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Valerio Therapeutics Reports its Half-Year 2024 Financial Results and Provides an Update on its Activities

- **Acquisition of Emglev Therapeutics to focus on discovering single-domain antibodies (sdAbs)**
- **The VIO-01 trial is currently in Phase 1 dose escalation**
- **R&D efforts maintained for optimization of the PlatON™ platform, targeting new assets in combination with DNA decoys**
- **Continue to evaluate opportunities for business partnerships**

Paris (France), September 30, 2024 – 8 pm CEST – Valerio Therapeutics S.A. (Euronext Growth Paris: ALVIO), hereafter "Valerio Therapeutics" or the "Company"), a clinical-stage biotechnology company specializing in the development of innovative drugs targeting tumor DNA Damage Response (DDR) and driver oncogenes, today announced the publication of the Company's 2024 half-year report. The 2024 half-year report is available to the public on the Company's website/investor relations/financial information.

On September 29, 2024, Valerio portfolio was extended with the acquisition of Emglev Therapeutics, bringing to the Company, through its subsidiary Valour Bio, a unique proprietary platform of fully synthetic single domain antibodies (sdAbs), Valour Bio has been established as a wholly owned subsidiary of Valerio Therapeutics to focus on discovering single domain antibodies (sdAbs) as drug and radio conjugates, bispecific T-cell engagers, blocking and binding sdAbs, or CAR-T sdAb drug candidates for multiple therapeutic areas (see section "post-closing events").

Dr. Shefali Agarwal, President and CEO of Valerio Therapeutics, said: *"The first half of 2024 was an important phase for our Company. By initiating a Phase 1 clinical trial in VIO-01 and continuing to develop our pipeline, we highlighted our will to use innovative technologies, such as DNA decoys, to advance new anti-cancer treatments. Additionally, we are also very excited about the acquisition of Emglev Therapeutics through our newly formed subsidiary Valour Bio, which highlights our vision to develop innovative drugs using next-generation technology. Emglev's sdAb technology offers unique advantages in the conjugation of sdAb in different modalities such asradio-conjugates, bispecific T-cell engagers, blocking sdAbs and CAR-T sdAb drugs. Combining Emglev's talent and expertise in sdAb with the knowledge and skills of Valerio Therapeutics' research and development teams will enhance opportunities to improve the care of people living with debilitating diseases."*

FINANCIAL RESULTS FOR THE FIRST HALF OF 2024

Consolidated income statement (IFRS) In thousands of euros	June 30, 2024	June 30, 2023
Revenues, of which:	**0**	**0**
Recurring revenues	0	0
Non-recurring revenues	89	0
Operating expenses, including:	**(10,839)**	**(11,622)**
R&D expenditure with third parties	(4,360)	(5,643)
Other current operating income	2	28
Current operating income	**(10,837)**	**(11,594)**
Other non-recurring operating income	(88)	0
Income from companies accounted for by the equity method		
Operating income after share of profit of associates	**(10,925)**	**(11,593)**
Financial income	(33)	(50)
Income tax expense	0	0
Net income	**(10,958)**	**(11,644)**

The half-year accounts as of June 30, 2024, drawn up according to IFRS standards and approved by the Board of Directors on September 30, 2024, have not been audited nor been the subject of a limited review.

The Group did not record any consolidated revenues for the period ended June 30, 2024.

Operating expenses amounted to €10.8 million. The decrease compared to €11.6 million in first-half 2023 is mainly due to €700K loss reduction due to a decrease in payroll.

The financial loss as of June 30, 2024, amounted to €33k compared to a loss of €50k as of June 30, 2023.

The Group's total net loss was thus €11 million in the first half of 2024, compared with a net loss of €11.6 million for the same period in 2023.

CASH POSITION AS OF JUNE 30, 2024

The Group's cash balance on June 30, 2024, was €4 million, compared with €6.8 million on December 31, 2023. The change in cash is mainly due to the shareholders' loans received from Artal and Financière de la Montagne in May 2024, and the expenses incurred for acquiring Emglev in cash and developing its research programs.

The cash on hand as of June 30, 2024, along with the receipt of the Research Tax Credit, the Clinical partnership, the Service agreement with Valour Bio, and the optimization of the operational expenses, provides Valerio Therapeutics with financial visibility through the end of 2024.

HIGHLIGHTS OF THE FIRST HALF OF 2024 AND RECENT DEVELOPMENTS

VIO-01

VIO-01, formerly OX425, is a Pan-DDR DNA Decoy Targeting Multiple Proteins & Repair Pathways and represents the most optimal drug candidate selected to enter preclinical development. VIO-01 traps several DDR Proteins Inhibiting Different DNA Repair Pathways. VIO-01 reaches the nucleus and acts as a decoy for several DNA repair enzymes. It has an increased resistance to nucleases and plasmatic stability.

Valerio Therapeutics presented new preclinical data confirming the pan-DDR DNA decoy effect of VIO-01 and the high anti-tumor activity in tumor models independently from the homologous recombination repair status on April 19, 2023, at the American Association for Cancer Research (AACR) Annual Meeting. The Company also presented new preclinical data confirming VIO-01's capability to abrogate several DNA repair pathways and induce a drug-driven synthetic lethality without the need for a combined treatment.
VIO-01 underwent late-stage IND-enabling preclinical development in 2023, with the execution of regulatory toxicology and ADME/PK studies. This package allowed IND submission to FDA followed by approval to start first-in-human clinical trial.

In clinical development

The Company gained IND clearance from the FDA in November 2023 to conduct a Phase1/2 trial evaluating VIO-01 in patients with recurrent or metastatic homologous recombination repair mutated or homologous repair deficient solid tumors. The trial is currently in Phase 1 dose escalation which is evaluating the safety, tolerability, dose-limiting toxicities and recommended phased 2 dose of VIO-01. Currently, the trial has enrolled 6 patients across two dose levels. The VIO-01 trial is currently in Phase 1 dose escalation, evaluating the safety, tolerability, dose-limiting toxicities, and recommended Phase 2 doses of VIO-01. Currently, the trial has enrolled 6 patients across two dose levels. VIO-01 has shown an acceptable safety profile and plans to proceed through dose escalation for the remainder of 2024. Once the recommended dose is determined, the trial is planned to proceed to the Phase 2 expansion, which will evaluate the activity of VIO-01 in HRD+ ovarian cancer and in HRRm/HRD+ solid tumors. The Phase 2 expansion is planned to assess the preliminary efficacy. Based on the evidence generated in the Phase1/2 trial further development may include additional combinations of chemotherapy or targeted therapies with VIO-01 or development in additional solid tumors.

3rd generation of PlatON platform – the DecoyTAC platform

Valerio Therapeutics continued to optimize the PlatON™ platform to develop more potent assets coupled to innovative technologies, with the objective to combine PlatON™ platform's DNA decoys with the targeted protein degradation strategy offered by PROTACs (PROteolysis-TArgeting Chimeras) technology. PROTACs technology and other tumor specific targeting options may be a novel class of heterobifunctional molecules that can selectively degrade target proteins within cells. This approach offers several advantages over the other molecules involved in modulating the DNA damage response, such as increased selectivity and reduced toxicity. This specific strategy involves generating DecoyTAC combining our vectorized DNA decoy molecules capable of efficient cell penetration with a linker+E3 ligand promoting the complete degradation of the target proteins, thereby presenting a novel mechanism of action.

The exploration of the convergence of PROTACs and DNA Decoys aims to not only propose new therapeutic modalities against DDR proteins but also against transcription factor proteins that are challenging to target. Through these efforts, the Company strives to advance the field of oncology drug development and contribute to the treatment of cancer patients.

AsiDNA™

AsiDNA™ is a *first-in-class* DNA Decoy that traps and sequesters DNA-PK, a complex of proteins involved in the DNA Damage Response. AsiDNA™ thus induces inhibition of DNA-PK-dependent DNA repair in tumor cells, which nevertheless continues its replication cycle but with damaged DNA, thus leading to cell death. AsiDNA is used in combination with other tumor DNA damaging agents such as radiotherapy and chemotherapy, or in combination with inhibitors of a specific repair pathway such as PARPi or other targeted therapies, to increase their efficacy, notably by abrogating any resistance to these treatments, without increasing toxicity. AsiDNA™ specifically targets tumor cells and has a very favorable safety profile in humans observed in four Phase 1/1b clinical studies.

Given the limited efficacy observed during phase 1 clinical trials especially as a monotherapy, it was not considered beneficial for patients to further pursue clinical development of AsiDNA™ or initiate a phase 2 study. Furthermore, AsiDNA™ is assumed to

generate no revenue and only have minor carrying costs for company industrial property. For all these reasons, it was decided to deprioritize AsiDNA™ clinical investigation to focus efforts on the development of VIO-01, our second-generation drug candidate.

GOVERNANCE AND CORPORATE

As of the date of this report, the Board of Directors is composed of 7 members, 6 men and 1 woman, including 3 independent members.

OUTLOOK

In 2024, the Company will continue to pursue its value-creation strategy based on developing its therapeutic innovations up to proof-of-concept studies in human and then generate revenues through agreements with other pharmaceutical companies capable of pursuing their development.

The Company anticipates the following major events:

AsiDNA™

- The U.S. phase 1b/2 trial of AsiDNA in combination with Olaparib in ovarian, breast, and prostate cancers was discontinued before proceeding to Phase 2 as the company has prioritized efforts and resources to the next-generation candidate VIO-01. The development of AsiDNA has been deprioritized, and no clinical studies investigating its use are ongoing.

VIO-01 (formerly OX425)

- Continuation of dose escalation throughout 2024.
- Initiation of Phase 2 expansion 2H 2025.

platON™

- Continued evaluation and optimization of PlatON platform and potential new drug candidates.

Emglev / proprietary platform of fully synthetic single domain antibodies (sdAbs)

- Valour Bio has been established as a wholly owned subsidiary of Valerio Therapeutics to focus on discovering single domain antibodies (sdAbs) as drug and radio conjugates, bispecific T-cell engagers, blocking and binding sdAbs, or CAR-T sdAb drug candidates for multiple therapeutic areas.
- Valerio Therapeutics' R&D team will provide services to Valour Bio throughout 2024 and beyond to develop the first proof-of-concept bispecific nanobody for the treatment of autoimmune disease.

Additionally, Valerio Therapeutics is continuing to actively evaluate business partnerships that can be synergistic with its pipeline and team. Valerio Therapeutics believes that, given its current activities, it has no further comments to make on trends that would likely affect its recurring revenues and general operating conditions from the end of the last fiscal year, which ended December 31, 2023, until the date of publication of this report.

The 2024 half-year financial report is available on the Company's website.

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About Valerio Therapeutics

ValerioTX (Euronext Growth Paris: ALVIO) is a clinical-stage biotechnology company developing innovative oncology drugs targeting tumor DNA-binding functions through unique mechanisms of action in the sought-after field of DNA Damage Response (DDR). The Company is focused on bringing early-stage first-in-class or disruptive compounds from translational research to clinical proof-of-concept, a value-creating inflection point appealing to potential partners.

PlatON is ValerioTX's proprietary chemistry platform of oligonucleotides acting as decoy agonists**,** which generates new innovative compounds and broadens the Company's product pipeline.

VIO-01 (formerly OX425), the second compound from platON™, is a novel pan-DDR Decoy with high antitumor activity. It also mediates multiple immunostimulatory effects by activating the STING pathway**.** The VIO-01 trial is currently in Phase 1 dose escalation, evaluating the safety, tolerability, dose-limiting toxicities, and recommended Phase 2 doses of VIO-01. Currently, the trial has enrolled 6 patients across two dose levels. VIO-01 has shown an acceptable safety profile and plans to proceed through dose escalation for the remainder of 2024. Once the recommended dose is determined, the trial is planned to proceed to the Phase 2 expansion, which will evaluate the activity of VIO-01 in HRD+ ovarian cancer and HRRm/HRD+ solid tumors. The Phase 2 expansion is planned to assess the preliminary efficacy.

DecoyTAC: the 3rd generation platON™ platform**,** leveraging the unique MOA of DNA decoy therapeutics coupled to targeted protein degradation (PROTAC). This evolution expands the activity of platON™ platform beyond DNA repair by targeting other proteins such as transcription and epigenetic factors, in oncology and outside oncology for other diseases like inflammatory and muscular diseases.

For further information, please visit www.valeriotx.com.

Forward looking statements

This communication expressly or implicitly contains certain forward-looking statements concerning Valerio Therapeutics and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Valerio Therapeutics to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Valerio Therapeutics is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise. For a discussion of risks and uncertainties which could cause actual results, financial condition, performance or achievements of Valerio Therapeutics to differ from those contained in the forward-looking statements, please refer to the risk factors described in the most recent Company's financial report or in any other periodic financial report and in any other press release, which are available free of charge on the websites of the Company Group (https://valeriotx.com/) and/or the AMF (www.amf-france.org).

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