BioLineRx Issues Letter to Shareholders

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- Company outlines strategic long-term vision and financial outlook -

TEL AVIV, Israel, Jan. 21, 2025 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today issued the following letter to shareholders.

To my fellow shareholders,

It has been approximately two months since we announced a major strategy shift with the signing of an exclusive license agreement with Ayrmid Ltd. to commercialize APHEXDA® (motixafortide), the next-generation stem cell mobilization agent that we successfully shepherded from early clinical development through FDA approval and commercial launch in September 2023. Following such a transformational transaction, I wanted to provide more granularity regarding our vision for our company moving forward, as we remain as committed as ever to maximizing value for our shareholders.

To fully understand where we plan to go, it is important to recap the salient terms of the license agreement with Ayrmid Ltd. (Ayrmid), as well as the previously announced license agreement that we entered into with Guangzhou Gloria Biosciences Co., Ltd. (GloriaBio). Both agreements provided significant non-dilutive upfront capital, while allowing us to retain upside potential from royalties on future sales of APHEXDA, as well as from potential future commercial and development milestones in the respective territories. We expect these collaborations to provide a growing stream of cash flows into our company over time while we work to rebuild our pipeline with new assets.

Ayrmid

The license agreement with Ayrmid, which we announced in November 2024, gives Ayrmid the right to develop and commercialize APHEXDA (motixafortide) across all indications, excluding solid tumor indications, and in all territories other than Asia. In exchange for the license, we received a $10 million upfront payment, and are eligible to receive up to an additional $87 million in potential commercial milestones, plus royalties ranging from 18% to 23% on net sales of APHEXDA. In addition, certain funds managed by Highbridge Capital Management LLC, Ayrmid's principal shareholder, executed a $9 million equity investment in the Company.

GloriaBio

The license agreement with GloriaBio, which we first announced in August 2023, gives GloriaBio the right to develop and commercialize motixafortide across all indications in the Asia region, beginning with stem cell mobilization (SCM), followed by pancreatic ductal adenocarcinoma (PDAC). In exchange, we received a $15 million upfront payment, and are eligible to receive up to ~$50 million in potential development and regulatory milestones in China and Japan, as well as up to ~$200 million in potential commercial milestones based on defined sales targets. We are also eligible to receive tiered double-digit royalties on net sales. In addition, a $14.6 million equity investment in the Company was executed here as well.

BioLineRx 2.0

As it pertains to BioLineRx, or what I now like to call 'BioLineRx 2.0', we have returned to our roots as a lean drug development company, leveraging the many years of experience and the track record of success that our team brings, as evidenced by our successful development of motixafortide, which we advanced from early-stage clinical development through a successful Phase 3 trial, and culminating with FDA approval in September 2023.

We have retained the rights to develop motixafortide across all solid tumor indications, in all territories other than Asia, including in pancreatic ductal adenocarcinoma (PDAC), for which an investigator-initiated Phase 2b trial, sponsored by Columbia University, and supported equally by BioLineRx and Regeneron, is ongoing at a relatively minimal cost to BioLineRx. A second Phase 2b trial in PDAC is being planned by GloriaBio, at no cost to us. We expect these pipeline programs to continue to advance without any significant expense to our Company, while providing the potential for a meaningful future upside.

At the same time, a key component of our strategy moving forward is to in-license additional assets in oncology and/or rare diseases over the next two years that we can advance through clinical development. We have substantial experience in scouting and assessing assets in transactions with back-ended, success-based consideration, which can be acquired or licensed for a modest upfront payment, and with relatively modest and affordable clinical development programs. We are actively working on this initiative and are being presented with many promising opportunities that meet these criteria. Visibility on our progress with this initiative, like most companies, will be minimal until we have a tangible agreement to announce.

Our longer-term vision is to develop innovative assets with significant potential value whose development costs have been offset by the royalties and milestones from our existing motixafortide partnerships. We aim to continue pursuing new partnerships on these programs to create additional value for our shareholders.

Strengthened Balance Sheet and Streamlined Cost Structure Provide Runway through H2 2026

Proceeds from the Ayrmid and GloriaBio transactions, together with the opportunistic $10 million equity financing that we completed in early January and our significantly reduced cost structure (our currently planned operating burn rate going forward is ~$12 million per year) are expected to provide

us with a current cash runway to execute upon our goals through the second half of 2026. This includes the relatively minor costs associated with continuing to support the PDAC trials, while also engaging in our planned pipeline expansion activities. Furthermore, it does not take into account any potential revenue upside generated from sales royalties or commercial milestones under our out-licensing agreements that I just described.

ADS Ratio Change Maintains Nasdaq Listing Compliance

Finally, to regain compliance with Nasdaq's minimum bid price requirement, we announced just a few days ago our intent to change the ratio of our American Depositary Shares to ordinary shares, from 15 ordinary shares per ADS to 600 ordinary shares per ADS. This is equivalent to a 1-for-40 reverse stock split, and will go into effect on January 30, 2025.

As we continue to execute on our long-term strategy, including the potential in-licensing of new assets, maintaining our Nasdaq exchange listing is a critical objective. By implementing this change, we hope to regain compliance with all of Nasdaq's applicable requirements, allowing us to continue to enjoy all the benefits that such a listing confers.

In closing, we are entering 2025 with a renewed focus on innovative drug development within our core competency areas, a strengthened balance sheet with $29.5 million of cash, a very lean cost structure, and a cash runway based on our current operating plan through the second half of 2026. With these strategic actions completed, I believe we are well positioned to create enduring value for our shareholders while introducing novel therapeutics for patients suffering from cancer or rare diseases.

I am excited about what the future holds for BioLineRx, both for this year and beyond, and I look forward to keeping you apprised of our continued progress, beginning with our fourth quarter 2024 results release in March.

Thank you for your continued support.

Sincerely,
Phil Serlin

Philip Serlin
Chief Executive Officer

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases. The company's first approved product is APHEXDA® (motixafortide), with an indication in the U.S. for stem cell mobilization for autologous transplantation in multiple myeloma, which is being developed and commercialized by Ayrmid Ltd. (globally, excluding Asia) and Gloria Biosciences (in Asia). BioLineRx is utilizing its end-to-end expertise in development, regulatory affairs, manufacturing and commercialization to advance its innovative pipeline and ensure life-changing discoveries move beyond the bench to the bedside.

Learn more about who we are, what we do, and how we do it at www.biolinerx.com, or on Twitter and LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

Various statements in this release concerning BioLineRx's future expectations constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," and "would," and describe opinions about future events. These include statements regarding management's expectations, beliefs and intentions regarding its future prospects, including BioLineRx's cash runway. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Factors that could cause BioLineRx's actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: the initiation, timing, progress and results of BioLineRx's preclinical studies, clinical trials, and other therapeutic candidate development efforts; BioLineRx's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; whether BioLineRx's collaboration partners will be able to execute on collaboration goals in a timely manner; whether the clinical trial results for APHEXDA will be predictive of real-world results; BioLineRx's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of BioLineRx's therapeutic candidates, including the degree and pace of market uptake of APHEXDA for the mobilization of hematopoietic stem cells for autologous transplantation in multiple myeloma patients; whether access to APHEXDA is achieved in a commercially viable manner and whether APHEXDA receives adequate reimbursement from third-party payors; BioLineRx's ability to establish, operationalize and maintain corporate collaborations; BioLineRx's ability to integrate new therapeutic candidates and new personnel; the interpretation of the properties and characteristics of BioLineRx's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; the implementation of BioLineRx's business model and strategic plans for its business and therapeutic candidates; the scope of protection BioLineRx is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; estimates of BioLineRx's expenses, future revenues, capital requirements and its needs for and ability to access sufficient additional financing, including any unexpected costs or delays in the commercial launch of APHEXDA; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and BioLineRx's industry; statements as to the impact of the political and security situation in Israel on BioLineRx's business, which may exacerbate the magnitude of the factors discussed above. These and other factors are more fully discussed in the "Risk Factors" section of BioLineRx's most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 26, 2024. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

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