BLRX Earnings Call Transcript

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Operator: Ladies and gentlemen, thank you for standing by. Welcome to the BioLineRx Third Quarter 2025 Financial Results Conference Call. [Operator Instructions] As a reminder, this conference is being recorded. I would now like to turn over the call to Irina Koffler, Investor Relations. Irina, please go ahead.

Irina Koffler: Thank you, operator, and welcome, everyone. Thank you for joining us on our quarterly results conference call. Earlier today, we issued a press release, a copy of which is available in the Investor Relations section of our website. It was also filed as a 6-K. I'd like to remind you that certain statements we make during the call will be forward-looking. Because such statements deal with future events and are subject to many risks and uncertainties, actual results may differ materially from those in the forward-looking statements. For a full discussion of these risks and uncertainties, please review our annual report on Form 20-F and our quarterly reports on Form 6-K that are filed with the U.S. Securities and Exchange Commission. At this time, it is now my pleasure to turn the call over to Mr. Phil Serlin, Chief Executive Officer of BioLineRx.

Philip Serlin: Thank you, Irina, and good morning, everyone, and thank you for joining us on today's call. As has been our practice, I will begin with a few prepared remarks before turning the call over to Mali Zeevi, our Chief Financial Officer, to briefly recap our financials. Afterwards, we will take your questions. Ella Sorani, our Chief Development Officer, is also available for Q&A.; I would like to begin this morning with a recap of our very significant and transformational announcement that we established a JV with Hemispherian, a Norwegian privately held biotech company to develop GLIX1, a highly innovative molecule for the treatment of glioblastoma and other cancers. The JV combines our proven track record of clinical and regulatory success, having advanced APHEXDA through clinical development and FDA approval with Hemispherian's expertise in small molecule cancer drug discovery, specifically in the area of DNA damage response research that leverages a unique mechanism of action and targets cancer cells. With these complementary capabilities, I believe we are very well positioned to bring much needed innovation to the most challenging cancer types while creating long-term value for our respective shareholders. GLIX1 is a first-in-class oral small molecule. As mentioned, GLIX1 is a very innovative molecule with a unique mechanism of action that targets DNA damage response in cancer cells while sparing healthy cells. Based on this unique MOA, the fact that it crosses the blood-brain barrier as well as highly impressive preclinical results, the first indication to be investigated will be glioblastoma or GBM, both newly diagnosed and recurrent. The FDA cleared Hemispherian's IND in August. And with the JV now up and running, we are planning to initiate a first-in-human Phase I/IIa glioblastoma trial in the first quarter of next year. At the same time, GLIX1 is a versatile molecule that has shown compelling antitumor activity in a large variety of cancer cell lines and other cancer models as well, and we will continue to advance preclinical activities in support of potential trials in other high unmet need cancer indications. Briefly recapping the terms of the JV agreement, Hemispherian contributed the global rights of GLIX1 to the JV, and we are responsible for managing, performing and funding all JV clinical development activities. In consideration for our respective contributions as of the JV's inception, Hemispherian holds 60% of the JV's share and BioLine holds 40%. We will continue to increase our stake over time up to a 70% stake as we continue to invest additional capital into the program. The unmet need in glioblastoma is significant. It is the most

common and aggressive form of primary brain cancer. The current standard of care treatment was established more than 20 years ago with only limited improvements since that time. Treatment includes surgical resection followed by radiotherapy and concomitant and adjuvant chemotherapy, but the prognosis for patients is poor with median survival of approximately 12 to 18 months following diagnosis. GBM occurs at all ages, but peaks with individuals in their 50s and 60s with an increasing incidence driven by an aging global population. New and better treatments are desperately needed that can improve survival, maintain quality of life and delay tumor progression. By 2030, the annual incidence of GBM is expected to be approximately 18,500 patients in the U.S. and approximately 13,400 across the EU 4+1, France, Germany, Italy, Spain and the U.K. This translates into total addressable markets across both the newly diagnosed and recurrent settings of more than $3.7 billion in the U.S. and Europe alone. We view this as a wide open market with few competitors. In terms of next steps, as mentioned, GLIX1's IND was cleared by the FDA this past August, and we are planning to initiate a Phase I/IIa study in the first quarter of next year. Data from the Phase I part of the trial is anticipated in the first half of 2027, but we may provide periodic updates earlier. Notably, 2 renowned experts in the area of glioblastoma, Dr. Roger Stupp and Dr. Ditte Primdahl of the Malnati Brain Tumor Institute at Northwestern University will serve as principal investigators for the study. We already talked about GLIX1's unique mechanism of action as well as the fact that we believe this novel molecule has potential clinical utility across a range of cancers. To that end, we were very pleased to announce just a few days ago that we received a notice of allowance from the USPTO for a key patent covering the use of GLIX1 for the treatment of all cancers in which cytidine deaminase or CDA is not overexpressed beyond a specific threshold. It is estimated that as many as 90% of all cancers, both solid tumor and hematological cancers fall into this category, and we have already seen potent antitumor activity in other cancer models in which GLIX1 has been evaluated. So while glioblastoma is our lead indication, as previously mentioned, we are planning to expand the development of GLIX1 into additional cancer indications once safety and dosing are successfully established. In this regard, we will continue to advance preclinical work in other cancers in parallel with our glioblastoma study. We believe the versatility of GLIX1 provides us with multiple opportunities to advance cancer patient care while creating value for our company. Importantly, this new patent broadens and strengthens GLIX1's patent protection until 2040 with a possible patent term extension of up to 5 years. In addition to the recently allowed U.S. patent just referenced, GLIX1 is covered by 2 additional key patent families covering its use alone and in combination with established anticancer agents. GLIX1 for use in treating cancer in the central nervous system, such as glioblastoma is covered by patents issued in the U.S., Europe and 13 other countries. The patents are valid until at least 2040 with a possible patent term extension of up to 5 years. And then GLIX1 in combination with PARP inhibitors for use in treating homologous recombination proficient cancers, which represent the majority of cancers is covered by a pending international patent application. Corresponding national-based patents if granted will be valid until at least 2044 with a possible patent term extension of up to 5 years. So we are very pleased to have brought this highly innovative molecule into our pipeline, and we look forward to keeping you apprised of our progress as we pursue its development in a range of very challenging cancers. Turning now to pancreatic cancer, or PDAC. Recall that we retained the rights to develop motixafortide in PDAC as part of the Ayrmid out-licensing agreement, and we continue to support its ongoing development in this indication. A randomized Phase IIb clinical trial sponsored by Columbia University and supported by both Regeneron and BioLineRx, known as CheMo4METPANC continues to enroll patients. The CheMo4METPANC trial is evaluating motixafortide in combination with the PD-1 inhibitor, cemiplimab and standard chemotherapies, gemcitabine and nab-paclitaxel. A prespecified interim analysis is planned for when 40% of progression-free survival events are observed. Results for this trial, if positive, could be a significant value inflection point for our company and signal new hope for patients suffering from this very challenging tumor type. We look forward to keeping you up to date on our progress with this important program. In terms of cash, our balance sheet remains strong. We ended the third quarter with cash and equivalents of approximately $25.2 million, which is sufficient to fund our operating plan as currently contemplated into the first half of 2027. We also have the potential benefit of royalties and milestone-driven revenue from our license agreements with both Ayrmid and Gloria Biosciences. Our goal continues to be to help as many patients as possible while creating enduring value for our

shareholders. Before turning the call over to Mali to review our financials in more detail, I'd like to briefly touch on APHEXDA's performance in the third quarter. The Ayrmid team continues to make progress driving APHEXDA adoption, generating sales of $2.4 million in Q3 2025, which resulted in $0.4 million of royalty revenue to BioLineRx. We remain optimistic about the role that APHEXDA can play in the new multiple myeloma treatment paradigm and look forward to meaningful growth from this next-generation stem cell mobilization agent. Recall that when we executed the Ayrmid out-licensing agreement last year, we obtained not only the rights to commercialize APHEXDA in stem cell mobilization for multiple myeloma, but also the rights to develop motixafortide across all other indications, excluding solid tumor indications and in all territories other than Asia. This includes the evaluation of motixafortide in sickle cell disease. A Phase I investigator-initiated trial sponsored by Washington University School of Medicine recently concluded, and we are very pleased to announce that an abstract detailing final positive results for this proof-of-concept study has been accepted for presentation at this year's ASH Annual Meeting, which is taking place December 6 to December 9. Hitting a few of the highlights, the trial, which enrolled 10 subjects evaluated motixafortide both as monotherapy and in combination with natalizumab for the mobilization of hematopoietic stem cells for gene therapies in sickle cell disease. The study demonstrated that motixafortide alone and in combination with natalizumab was safe and well tolerated. In addition, motixafortide alone and in combination with natalizumab demonstrated robust hematopoietic stem cell mobilization in the peripheral blood, resulting in high collection yields. Furthermore, in 2 subjects who had previously undergone mobilization with plerixafor, motixafortide alone and in combination with natalizumab resulted in nearly 3x greater mobilization and subsequent collection yield of stem cells as compared to plerixafor. In conclusion, this trial demonstrated the potential of motixafortide alone and in combination with natalizumab as a novel G-CSF-free regimen to safely optimize hematopoietic stem cell mobilization in sickle cell disease. These results strongly support continued development in this indication. The current standard of care mobilization agent, G-CSF is contraindicated in patients with sickle cell disease. So there is an urgent need for an agent that can reliably produce the very large quantities of stem cells that manufacturing and transplantation require in this indication, around 20 million CD34+ cells per kilogram without further burdening already constrained apheresis capacity. We believe motixafortide has the potential to expand access to stem cell mobilization and transplantation in sickle cell disease, which is potentially curative for these patients. Now let me turn the call over to Mali to provide a financial update. Mali, please go ahead.

Mali Zeevi: Thank you, Phil. As is our practice, I will only go over the most significant items in our financial statements, revenues, cost of revenues, research and development expenses, sales and marketing expenses, net loss and cash. I invite you to review the 6-K that we filed this morning, which contains our financials and press release. Total revenues for the third quarter of 2025 were $0.4 million, reflecting the royalties paid by Ayrmid from the commercialization of APHEXDA in stem cell mobilization in the U.S. Cost of revenues for the third quarter of 2025 was immaterial. Both revenues and cost of revenues in 2025 are not comparable to the same period in 2024, which primarily reflect a portion of the upfront payments received by us under the Gloria license agreement as well as direct commercial sales of APHEXDA by BioLineRx prior to the Ayrmid transaction in November 2024. Research and development expenses for the third quarter of 2025 were $1.7 million compared to $2.6 million for the third quarter of 2024. The decrease resulted primarily from lower expenses related to motixafortide following the out-licensing of U.S. rights to Ayrmid as well as a decrease in payroll and share-based compensation, primarily due to a decrease in headcount. There were no sales and marketing expenses for the third quarter of 2025 compared to $5.5 million for the third quarter of 2024. The decrease resulted primarily from the shutdown of our U.S. commercial operations in the fourth quarter of 2024 following the Ayrmid out-licensing transaction. General and administrative expenses for the third quarter of 2025 were $0.8 million compared to $1.4 million for the third quarter of 2024. The decrease resulted primarily from lower payroll and share-based compensation, primarily due to a decrease in headcount as well as small decreases in a number of general and administrative expenses. Net loss for the third quarter of 2025 was $1 million compared to net loss of $5.8 million for the third quarter of 2024. As of September 30, 2025, the company had cash, cash equivalents and short-term bank deposits of $25.2 million, sufficient to fund operations as currently planned into the first half of

2027. And with that, I'll turn the call back over to Phil.
Philip Serlin: Thank you, Mali, and thank you to everyone joining this call. Operator, we will now open the call to questions.
Operator: [Operator Instructions] The first question is from Joe Pantginis of H.C. Wainwright.
Joseph Pantginis: If you don't mind, I'm going to ask all 3 of my questions at the same time because there is some background noise. So please bear with me. So first, I wanted to get a sense as we look towards the upcoming clinical study for GLIX1, as you look early on for PK and PD markers, are there any potential PD markers that you look to release that might be correlated with clinical activity as people look to tease out any additional information from the study, number one. Number two, what would you say your intermediate or longer-term needs are for manufacturing capacity for GLIX1? And number three, thank you for taking these as you look towards additional tumor indications, when do you think we might see some preclinical data readouts and what those indications might be?
Philip Serlin: Thanks, Joe. So first of all, thanks for joining the call. Ella, do you want to take the question?
Ella Sorani: Yes, sure. Joe, thanks for your question. So the first question with regards to PK and PD markers during the clinical trial of GLIX. PK is an easy one. Of course, we are planning to take extensive PK data during this trial. With regards to pharmacodynamic markers, we do have pharmacodynamic markers for GLIX1. However, they are from biopsies. And since we are talking in the first part at least of the study, about recurrent GBM -- biopsies during or following treatment will not be easy to be obtained. Having said that, if there are going to be surgeries along the trial, then we are planning to use those in order to get some input with regards to these biomarkers. I hope this answers the question.
Joseph Pantginis: Yes.
Philip Serlin: And as far as the immediate needs for manufacturing, I can say that we're manufacturing at a world-class CDMO. We don't anticipate any need to change manufacturers or whatever. I think the current manufacturer has more than enough capacity and the batch size is correct for us to move forward all the way to Phase IIa.
Ella Sorani: And regarding your third question on results of preclinical models. So we are performing then with regards to when we will be able to present results probably in -- well, the plan would be in one of the conferences next year.
Operator: The next question is from John Vandermosten of Zacks.
John Vandermosten: So why the activities to commercialize APHEXDA are responsible at Ayrmid, I wanted to see if you can help me think about like a medium-term target for market penetration based on today's vantage point. Is that something you can help me with, Phil?
Philip Serlin: We can't really help you with it. We're not -- we're no longer the owner, so to speak, of the asset in the territories that Ayrmid holds. And so we're not really giving guidance at this time since it's no longer our product. I wish I could give you a better answer than that, but I'm really not able to.
John Vandermosten: Okay. And then shifting on to GBM. What would be a reasonable target for an improvement in overall survival for GBM that would get established pharma interested and get the FDA to be on board with approval? I know, again, that's well down the road, but I was wondering what you had in mind in terms of what would be material enough to get all parties, all stakeholders interested?
Ella Sorani: Yes. So with regards to that, I think it depends, of course, if you're talking recurrent GBM or newly diagnosed GBM. I think for the newly diagnosed, the benchmark would be -- I mean, temozolomide was approved based on improvement of median overall survival of approximately 2.5 months. So that would probably be sufficient for -- in terms of improvement of overall survival for newly diagnosed GBM. For recurrent GBM, I think the bar would even be lower in terms of improved efficacy.
John Vandermosten: Okay. That's very helpful. And then just a question on the financial statements. So your investments in the JV, how will they appear on your financial statements? Is that considered R&D; expense? Or will it end up somewhere else? And I know there's a few different components there, like a periodic piece and then the investments in the JV itself.
Philip Serlin: Yes. So we ultimately control the JV. We have control of the Board of Directors, and we also have control of the joint development committees, et cetera. So we're actually consolidating the JV in our financial statements. And so therefore, all of the expenses in the JV will be reflected in the

specific financial statement line items as if we were -- as if it was just being done directly at BioLine.
John Vandermosten: Okay. So those are all considered R&D; expense, including that, I think that $80,000 amount.
Philip Serlin: Yes, of course. Yes. That $80,000 amount is actually -- is for specific services, transition services and what have you. So it will all be reflected in R&D; expenses, I believe you're correct.
Operator: [Operator Instructions] There are no further questions at this time. Mr. Serlin, would you like to make your concluding statement?
Philip Serlin: Yes, I would. Thank you, operator. In closing, we remain very excited about this new vision for BioLineRx and believe we have the expertise and resources to drive meaningful innovation for patients with some of the most challenging cancer types. I am very excited about what the future holds for BioLineRx in 2026 and beyond. Thank you all very much for your continued interest in BioLineRx. Be safe, and have a great day.