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Thursday, August 14, 2025 at 8:30 a.m. ET

Chief Executive Officer ? Ofer Gonen

Chief Financial Officer ? Hani Luxenburg

EVP, Strategy and Corporate Development ? Barry Wolfenson

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Total Revenue-- Operating loss was $5.7 million for Q2 2025, up 43% sequentially from Q1 2025 and higher year-over-year compared to Q2 2024, primarily from increased product sales and improved revenue mix.

Gross Profit-- $1.3 million, or a 23.5% margin, for Q2 2025, compared to $400,000, or 8.8%, in the prior year period, reflecting improved mix.

R&D Expenses-- Research and development expenses were $3.5 million, compared to $1.9 million in the prior year period, primarily from investment in the EscharEx VALUE Phase III study.

SG&A Expenses-- SG&A expenses totaled $3.6 million, compared to $3 million in the prior year period, mainly driven by increased share-based compensation.

Operating Loss-- $5.7 million total revenue for Q2 2025, compared to $4.5 million in Q2 2024.

Net Loss-- Net loss was $13.3 million, or $1.23 per share, for Q2 2025. Compared to $6.3 million, or $0.68 per share, in Q2 2024, Mainly due to $6.6 million in non-cash financial expenses from warrant revaluation in Q2 2025.

Adjusted EBITDA Loss-- Adjusted EBITDA loss was $4.5 million for Q2 2025. Up from $3.4 million in the prior year period.

Cash Position-- $32.9 million in cash, cash equivalents, and deposits as of June 30, 2025, including $2.3 million for manufacturing facility CapEx in the first half of 2025.

Warrant Funding Potential-- Up to $32 million in proceeds available from Series A warrants exercisable through November 2026 at $13.47 per share.

NexoBrid U.S. Revenue Growth-- 52% year-over-year revenue growth for NexoBrid in Q2 2025, according to Vericel, driven by higher hospital orders and additional ordering centers.

Manufacturing Scale-Up-- Facility commissioning on track for completion by year-end, with regulatory approval to follow, addressing global capacity constraints.

EscharEx VALUE Phase III Trial-- Actively enrolling, with a target of 216 patients across 40 sites in the VALUE Phase III study for venous leg ulcers; an interim sample size assessment will occur after 65% patient completion in the VALUE Phase III trial, with the interim readout expected by mid-2026.

Key Strategic Partnerships-- New collaborations with ConvaTec and SCT established to integrate

category-leading wound care products into pivotal trials.

Peer-Reviewed Data-- A new post hoc analysis from the earlier Phase II study, published in Advances in Wound Care, reported wound bed preparation as a key predictor, with a 90% non-healing rate in unprepared wounds (p=0.0004), directly supporting EscharEx's clinical endpoint.

U.S. Government Funding-- $3.6 million awarded by the Department of Defense in Q2 2025 for room-temperature NexoBrid, bringing total program funding to $18.2 million.

BARDA Collaboration-- All U.S. facility planning costs 100% funded by BARDA, with ongoing engagement toward domestic manufacturing site development and inclusion in new long-term RFP.

Future Clinical Milestones-- Planned randomized head-to-head EscharEx vs. collagenase trial to enroll 45 patients in 2025; The diabetic foot ulcer trial is targeted to start in the second half of 2025, pending FDA protocol feedback.

Inventory Status-- NexoBrid inventory at zero, with all production sold immediately; significant revenue ramp contingent on commissioning and regulatory approvals for new facility.

MediWound Ltd. (MDWD -0.53%) reported sequential and year-over-year revenue growth for Q2 2025, driven by rising NexoBrid U.S. sales and expanded clinical investments in EscharEx. Regulatory and clinical operations for pivotal trials and manufacturing expansion remain on track, with new partnerships established to reinforce market access and trial support. Recent peer-reviewed data highlight EscharEx?s role in wound bed preparation, while updated reimbursement policies require wounds to be properly prepared for eligibility. Ongoing and potential government funding, including BARDA and DoD awards, improve liquidity and operational runway

as management closes in on key clinical and manufacturing milestones.

CEO Gonen said, "The EscharEx VALUE Phase III trial is actively enrolling patients," and European activation progressing as planned.

Wolfenson confirmed, "The follow-up period is a three-month period. That's always been part of the study." clarifying protocol consistency with new compression therapy partner integration.

Net loss increase was explicitly attributed to non-cash warrant revaluation expenses, not direct cash outflow.

BARDA?s new ten-year RFP specifically targets NexoBrid stockpiling and room temperature formulation, with MediWound Ltd. directly supporting the process through its commercial partner.

All current NexoBrid production is immediately sold, with CEO Gonen stating, "we have zero inventory." highlighting the global demand and existing supply limits until new facility approval.

BARDA: Biomedical Advanced Research and Development Authority; a U.S. federal agency funding medical countermeasures such as NexoBrid for national preparedness.

EscharEx: MediWound Ltd.'s enzymatic debridement therapy under clinical development for chronic wound care, including venous leg ulcers and diabetic foot ulcers.

NexoBrid: Approved MediWound Ltd. biopharmaceutical for enzymatic eschar (burn tissue) removal in severe thermal burns.

CTP: Cellular and/or Tissue-Based Product; advanced wound care treatment usually used as skin substitute.

DFU: Diabetic Foot Ulcer; a difficult-to-heal wound prominent in diabetes patients, targeted by EscharEx development.

VLU: Venous Leg Ulcer; a chronic wound type being studied in EscharEx pivotal clinical trials.

RFP: Request for Proposal; a formal solicitation from a government agency (e.g., BARDA) to procure products or services.

Ofer Gonen, Chief Executive Officer of MediWound Ltd., and Hani Luxenburg, Chief Financial Officer. Barry Wolfenson, EVP of Strategy and Corporate Development, is also participating in today's call. Following our prepared remarks, we will open the call for Q&A. Now I would like to turn the call over to Ofer Gonen, Chief Executive Officer of MediWound Ltd. Ofer?

Ofer Gonen: Hi. Thank you, Dan, and good morning, everyone. In the second quarter, we continued to execute across our clinical, commercial, and operational objectives. The EscharEx VALUE Phase III trial is actively enrolling patients, and with new collaboration established with ConvaTec and SCT, all the relevant global wound care leaders are now engaged in our clinical programs. At the same time, NexoBrid continues to gain traction in the U.S. market, and the commissioning of our manufacturing scale-up remains on track for completion by year-end. As a result of these activities, we are in a strong position to achieve several key milestones over the next twelve months that are expected to advance our strategic and financial objectives.

Now let's begin with an update on EscharEx, our late-stage enzymatic debridement therapy for

chronic wounds. Enrollment in the VALUE Phase III study for venous leg ulcers is actively progressing. This global trial aims to enroll 216 patients across 40 sites in the United States and Europe. Once 65% of those patients have completed treatment in the VALUE trial, we will perform an interim sample size assessment. We expect this readout to take place by mid-2026. During this quarter, we further strengthened our network of research partners. We established new collaborations with SIT and ConvaTec to support both the ongoing VLU trial and the planned DFU trial.

Specifically, SCT's JOBS medical compression therapy products are now included in the VALUE trial protocol, and ConvaTec's aqua cell dressings will support the DFU study. Both of these category-leading partnerships complement our current relationships with Solventum, Molnicki, Keresys, Mimetics, and reinforce the broad validation of EscharEx within the wound care ecosystem. In addition, a new post hoc analysis from our earlier Phase II study was published yesterday in Advances in Wound Care. It's a leading peer-reviewed journal. The analysis confirms that wound bed preparation is a key predictor of healing in venous leg ulcers, and that without it, chronic wounds rarely heal.

Wounds that failed to achieve wound bed preparation had a 90% probability of not healing in the study, while those that achieved it were four times more likely to close. P value was 0.0004. These data validate EscharEx's potential to improve healing outcomes by accelerating wound bed preparation, which is the primary endpoint of our Phase III study. While wound bed preparation has been recognized for nearly two decades as a core principle in chronic wound healing, this is the first time that this concept has been confirmed with robust clinical evidence. Now let's turn our attention to NexoBrid, our innovative enzymatic therapy for severe burns. In the United States, adoption continues to expand.

Our partner Vericel reported 52% year-over-year revenue growth for NexoBrid in the second quarter, driven by increases in both hospital unit orders and the number of ordering centers. Operationally, the commissioning of our new manufacturing facility remains on track towards completion by year-end, with regulatory authority review and approval determining the timing of enabling the commercial output. Capacity expansion is critical for us in order to support our global growth. We also continued planning for future U.S.-based manufacturing as part of our collaboration with BARDA. In parallel, we were awarded an additional $3.6 million in non-dilutive funding from the U.S.

Department of Defense to support the development of a room temperature stable formulation for NexoBrid, bringing the total program funding to $18.2 million. This supplemental funding will enable expansion of our CMC activities, enhancement of in-house manufacturing capabilities, and initial preparations for the clinical trial. Now I'd like to turn the call over to Hani to review our financial performance in more detail. Hani?

Hani Luxenburg: Thank you, Ofer, and good morning, everyone. Let's turn to our financial results for the 2025 second quarter. Revenue grew 43% sequentially and also increased year-over-year. The growth reflects higher product sales and a more favorable revenue mix. Total revenue was $5.7 million, up from $5.1 million in 2024. Gross profit for the quarter was $1.3 million or 23.5% of revenue compared to $400,000 or 8.8% in the prior year period. The margin increase reflects a more favorable revenue mix. Research and development expenses were $3.5 million compared to $1.9 million in 2024, driven by continuing investment in the EscharEx VALUE Phase III study. SG&A expenses totaled $3.6 million versus $3 million last year, primarily due to increased share-based compensation.

Operating loss was $5.7 million compared to $4.5 million in Q2 2024. Net loss was $13.3 million or

$1.23 per share compared to a net loss of $6.3 million or $0.68 per share in the same period last year. The increase was mainly driven by $6.6 million in non-cash financial expenses in 2025, reflecting the revaluation of our warrants. Adjusted EBITDA loss was $4.5 million compared to $3.4 million in 2024. Looking at our performance for the first half of the year, total revenue was $9.7 million compared to $10 million in 2024. The slight decrease was primarily due to lower BARDA-funded development revenue as the NexoBrid R&D program nears completion.

Gross profit was $2.1 million or 21.5% of revenue compared to $1.1 million or 10.5% in the prior year period. R&D expenses rose to $6.4 million from $3.4 million last year, driven by clinical investment in EscharEx. SG&A expenses were $6.6 million compared to $5.9 million in the same period of 2024. Operating loss for the first half was $10.9 million compared to $8.2 million last year. Net loss for the period was $14 million or $1.30 per share versus $16 million or $1.73 per share in the prior year period. Adjusted EBITDA loss was $8.5 million compared to $6.2 million in 2024. Now, turning to our balance sheet.

As of June 30, 2025, we had $32.9 million in cash, cash equivalents, and deposits, compared to $43.6 million at year-end 2024. During the first half of the year, we received $700,000 from the exercise of Series A warrants and used $11.9 million to fund our operations, including $2.3 million in CapEx, primarily related to our new manufacturing facility. An additional $1.8 million in warrant exercise proceeds was received after the quarter end. As of today, the exercise of outstanding Series A warrants could provide us with up to $32 million in proceeds. These warrants have an exercise price of $13.47 per share and may be exercised through November 2026.

We believe our current cash position, together with potential proceeds from deals in the money warrant, provide us with the financial flexibility to advance our key program and support operational needs through upcoming milestones. That concludes my review of the financials. Ofer, back to you.

Ofer Gonen: Thank you, Hani. To close, the 2025 reflects disciplined execution in line with our strategic priorities. We remain focused on three core objectives: advancing the EscharEx VALUE Phase III trial towards enrollment targets, completing commissioning of our expanded manufacturing facility to meet anticipated demand, and building global recognition of EscharEx through clinical collaborations and peer-reviewed publications. Progress across these areas is on track, positioning MediWound Ltd. for a meaningful milestone in the months ahead. With that, I will now turn the call back to the operator to open the line for questions. Operator?

Operator: Thank you. We will now begin the question and answer session. To ask a question, you may press star then one on your touch-tone phone. If you are using a speakerphone, please pick up your handset before pressing the keys. If at any time your question has been addressed and you would like to withdraw your questions, the first question comes from the line of Josh Jennings with TD Cowen. Please go ahead.

Josh Jennings: Hi. Good morning, Ofer, Hani, and Barry. It was great to see the post hoc analysis from the EscharEx Phase II trial published. And I wanted to just, I mean providing another strong signal for success and value. But I wanted to just check-in and see are there any other publications that we should have on our radar that are coming up in the back half of 2025 or into 2026? And then also just wanted an update on the head-to-head trial versus Santal and just making sure that's still on the docket for this year to kick off.

Ofer Gonen: Hey, Josh, it's great to have you with us, as always. Addressing your first question regarding publications, indeed, there are a few other publications that we are not discussing at this stage, but the focus will turn towards diabetic foot ulcer trials. We have data about that. Our motivation here is to gain a lot of appetite across relevant KOLs before we start the trial. There are

some very important conferences, the FCON, SAWC, that are upcoming. I would expect to see additional publications around those conferences. As for the head-to-head trial, we are launching a randomized study in 2025 to compare EscharEx directly to collagenase. This trial is on track.

Our plan is to enroll 45 VLU patients and to split them between EscharEx, placebo, and Santyl or Eruxol in Europe. Yes, this is still our plan.

Josh Jennings: Excellent. And, you know, BARDA seems to be stepping up. I was hoping you could just give us a review. I know you've done this in the past but just of the U.S. facility and BARDA-funded planning and design. Maybe just help us I guess remember or just better understand the funding there. Is it fully funded? Will MediWound Ltd. have control of that manufacturing facility once it's completed? Maybe just review the details there, and then I have another follow-up question on BARDA interactions too.

Ofer Gonen: Okay. This is definitely an important topic for us. So governments around the world took note of NexoBrid's impact during the Israel Hamas war. In particular, the U.S. government showed interest in a domestic backup site. Apparently, they are not interested in being dependent on manufacturing in Israel. So we started planning and site selection in the United States. The funding of this process is 100% done by BARDA, and we are now getting ready for the second part. Once we know the prices, the cost, location, we can discuss with the U.S. government the funding of the facility as a whole. I hope I answered the question.

Josh Jennings: You did, thanks. And BARDA has also published an RFP request for proposal for enzymatic debridement products for treatment of deep and full-thickness severe burn injuries. Just maybe just review the elements of that RFP and any progress and how you expect that to play out for MediWound Ltd. and then the NexoBrid franchise. Thank you.

Ofer Gonen: Yeah. So around BARDA, again, they issued just recently an RFP that's covering three major elements, stockpiling of NexoBrid, room temperature stable formulation for nonsurgical debridement agent, and trauma and blast injury solutions. The program is expected to start in 2025, and it's a contract that should be for ten years. As Vericel disclosed in the last earnings call, they have initiated an RFP process. Where we sell they hold the U.S. commercial rights of NexoBrid, so they're the leader in this effort in the United States. Of course, as MediWound Ltd., since we have a lot of interest in that, we are providing full support.

Hopefully, in the next quarter's call, we will be able to elaborate further about the outcome.

Josh Jennings: Thanks so much. Appreciate it.

Ofer Gonen: Thank you.

Operator: Thank you. Next question comes from the line of Maya Eskandarani with H.C. Wainwright. Please go ahead.

Maya Eskandarani: Hello, folks. Congrats on the progress this quarter. My question is with respect to the addition of a new compression method for the Phase III VALUE trial. So I believe that brings the total up to five. Can you explain how you plan to distribute these, which is the physician's choice of compression method across the 216 patients? Thank you.

Ofer Gonen: Hi, Maya, and thank you for joining the call. Barry, can you step in and address that?

Barry Wolfenson: Sure, of course. Hi Maya, good question. Actually, the FDA in these wound

healing studies always looks for a follow-up period after the wounds have come to complete closure, just to assess the durability of that closure. So these medical compression therapy products from Essity will be used for that subsegment of patients that have come to complete closure. And what we wanted to do, as we've done with the rest of the products, is to standardize it so that all the patients are getting the same level of treatment. And so Essity, one of their big lines is JOBST, It's one of the leading lines of medical compression therapy. And we're actually using two different versions of it.

One is a custom product depending on if the patient has very particular and oddly shaped legs, and the other one is a more standardized product. But it'll be just for those patients that have come to complete closure throughout the trial and are in that follow-up period.

Maya Eskandarani: All right, thank you. And can you confirm that timelines are similar if not the same as before the addition of the JOBST product for compression to the protocol?

Barry Wolfenson: Yes, it doesn't change the timelines at all. The follow-up period is a three-month period. That's always been part of the study.

Maya Eskandarani: Okay, thank you very much.

Ofer Gonen: Thank you.

Operator: Thank you. Next question comes from the line of Michael Okunewitch with Maxim Group. Please go ahead.

Michael Okunewitch: Hey, guys. Thank you so much for taking my questions today. Congrats on all

the great progress.

Ofer Gonen: Thank you for joining us.

Michael Okunewitch: I guess just to start out, on the VALUE study, has the patient recruitment and enrollment process matched your expectations? I know you haven't given specific numbers, but I guess just is the trend going in a favorable way? Is it exceeding expectations? Could you give a bit more color on that?

Ofer Gonen: As you can as I said, one of the main focuses of MediWound Ltd. is executing on this trial. As you know, we succeeded in fourteen out of 14 clinical trials in the past. Our main objective is to succeed in this most important trial. So the enrollment is progressing well. In the United States, most sites, almost all of them, are already active and recruiting patients. In Europe, the activation is a little bit slower due to regulatory timelines. You know, while IND review in the United States typically takes thirty days, under the CTIS system in Europe, the process can extend up to one hundred and six days because of multi-country coordination, etcetera.

But all these steps are complete and the European sites are being activated. It's too early to say if we are going to meet the expectation, but currently, so far so good. We feel that the trial itself generated a lot of interest both in the United States and in Europe. There are many patients, as you can imagine, we are focusing on picking the right ones in order for this trial to be a success.

Michael Okunewitch: Thank you for the additional color there. Now also, you're now collaborating with basically all of the major wound care companies. So my question is, will having six different products across both of the pivotal studies, is this going to basically demonstrate to physicians that EscharEx can be used universally regardless of whatever preferred supportive products they have?

Barry Wolfenson: Sure, yeah. Hi Mike, good question. As we did in the for the CTP or skin substitutes where for the VLU study we're using EpiFix and for the DSU it's Kerasis Coloplast. This is why for the moist wound, the advanced wound dressings we're using Mundeleca in the VLU and now we're going with ConvaTec for the DFU is to hit that exact goal that you stated, to just to indicate that EscharEx does not need to be used alongside of any particular PTT or wound dressing or kind of compression therapy, but it could be used with any product that would be considered standard of care.

Michael Okunewitch: Yep, thank you. Great to hear. And then just one last one for me before I hop into the queue. What areas currently are particularly underserved for NexoBrid? Are there any particular regions where you expect the excess demand will fill as your new manufacturing comes online?

Ofer Gonen: It's as if you participated in our internal meetings because we are discussing it internally quite thoroughly. The demand is quite substantial these days across all the regions, but the reason can be that all of them know that we are limited. So every territory wants to make sure that they have enough NexoBrid, so maybe they a little bit inflate the demand. As far as we are concerned, once we have the if you look at our guidance, we feel strongly that we can meet the guidance for the upcoming years. And if we will have a positive surprise in a certain territory, that will just serve us. Other than that, we just know that we have additional demand.

We are not spending energies at all on marketing. And I believe that next year, after the facility is completed and approved by FDA and EMA, I think we will have better color on that.

Michael Okunewitch: All right. Thank you very much. And once again, congrats on all the great

progress you're making.

Ofer Gonen: Thank you.

Operator: Thank you. Next question comes from the line of Chase Knickerbocker with Craig Hallum. Please go ahead.

Chase Knickerbocker: Good morning. Thanks for taking the questions. Maybe just to start on the DFU side of things. Could you give us an update on kind of the timelines as far as when and how you'll get that relevant feedback that you need from FDA to kind of finalize design? And then just can you give us an update on kind of how you're thinking about the timelines there? Thanks.

Ofer Gonen: Hey, Chase, great to have you with us again today. As for the DFU, we guided that in the second half of the year, which means, as we speak, we are approaching the FDA in order to get feedback on the protocol for the next study. These processes typically take around ninety days. I think we will be then ready to get ready for the trial, but according to our guidance, we'll start in the second half of next year, and we are on track with that as well.

Chase Knickerbocker: Got it. And then just a little bit more granular maybe on the VLU side. Can you give us an update on kind of the 40 centers, how many are active Sorry if I missed it. And then, you know, there's at some wound care centers, there's some competition for patients for some of these SkinSub trials. Can you speak to if you're seeing any sort of competition for patients from some of those trials, just kind of general thoughts on enrollment is kind of what I'm looking for, Ofer.

Ofer Gonen: Again, this is a great question that keeps us awake at night. There are around 50% of the centers. We aim to open around 40 centers. We are not giving granular numbers, but we are

getting to that target. We are very close to that, to open 40 centers, 50% of them in the United States. The vast majority of the sites in the United States, maybe one or two are not open, all of them are open, activated, and recruiting patients. So in the United States, we are where we expect it to be. As for Europe, it's too early to say.

What we said that by the end of the third quarter, we think that the majority of the sites will be open there, and I think that we will meet this guidance as well. I strongly believe that we will meet this guidance as well. So in Europe so in the Phase III trial, according to our plans, we are in a good shape. As for competition, the competition of additional trials, of course, is irrelevant for Europe, because the vast majority of the trials of CTPs are now in the United States. When we chose the trial, we did a process of validating sites that we feel that are the best for our needs.

We made sure that the trials are being done in places without competition. Of course, things vary and change from time to time. Currently, we don't see a big impact from CTPs. I'm not sure that a CTP trial can compete with a biological trial. Each patient in our trial costs around $100,000. I'm not sure that these are the numbers that CTP trials that are much simpler. I'm not sure that this is the number that they are paying.

Chase Knickerbocker: Understood. And then, just last for me. You know, I had gotten your thoughts on we had gotten your thoughts on this previously. But, you know, the CTP SkinSub reimbursement kind of changes that are now kind of being proposed are a little bit different than before with that with the price cap that's being proposed. As we move into the final rule in November, we'll see how that shapes up. But can you kind of give us any thoughts as far as how you think that impacts the industry and how it might relate to future utilization of EscharEx?

Barry Wolfenson: Sure, of course. Hey, Chase. As far as the question on how it's going to shape the

industry, my frank belief is it will help to clean up the industry. You know, around these skin substitutes there's been issues over the years and a couple of these changes will really help to clean things up. One of them being that only those products that have demonstrated good clinical evidence will be eligible for Medicare reimbursement. And within that changed local coverage determination document there's also stipulation that the wounds need to be properly prepared. So they need to be fully debrided and ready for application of a skin substitute prior to being eligible for reimbursement.

And of course, especially given the publication that we've just announced today on the importance of wound bed preparation and how EscharEx impacts that, this is a huge win for us. This is what EscharEx does well and it will be well suited as a tool for anyone on that side of the business that's looking to apply a CTP onto a patient. And then the second part of it is a cleanup of the pricing loophole, which will bring everything back down to a similar level. And it will allow really the better products to flourish. And for physicians to look for ways to more quickly get to use these CTPs.

And we think again that's going to be where EscharEx provides impact because of its quick time to complete debridement and wound bed preparation.

Chase Knickerbocker: Great. Thanks, everyone.

Ofer Gonen: Thank you, Chase.

Operator: Thank you. Next question comes from the line of Scott Henry with AGB. Please go ahead.

Scott Henry: Thank you and good morning or afternoon depending on your location. A couple questions. First, you did reiterate that the manufacturing expansion is on track, operational capacity

by the end of the year 2025. Could you talk about when you would expect to file in the EU and in the U.S? I believe the EU is first. Thank you.

Ofer Gonen: Hey, Scott. Yeah, demand for NexoBrid is rising with those new launches and governmental interest and all the expanded indication that we are working on. So capacity is one of the biggest issues that we are addressing, because it is critical to support the global growth. The commissioning process, all the validations and everything that is required in order to be done is progressing well. What we guided that by the end of the year, everything will be completed, and we will start submission to the regulatory authorities. Stability testings in the for Europe is three months, and in the United States, it's six months.

So our estimation that in 2026, we will get approval from EMA, and in 2026, we will get approval from the FDA. The guidance of the revenue that we are presenting reflects those estimates.

Scott Henry: Okay, great. Thank you for that color. And then with regard to NexoBrid, given the capacity you have currently, we did see some growth from first quarter to second quarter, but the level is somewhat limited for the past kind of five quarters. Do you think will there be any room for expansion in 2025? Or are you just limited by the ability to make the product?

Ofer Gonen: So again, we have a guidance of $24 million revenue in 2025. We are able to meet this guidance. The surplus of the revenue will not come from additional NexoBrid. NexoBrid, we have zero inventory. Everything which is manufactured immediately is being sold. The additional the ramp up in the revenue in the second half of the year is from development services and not from NexoBrid. The ramp up with NexoBrid will be available only once we will get the first approval, EMA approval, for the new facility.

Scott Henry: Okay. Great. And I know you've talked about, BARDA funding already in the call, and it seems like that's very much on track. But three months ago, six months ago, there was some concern about BARDA funding in general given the political environment in the U.S. Is that environment currently? Are you back to kind of normal operations? Has it eased? Or is there any overhang left from that political environment?

Ofer Gonen: So this is a great question. In the previous quarter, we said that we had some delays in receiving revenue from both BARDA and DoD. And this quarter, you see the opposite. You see that debriding burns or treating burns people or burns soldier became kind of a priority. BARDA submitted an RFP. BARDA decided to support building a manufacturing facility in the United States. The Department of Defense increased the award, the non-dilutive funding that they are granting us for development of a room temperature stable formulation to be used in the battlefield.

So as far as we see, these projects are considered a priority around the Department of Defense and the Ministry of Health of the United States, and we are, of course, satisfied with that.

Scott Henry: Okay. Great. And perhaps a final question for Hani. Expenses in the quarter, I believe, roughly $7 million operating expenses. Would you expect that to increase in the second half? Or is that kind of a high watermark? It was a little higher than the first quarter. Just trying to get a sense of the trends.

Hani Luxenburg: Hi, Very good question. So in respect to our operating expenses, I will expect it to increase a little bit in the second half. As Ofer mentioned before, in the United States, most of the sites already recruiting patients, but in Europe, there was a slight delay because of the regulatory process, and those steps are now completed in Europe and European sites are being activated. This will result in higher R&D expenses in 2026. Hope I answered your question.

Scott Henry: Sid, that was great. Thank you. And thank you for answering the questions.

Operator: Thank you. Next question comes from the line of Maya Eskandarani with H.C. Wainwright. Please go ahead.

Maya Eskandarani: Thank you for taking my additional question. My question is actually also related to FDA turnover and the possibility of delays. So for the new NexoBrid facility, are inspection timelines on track? And otherwise, do you expect any changes to that timeline? Thank you.

Ofer Gonen: Hi, Maya. Again, this question is we are participating in all kinds of seminars and trying to understand exactly how FDA what the plans are for inspecting facilities that not in the United States. As far as we understand, inspections that are not expected now, let's say they're expected in one or two quarters from now, no one sees any problem with those. And since the FDA inspection is only expected in the second half or in the end of 2026, we don't see any issue with that.

Having said that, if you look at the guidance of our revenue, it is mainly determined by the approval of EMA, and there are no issues with approving our facility by the EMA because the inspectors are Israelis. So our estimation is that early or by half, by mid-2026, the new facility will be able to manufacture substantial amounts and to send it to territories that are substantial, like Europe and other countries that are linked to the EMA.

Maya Eskandarani: Okay. And a quick follow-up question. Are the BARDA, RFP and new DoD funding both able to be used for the development of the room temperature stable formulation?

Ofer Gonen: You are on spot. Importantly, BARDA has also expressed an interest in the program of

the room temperature stable formulation that initially was funded by the DoD. In the recent RFP that BARDA just published, you can see that room temperature stable formulation for nonsurgical debridement is specifically highlighted as one of the areas of focus. As you can imagine, NexoBrid that is stable in room temperature can be used not only for soldiers not only for military uses, also a lot of civilian scenarios are relevant. So yes, both agencies are very interested in this program.

Maya Eskandarani: Okay, that does it for me. Thank you.

Ofer Gonen: Thank you, Maya.

Operator: Thank you. This concludes our question and answer session. I would now like to turn the conference back over to Ofer Gonen for closing remarks.

Ofer Gonen: Thank you, everyone, for joining us today. We look forward to updating you again on our next quarterly call.

Operator: Thank you. The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.

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