period of 2024. The increase was primarily due to noncash expenses related to performance- based options or PSUs, following the successful SHIELD II Phase III trial, which triggered the vesting of the PSUs. Marketing and business development expenses were $0.7 million, compared to $0.3 million for the same period of 2024. For the second quarter of 2025, the company had a net loss of $10 million or $0.78 per share, compared to a net loss of $6.3 million or $1.25 per share in the second quarter of 2024. For the 6 months ended June 30, 2025, R&D; expenses were $12.3 million, compared to $9.8 million for the same 6-month period of 2024. G&A; expenses were $3.7 million, compared to $2.1 million for the same period of 2024. Marketing and business development expenses were $1 million, compared to $0.5 million for the same period of 2024. The company had a net loss of $18.2 million or $1.48 per share, compared to a net loss of $12.7 million or $2.62 per share in the 6-month period ended June 30, 2024. With that, we will now open the call to your questions. Operator?

Operator: [Operator Instructions] The first question comes from the line of Chase Knickerbocker from Craig-Hallum.

Chase Richard Knickerbocker: Maybe just on the NDA filing. So if I think about what is kind of left to be done between now and 1Q, can you kind of walk us through the larger items? And then particularly, obviously, on the CMC side, can you talk about your preparations as they continue to progress on products, et cetera, preparing for that 1Q filing?

Dikla Czaczkes Akselbrad: Sure. We are in the finalization stages of the CMC and the clinical module. So those will be the first that we will submit. There are some points that are still being collected. And obviously, the preparation and the finalization of the document is taking time. Documents have already been reviewed by our external FDA consultants as a first [indiscernible]. And we are now preparing, first of all, the CSR and all the package for pre-NDA meeting, meaning that we would like to meet with the FDA before the end of this year for pre-NDA meeting -- agreement while we are prior to submitting the NDA and then early 2026 in the first quarter to submit the NDA. In parallel to that, obviously, we are in preparation for the [indiscernible] review. This is something that is ongoing. The facility has been reviewed a couple of times already, both by the Israeli Ministry of Health and European QP. But still there is always room to prepare further for an FDA review and get the facility ready for the commercialization stage. So to summarize, we will be submitting in the next few weeks a pre-NDA meeting request, which we expect during the year and early next year, Q1, we will submit the NDA.

Chase Richard Knickerbocker: Got it. Maybe just one on -- can you talk about kind of the path forward for the GLP-1 program as far as when we might see some data there and kind of early stage plans in that program? And then just second, last for me. If we think about the Advance partnership, when should we expect some potential milestones from that post data? Is that going to be regulatory? Or will there be anything that triggers from the data itself from the Phase III?

Dikla Czaczkes Akselbrad: Sure. So the GLP-1 is a program that we're very excited, both because of the broader consequences of it of having [indiscernible] injected in a form that support an average of 50 or about 60 days of content and linear, but also this being a field with so much unmet need and patients that still do not benefit from the current and [indiscernible] being quite harsh on this medication. So what we think is our main benefit from both the prolonged, both the aspect that we can have relatively

longer than without the drug and also the aspect of avoiding the [indiscernible] characterizing current regimen to treatment. In terms of the time line, we are now going into more robust preclinical studies where what we would like to show is both [indiscernible] to support the risk profile that we see in cell in PK studies in bloodstream. This is also, I think, very important for potential partners. And at this stage, we see this program semaglutide started with the GLP-1, but this could be extended being pursued into the clinic collaboration with one of the large player in this field.
Chase Richard Knickerbocker: And then just on the Advance partnership...
Ori Warshavsky: I just wanted to some [indiscernible] as we're getting some messages that the line is not great. So please tell us if [Technical Difficulty].
Dikla Czaczkes Akselbrad: So regarding the partnership, we are in active and -- the partnership is active and continuous both through the clinical stage as well as now in preparation for the submission as part of the relationship with Advance [Technical Difficulty] submission. And the question was where should we expect [Technical Difficulty]. Definitely, there is a milestone that is expected as more than 3 years have passed since we've signed with Advance, both Advance and [Technical Difficulty] there are some adjustments that needs to be assessed, and this is what we are doing now. I don't expect it to take too long. And once there is anything to announce around that we will obviously announce. But as I said before, we are very pleased with the relationship. I think there is a trust that has been built during the years and appreciation and Advance is now starting to put more effort into the prelaunch activities. So both parties have an interest to finalize this.
Operator: Your next question comes from the line of Roy Buchanan from Citizens.
Douglas Royal Buchanan: Okay. Great. I'm not sure if she's on the call, but I had a couple for Dr. Tweezer-Zaks. So...
Dikla Czaczkes Akselbrad: Could you repeat the question?
Douglas Royal Buchanan: Yes, I'll try to repeat it. So if Dr. Tweezer-Zaks is on, I was going to ask, I guess, the most compelling reason for joining the company as Chief Medical Officer, D-PLEX100 or the broader PLEX platform, if you could just comment on that? And then what she's going to focus on, I guess, most intently for the next 12 to 24 months?
Dikla Czaczkes Akselbrad: Sure. So I think this is a really nice addition to our management team. And it's nice because Dr. Tweezer-Zaks was on our Board for almost 2 years. So she knows [indiscernible] intimately. She knows the programs intimately. She knows the good and the bad and everything. And obviously, she [Technical Difficulty] other positions, but she decided to join us, and we're very pleased, and I think she is going to be a great addition to the team. With regards to how we view the CMO position and what is going to be the role going forward, specifically looking at the coming 2 years or so. We are now in a position, we started to do some prelaunch activities, some pre-commercialization activities as well as all the regulatory aspect. We have a great Phase III data that we want to have it all in front of as much surgeons as possible. Data obviously, we'd like to put it in the best review journal [Technical Difficulty] the preparation and maintain a robust clinical advisory to support broadening label as well as post-launch activities. We have a pipeline, which is another point that we would like assistance in directing our team and will allow another doctors and quite the experience that she has to lead this program.
Douglas Royal Buchanan: [Technical Difficulty] getting feedback. Heading into the likely approval and launch next year, undoubtedly, you'd like to bolster the balance sheet further. I guess do you just have a preferred -- and maybe you answered this with Advance response, but do you have a preferred way to do that nondilutive via partnering or something else? Can you just comment on that?
Dikla Czaczkes Akselbrad: [Technical Difficulty] we'll get. What was the second portion of the question?
Douglas Royal Buchanan: If you had a preferred way for bolstering the balance sheet beyond that for the launch and all of those extensive things.
Dikla Czaczkes Akselbrad: So as we said for quite some time, we are also looking to collaborate around that. So a portion, obviously, of the effort will be financed and taken by our partner. And in terms of other activities, again, we do rely on payments that we expect will be coming both from our existing partners as well as new partners.
Operator: Apologies. We do seem to be having technical issues. If I could hand back for closing remarks.

Dikla Czaczkes Akselbrad: Truly apologizing for that. Thank you for joining PolyPid's Second Quarter 2025 Earnings Conference Call. The second quarter of 2025 was a pivotal period for PolyPid. The positive SHIELD II Phase III results represent a significant milestone in our journey to begin D-PLEX -- to bring D-PLEX100 to market. We are now focused on preparing our regulatory submissions, advancing our commercial preparations and exploring partnership opportunities to maximize the value of D-PLEX100. We are also excited about the progress we have made in extending our pipeline with the GLP-1 program, which leverages our extensive long-term experience to address significant unmet need in the treatment of metabolic disease. As always, we are grateful to our team members, shareholders and all external partners for their commitment to our mission. We look forward to speaking with you again on our next conference call. And if anyone wants to further ask questions that were not asked on the call, please reach out to us.

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