

Valerio Therapeutics Reports its Half-Year 2023 Financial Results and Provides an Update on its Activities

- **New identity unveiled, with the aim at developing innovative therapies against cancer**
- **R&D efforts maintained for VIO-01 (formerly OX425) and AsiDNATM**
- **Optimization of PlatONTM platform, targeting new assets in combination with DNA decoys**
- **Cash position of €16.8 million as of June 30, 2023, strengthened by a €12 million capital increase**
- **Financial visibility assured until Q2 2024**
- **Continue to evaluate opportunities for business partnerships**

Paris (France), September 28, 2023 – 8:00 p.m. 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), today reports its consolidated half-year financial results to June 30, 2023, and provides an update on its activities.

Dr. Shefali Agarwal, President and CEO of Valerio Therapeutics, said: *“The first half of 2023 was an important phase for our Company. By renaming ourselves Valerio Therapeutics, we highlighted our will to use innovative technologies such as DNA decoys to advance new anti-cancer treatments.*

AsiDNATM, our first-in-class drug candidate, is currently being evaluated in an ongoing 1b/2 trial in the United State. This study is in combination with Olaparib in recurrent ovarian, breast and metastatic castration-resistant prostate cancer and the objective is to assess the safety and tolerability of the combination as well as to determine the recommended Phase 2 dose. Patient recruitment is progressing, and Top-line results are expected this year.

In parallel, AsiDNATM has also continued to be evaluated in two additional studies in collaboration with French academic research centers, the first one by Gustave Roussy to combat PARP inhibitor resistance in second-line maintenance treatment of recurrent ovarian cancer, and the second one by the Institut Curie in combination with radiotherapy in recurrent high-grade glioma in children.

Finally, our R&D efforts have been focused on the optimization of our PlatONTM platform and the development new therapeutic agents in oncology and other therapeutic agents. We now have a lead candidate from the OX400 compound family, VIO-01 (formerly OX425), a pan DNA repair decoy. This product works by abrogating several DNA repair pathways, inducing a drug-driven synthetic lethality without the need of a combined treatment. This potentially is first of its kind product with a broad applicability and thus represents a promising drug candidate to move forward to clinical development. We continue to explore new therapeutic pathways with PlatONTM and think that PROTACs (PROteolysis-TARgeting Chimeras) technology and other tumor specific targeting options may be a novel class presenting several potential benefits when combined with our DNA decoy molecules.

By all these progresses, Valerio Therapeutics is well positioned to rapidly advance breakthrough therapeutic candidates through Phase 2 development and, eventually, to contribute to the treatment of cancer patients globally. Additionally, we are also continuing active evaluation of business partnerships that can be synergistic to our pipeline and the team.”



FINANCIAL RESULTS FOR THE FIRST HALF OF 2023

Consolidated income statement (IFRS) In thousands of euros	June 30, 2023	June 30, 2022
Revenues, of which:	0	0
<i>Recurring revenues</i>	0	0
<i>Non-recurring revenues</i>	0	0
Operating expenses, including:	(11,622)	(9,631)
<i>R&D expenditure with third parties</i>	(5,643)	(4,107)
Other current operating income	28	282
Current operating income	(11,594)	(9,348)
Other non-recurring operating income	0	385
Income from companies accounted for by the equity method		
Operating income after share of profit of associates	(11,593)	(8,963)
Financial income	(50)	(2,448)
Income tax expense	0	(59)
Net income	(11,644)	(11,471)

The half-year accounts as of June 30, 2023, drawn up according to IFRS standards and approved by the Board of Directors on September 28, 2023, have not been audited nor been the subject of a limited review; being remembered that a new auditor was appointed at the shareholders' meeting held on 6 June 2023.

The Group did not record any **consolidated revenues** for the period ended June 30, 2023.

Operating expenses amounted to €11.6 million. The increase compared to €9.6 million in 2022 is related to the strengthening of the scientific teams, and to the growth in R&D expenses. The latter increased by €1.5 million in the first half of 2023 to reach €5.6 million, mainly due to industrial development and manufacturing of clinical batches for AsiDNA™.

The **financial loss** as of June 30, 2023, amounted to €50k compared to a loss of €2.4 million as of June 30, 2022, mainly due to the cost of the bond issue with SWK Holdings.

The Group's total **net loss** was thus €11.6 million in the first half of 2023, compared with a loss of €11.4 million for the same period in 2022.

CASH POSITION AS OF JUNE 30, 2023

As of June 30, 2023, the Group's cash position was €16.8 million, compared to €14.6 million as of December 31, 2022. This increase comes from a €12 million financing obtained on June 9, 2023, from the Company's historical shareholders, Invus and Financière de la Montagne and a new investor, Agenus Inc. The net proceeds of this reserved share issue are intended for the development of VIO-01 (formerly OX425), both clinically and industrially, for ongoing and future clinical trials and more generally, to finance the Company's current expenses.

Following the completion of the capital increase, Invus Public Equities LP and Financière de la Montagne held 28.5% and 19% of the Company's capital respectively, based on a total of 154,364,273 shares. Agenus held 11.5% of the Company's capital.

These resources provide the Company with sufficient visibility to carry out its projects, including the expansion of the clinical development of AsiDNA™ and the continuation of the preclinical development of the platON™ compounds, including VIO-01, until the second quarter of 2024.



HIGHLIGHTS OF THE FIRST HALF OF 2023 AND RECENT DEVELOPMENTS

AsiDNA™

In the United States, the multi-center Phase 1b/2 study evaluating the safety and efficacy of AsiDNA™ in combination with the PARP inhibitor Olaparib in patients with epithelial ovarian cancer, breast cancer and metastatic castration-resistant prostate cancer who have progressed despite initial treatment with PARP inhibitors was initiated in December 2022, and is currently ongoing, with 1 patient enrolled in the study. The plan is to continue enrollment in the dose escalation phase until the third quarter 2023, convene a Safety Monitoring Committee (SMC) to review the data and identify dose for expansion.

In addition, during the first half of the year 2023, Valerio Therapeutics continued supporting two investigator induced studies conducted in collaboration with two academic research centers of excellence in oncology:

- The Revocan phase 1b/2 trial evaluating the addition of AsiDNA™ to combat PARP inhibitor resistance in second-line maintenance treatment of recurrent ovarian cancer. Gustave Roussy is the promoter of this study. The pace of recruitment has been slower than expected and 15 patients have been enrolled in this first part of the study. The first interim analysis of 10 patients was conducted in the first half of 2023, showing a Disease Control Rate (DCR) of 70 %, an overall reduction in the percentage of CA125 (tumor marker) in responding patients, which serves as a proof of concept of the treatment with AsiDNA™.
- The Phase 1b/2 trial evaluating AsiDNA™ in combination with radiotherapy in recurrent high-grade glioma in children, an indication with a particularly poor prognosis. The Institut Curie is the sponsor of this study, which is supported by a grant from the European Fight Kids Cancer program. The Company has announced the treatment of a first patient in August 2022, 7 patients were enrolled in this first part of the study, no data from the study has been disclosed yet.

VIO-01 (formerly OX425)

During the first half of 2023, the Company continued to optimize the OX400 pan-DDR DNA decoy family to improve its action on repair proteins, involved in the tumor DNA repair cascade, and its activation of the antitumor immune response via the cGAS-STING pathway.

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. Also, the Company 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 of a combined treatment.

3rd generation of PlatON™ 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 strive to advance the field of oncology drug development and contribute to the treatment of cancer patients.

Governance and Corporate

The Annual General Meeting of June 6, 2023, renewed the terms of Financière de la Montagne, represented by Mr. Nicolas Trebouta, and Robert Coleman as directors for three years. 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.

The Annual General Meeting also approved the change of company name to Valerio Therapeutics. This name change was accompanied by a new identity designed to better represent Valerio Therapeutics' ability to rapidly advance breakthrough therapeutic candidates through Phase 2 development, and to collaborate with partners for further development and commercialization. The ISIN code remained unchanged.

OUTLOOK

In 2023, the Company will continue to pursue its value creation strategy based on the development of its therapeutic innovations up to proof-of-concept studies in humans, and then generate revenues through agreements with other pharmaceutical companies capable of pursuing their development.

AsiDNA™

- Enrollment to continue in the U.S. phase 1b/2 trial in combination with Olaparib in ovarian, breast and prostate cancers to identify the RP2D in combination with Olaparib.
- Clinical updates expected in the second half of 2023 from phase 1b/2 trials conducted in France and European Union under the sponsorship of academic centers:
 - REVOCAN trial with Gustave Roussy ;
 - Pediatric trial in High-Grade Glioma with Institut Curie;
 - Submissions for publications in international scientific journals of the results of preclinical or clinical studies as part of the development plan to demonstrate the potential of AsiDNA.

VIO-01 (formerly OX425)

- Finalization of the IND-enabling preclinical studies.
- Preparation of an IND application with the FDA in second half-year 2023.

platON™

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

The 2023 half-year financial report is available on the [Company's website](#).



About Valerio Therapeutics

Valerio Therapeutics (Euronext Growth Paris) 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 Valerio Therapeutics's proprietary chemistry platform of DNA decoy therapeutics, which generates new innovative compounds and broaden the Company's product pipeline.

AsiDNA, the first compound from platON, is a highly differentiated, clinical-stage first-in-class candidate in the field of DNA damage response (DDR) applied to oncology. Its DNA decoy therapeutic mechanism acting upstream of multiple DDR pathways results in distinctive antitumor properties, including the ability to prevent or abrogate tumor resistance to targeted therapies such as PARP inhibitors and strong synergy with tumor DNA-damaging agents such as radio-chemotherapy. AsiDNA is currently being studied in Europe and the US in combination with other treatment modalities in difficult-to-treat solid tumors.

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. OX425 is currently undergoing IND-enabling preclinical development.

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 registration document 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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APPENDIX

CONSOLIDATED FINANCIAL STATEMENTS AT JUNE 30, 2023

CONSOLIDATED BALANCE SHEET

ASSETS (in thousands €)	June 30, 2023	December 31, 2022	Note
Non-current assets			
Intangible assets	20,531	20,531	4
Property, plant and equipment	774	794	
Rights of use	872	1,093	5
Other financial assets	240	90	
Total non-current assets	22,417	22,507	
Current assets			
Trade receivables and related accounts		1,473	6.1
Other current receivables	4,777	4,521	6.2
Cash and cash equivalents	16,826	14,586	7
Total current assets	21,603	20,579	
TOTAL ASSETS	44,020	43,086	

LIABILITIES AND SHAREHOLDERS' EQUITY (in thousands of €)	June 30, 2023	December 31, 2022	Note
Shareholders' equity			
Capital	38,591	27,877	8.1
Less: Treasury shares	-97	-81	8.2
Additional paid-in capital	28,991	27,705	8.3
Retained earnings	-32,666	-13,669	
Result	-11,644	-19,562	
Total shareholders' equity	23,176	22,270	
Non-current liabilities			
Non-current provisions	764	869	9.1
Deferred tax liability			
Non-current financial debts	7,547	8,104	9.2
Non-current lease liabilities	450	646	9.2
Other non-current liabilities		4,048	
Total non-current liabilities	8,762	13,667	
Current liabilities			
Current provisions		20	
Short-term borrowings and financial liabilities	1,212	1,003	10.1
Current lease liabilities	327	335	
Trade payables and related accounts	4,388	3,449	10.2
Other current liabilities	6,155	2,342	10.3
Total current liabilities	12,082	7,149	
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	44,020	43,086	



CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

In thousands of €	June 30, 2023	June 30, 2022	Note
Recurring revenue from license agreements			
Non-recurring revenue from license agreements			
Total revenues	0	0	11.1
Purchases consumed	-219	-242	
Personnel expenses	-5,011	-4,258	11.2
External expenses	-6,128	-4,652	11.3
Taxes	-28	-25	
Net depreciation and provisions	-111	-237	
Other current operating expenses	-127	-217	
Operating expenses	-11,622	-9,631	
Other current operating income	28	282	
Recurring operating income	-11,594	-9,348	
Other operating income	0	385	
Other operating expenses	-417	0	
Share of profit from equity affiliates			
Operating income after share of profit from equity affiliates	-11,593	-8,963	
Cost of net financial debt	-14	-2,154	
Other financial income	10	122	
Other financial expenses	-46	-416	
Financial income	-50	-2,448	12
Income before tax	-11,644	-11,412	
Income tax expense	0	-59	
- of which deferred tax			
Net income of all consolidated accounts	-11,644	-11,471	
Earnings per share	-0.08	-0.11	13

In thousands of €	June 30, 2023	June 30, 2022	Note
Earnings for the period	-11,644	-11,471	
Translation differences	133	113	
Other items that can be reclassified to profit or loss	133	113	
Actuarial gains and losses		93	
Other items that cannot be reclassified to profit or loss		93	
Other comprehensive income for the period, net of tax	133	207	
Total comprehensive income for the period	-11,511	-11,264	
Total comprehensive income attributable to:			
- owners of parent	-11,511	-11,264	
- non-controlling interests			



CONSOLIDATED STATEMENT OF NET CASH FLOWS

In thousands of €	Note	June 30, 2023	December 31, 2022	June 30, 2022
Consolidated net income		-11,644	-19,562	-11,471
+/- Net depreciation and provisions (excluding those related to current assets)	4, 5, 9.1	125	-167	48
-/+ Unrealized gains and losses related to changes in fair value				174
+/- Income and expenses calculated in relation to stock options and similar instruments	8.4	270	213	219
-/+ Other calculated income and expenses			724	
-/+ Capital gains and losses on disposals				
-/+ Dilution gains and losses				
+/- Share of profit from equity affiliates				
+/- Other items with no impact on cash				
Cash flow from operations after cost of net financial debt and tax		-11,249	-18,792	-11,029
+ Cost of gross financial debt	12	42	2,189	2,157
+/- Tax expense (including deferred taxes)			285	59
Cash flow from operations before cost of net financial debt and tax		-11,207	-16,318	-8,813
- Tax paid				
+/- Change in operating working capital requirements (including employee benefit liabilities)		2,087	-6,875	7,368
NET CASH FLOW PROVIDED BY OPERATING ACTIVITIES		-9,120	-9,443	-1,446
- Disbursements related to acquisitions of property, plant and equipment and intangible assets		-97	-488	-71
+ Cash receipts related to disposals of property, plant and equipment and intangible assets				
- Disbursements related to acquisitions of financial assets (non-consolidated shares)				
+ Cash receipts related to disposals of financial assets (non-consolidated shares)			80	3
+/- Impact of changes in the scope of consolidation				
+ Dividends received (equity affiliates, non-consolidated shares)				
+/- Change in loans and advances granted				
+ Investment grants received				
+/- Other flows related to investment operations				
NET CASH FLOW USED IN INVESTING ACTIVITIES		-97	-409	-68
+ Sums received from shareholders on capital increases				
. Paid by the shareholders of the parent company	8.1	12,000	7,875	7,961
. Paid by minority shareholders of consolidated companies				
+ Amounts received on exercise of stock options				
-/+ Net repurchases and resales of own shares	8.2		99	37
+ Cash inflow from new loans				
- Loan repayments (including finance leases)	9.2, 10.1	-550	1,513	2,343
Of which reimbursement of rights of use (IFRS16)		-166	-405	-238
+/- Other flows related to financing operations		-7	1	3
NET CASH FLOW USED IN FINANCING ACTIVITIES		11,443	6,463	10,343
+/- Impact of foreign exchange rate changes		12	87	144
CHANGE IN NET CASH FLOW		2,238	-3,301	8,974
INITIAL CASH FLOW		14,585	17,886	17,886
FINAL CASH FLOW		16,823	14,585	26,861