



Press Release

Poxel Reports Financial Results for First Half 2024 and Provides an Update on its Financial Position and Outlook

- **Following the non-adoption of certain financial delegations at the Annual General Meeting of November 28, 2024:**
 - **Cash runway significantly reduced**
 - **Redemption of the ORANE held by IRIS due, rendering redemption of the IPF Partners bonds also due in the absence of a new General Meeting authorizing the issue of new shares to redeem the ORANE**
 - **Without the renewal of the authorization by the General Meeting and subject to an agreement with its creditors, the Company may not be able to meet the redemption requests of IRIS and IPF Partners**
- **Suspension by the Company until further notice of the drawdown of new ORANE tranches under the equity-linked financing facility put in place with IRIS**
- **Downward revision of corporate officers' compensation**
- **Upcoming Combined General Meeting to be held on February 11, 2025, to adopt new financial delegations to maintain the cash runway to end-2025 and avoid the immediate redemption of the ORANE and the IPF Partners bonds**

LYON, France, December 9, 2024 – [POXEL SA](#) (Euronext : POXEL - FR0012432516), a clinical stage biopharmaceutical company developing innovative treatments for chronic serious diseases with metabolic pathophysiology, including metabolic dysfunction-associated steatohepatitis (MASH) and rare metabolic disorders, today announces its half-year financial results for the period ended June 30, 2024 and provides an update on its financial situation and outlook, in particular following the non-adoption of certain financial resolutions by the Annual General Meeting on November 28, 2024.



First Half 2024 Financial Statements (IFRS Standards)

Income statement¹

<i>EUR (in thousands)</i>	H1 2024 6 months	H1 2023 6 months
Revenue	1,162	955
Cost of sales	(1,146)	(955)
Gross margin	16	-
Net research and development expenses*	(521)	(2,424)
Depreciation and amortization of intangible assets	-	(16,572)
General and administrative expenses	(3,205)	(4,278)
Operating income (loss)	(3,710)	(23,274)
Financial income (expenses)	(3,548)	(2,968)
Income tax	-	-
Net income (loss)	(7,258)	(26,243)

*Net of R&D tax credit.

As already announced on September 9, 2024, Poxel reported revenue of EUR 1.162 million in the first half of 2024, as compared to EUR 955 thousand for the same period in 2023, mainly corresponding to the JPY 199 million (EUR 1,162 thousand²) of royalty revenue from Sumitomo Pharma, which represents 8% of TWYMEEG net sales in Japan.

Cost of sales amounted to EUR 1.1 million as of June 30, 2024, corresponding to the 8% royalties on net sales of Imeglimin in Japan due to Merck Serono, as part of the Merck Serono license agreement.

R&D expenses totaled EUR 0.5 million for the first half of 2024, as compared to EUR 2.4 million for the same period in 2023. R&D expenditures are net of the R&D Tax Credit (CIR) that represented income of EUR 0.1 million for the first half of 2024, as compared to EUR 0.3 million for the same period in 2023.

¹ The Statutory Auditors' review procedures have been completed. The Statutory Auditors' report stating that they are unable to form a conclusion on the condensed interim consolidated financial statements for the six months ended June 30, 2024, due to the going concern risk, will be issued in the next few days.

² Converted at the exchange rate as of June 30, 2024



General and administrative expenses came to EUR 3.2 million for the first half of 2024, as compared to EUR 4.3 million for the corresponding period in 2023, reflecting in particular the savings plan undertaken by the Company.

The financial loss amounted to EUR 3.5 million for the first half of 2024, as compared to EUR 3.0 million for the first half of 2023. This was mainly due to the interests attached to the Company indebtedness.

The net loss for the financial period ending June 30, 2024, came to EUR 7.3 million, as compared to EUR 26.2 million for the same period in 2023.

The Company will publish its half-yearly financial report in the next few days. This report will include the statutory auditors' limited review reports on the consolidated financial statements for the six months ended June 30, 2024.

Significant reduction in cash runway in the absence of full residual drawdown of the equity-linked financing facility

As announced on September 30, 2024, following the non-dilutive financing agreement with OrbiMed, the Company extended its cash runway to the end of 2025, assuming the inclusion of the full residual drawdown of the equity-linked financing facility put in place with IRIS³, the latter assuming that the Company has the necessary financial delegations at the time of drawdown and conversion of the ORANE.

The non-adoption of most of the financial delegations at the Annual General Meeting on November 28, 2024, and, in particular, the one relating to the issue of new shares in redemption of ORANE, which was intended to replace a similar delegation due to expire on December 20, 2024, entails, in accordance with the agreements entered into with IRIS and IPF Partners respectively, the redemption of the ORANE held by IRIS, the latter also results in the redemption of the IPF Partners bonds, unless a new Extraordinary General Meeting, convened no later than 63 days from the date of notification of the Company's failure to deliver new shares, adopts a resolution renewing the delegation necessary for the continued redemption of the ORANE in shares.

Despite the recent restructuring of the Company's debt made possible in particular by the monetization transaction with OrbiMed, which extended Poxel's cash runway to the end of 2025, the non-adoption of most financial delegations, and in particular that relating to the issue of new shares in redemption of ORANE, but also including more usual delegations for biotechnology companies willing to raise capital, places the Company, as well as its shareholders, in an unprecedented,

³ Since March 31, 2023, 16 additional tranches have been drawn down for a total of EUR 8.3 million. An additional amount of EUR 3.2 million could be drawn down by the Company depending on liquidity and exposure conditions under the IRIS contract and subject to the adoption of the Company's appropriate financial delegations.



uncertain and potentially very negative situation for the pursuit of its activities.

In particular, the non-adoption of the delegation allowing the issue of shares in redemption of ORANE held by IRIS for a total amount, to date, of EUR 4.3 million or that may still be issued in the event of the draw down of additional ORANE from IRIS (i.e. EUR 3.2 million) under the equity-linked financing program signed by Poxel with IRIS in August 2022 and renewed in March 2023, significantly affects the Company's cash flow forecasts and its ability to continue as a going concern.

In this context, and based on the cash position as of September 30, 2024, amounted to EUR 13.1 million and taking into account the following financial items affecting the Company's financial situation:

- (i) partial repayments of the PGE loans according to the new schedule agreed upon as part of the Company's debt restructuring with its creditors;
- (ii) advisory fees incurred in the framework of the transaction concluded with OrbiMed; and
- (iii) the anticipated business plan including strict control of operating expenses,

the Company now expects to be able to finance its operations and capital expenditures only until the end of the 1st quarter of 2025, at which point it would no longer be able to meet its expenses if the current situation is not resolved.

Significant additional financial risk

In the event of non-fulfilment by the Company of its obligation to deliver shares following a request for conversion of ORANE by IRIS resulting from an absence of financial authorization, IRIS may request, in accordance with the terms of the contract of issuance, the early redemption of all outstanding ORANE, i.e. EUR 4.3 million to date, unless the Company holds an Extraordinary General Meeting within 63 days of notification by IRIS of the failure to deliver shares and obtains the approval of the resolution to remedy the situation.

The failure by such an Extraordinary General Meeting to adopt a new authorization to redeem ORANE in shares would result in the ORANE becoming immediately redeemable.

In the event of non-adoption of this authorization, and in the absence of an agreement with IRIS and IPF Partners respectively, the latter would also have the right under the terms of the agreements relating to its bonds to impose its immediate redemption for an amount of EUR 17.1 million⁴ to date (including EUR 13 million in principal and EUR 4.1 million in exit fees).

⁴ Not including the residual amount of the deposit account set up in connection with the monetization of royalties with OrbiMed, which will be fully dedicated to repayment of this debt



In this case, the Company would not have the cash required to meet its anticipated redemption obligations, which would significantly compromise its ability to continue as a going concern and the continuation of its activities.

Convening of a new General Meeting aimed at adopting new financial delegations and resolutions relating to the compensation policy for corporate officers

As stated in the press release of November 29, 2024⁵ announcing the results of the Annual General Meeting of November 28, 2024, the Board of Directors noted that certain financial delegations as well as policies on the compensation of corporate officers had not been adopted.

Acknowledging the questions asked by the Company's shareholders prior to and during the Annual General Meeting, in particular concerning the continuation of the financing program underway with IRIS and the compensation policy for corporate officers, and also, the non-adoption of the aforementioned resolutions (including the very usual delegations for any biotech company having recourse to the issue of equity securities or securities giving access to capital for its financing), the Board of Directors has decided to suspend until further notice its drawings under the equity-linked financing facility put in place with IRIS.

The Board of Directors also decided to revise downwards the compensation policy for the Company's corporate officers. A new compensation policy will therefore be submitted to the next General Meeting.

As the Company's ability to comply with the going concern principle depends in particular on its ability to raise capital to finance its activities and to honor its commitments to its current financial creditors, the Board of Directors has thus decided to resubmit for shareholder approval new resolutions, firstly on financial matters and secondly on the compensation policy for its corporate officers at a Combined General Meeting to be held on February 11, 2025.

This Combined General Meeting will enable Poxel shareholders to assume their responsibilities with regard to their Company's financial situation, its going concern and their interests as shareholders.

In preparation for the forthcoming General Meeting, the convening of which will be announced in a press release, and to review the available options to explore financing and operational continuity options, the Company has also engaged discussions with its current creditors.

⁵ ["Poxel Announces Results from November 28, 2024 Annual General Meeting"](#), on November 29, 2024



Context of the preparation of the consolidated financial statements as of June 30, 2024

In light of the above-described factors, the Company believes that its ability to continue as a going concern is tied to the outcome of the shareholders' vote on the resolutions that will be submitted at the General Meeting scheduled on February 11, 2025.

The Board of Directors of December 6, 2024, approved the Company's condensed interim consolidated financial statements ended June 30, 2024, in compliance with the going concern principle, assuming that shareholders will cast a positive vote at the Extraordinary General Meeting to be held on February 11, 2025, which could extend its cash runway until the end of 2025.

At the meeting of the Board of Directors on December 6, 2024, the Statutory Auditors indicated that their report would include an inability to reach a conclusion on the condensed interim consolidated financial statements at June 30, 2024, due to the uncertainties surrounding going concern arising from the non-adoption of the financial resolutions by the Annual General Meeting on November 28, 2024, and the uncertainty associated with the adoption of new resolutions at the next General Meeting scheduled for February 11, 2025.

Indeed, if the resolutions presented to this General Meeting were not adopted and no new agreements were reached between the Company and its creditors, the Company would not have the cash resources to meet its early repayment obligations, which would significantly compromise its ability to continue as a going concern.

Next Financial Press Release:

- **Fourth Quarter 2024 Cash and Revenue update**, on February 19, 2025



About Poxel SA

Poxel is a **clinical stage biopharmaceutical company** developing **innovative treatments for chronic serious diseases with metabolic pathophysiology**, including **metabolic dysfunction-associated steatohepatitis (MASH)** and rare disorders. For the treatment of MASH, **PXL065** (deuterium-stabilized *R*-pioglitazone) met its primary endpoint in a streamlined Phase 2 trial (DESTINY-1). In rare diseases, development of **PXL770**, a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator, is focused on the treatment of adrenoleukodystrophy (ALD) and autosomal dominant polycystic kidney disease (ADPKD). **TWYMEEG®** (Imeglimin), Poxel's first-in-class product that targets mitochondrial dysfunction, is now marketed for the treatment of type 2 diabetes in Japan by Sumitomo Pharma and Poxel expects to receive royalties and sales-based payments. Poxel has a strategic partnership with Sumitomo Pharma for Imeglimin in Japan. Listed on Euronext Paris, Poxel is headquartered in Lyon, France, and has subsidiaries in Boston, MA, and Tokyo, Japan. For more information, please visit: www.poxelpharma.com

All statements other than statements of historical fact included in this press release about future events are subject to (i) change without notice and (ii) factors beyond the Company's control. These statements may include, without limitation, any statements preceded by, followed by or including words such as "target," "believe," "expect," "aim," "intend," "may," "anticipate," "estimate," "plan," "project," "will," "can have," "likely," "should," "would," "could" and other words and terms of similar meaning or the negative thereof. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that could cause the Company's actual results or performance to be materially different from the expected results or performance expressed or implied by such forward-looking statements. The Company does not endorse or is not otherwise responsible for the content of external hyperlinks referred to in this press release.

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Glossary

You will find below a list of words and/or expressions that are used in this press release or in Poxel's communication, with the aim to bring clarification and transparency:

- **Sumitomo Pharma fiscal year** runs April to March. As an example, Fiscal Year 2024 is April 1, 2024, through March 31, 2025.
- **TWYMEEG royalties:** As per the Sumitomo Pharma's agreement, Poxel is entitled to receive royalties from the sales of TWYMEEG (Imeglimin) in Japan
 - Sumitomo Pharma communicates gross sales of TWYMEEG, while TWYMEEG royalties are calculated on net sales.
 - Net sales represent the amount of gross sales to which are deducted potential rebates, allowances, and costs such as prepaid freight, postage, shipping, customs duties and insurance charges.
 - Poxel is entitled to receive escalating royalties of 8-18% on TWYMEEG net sales from Sumitomo Pharma.
- **Positive net royalties:** as part of the Merck Serono licensing agreement, Poxel will pay Merck Serono a fixed 8% royalty based on the net sales of TWYMEEG, independent of the level of sales. All royalties that Poxel receives from TWYMEEG net sales above that 8% level are considered as positive net royalties. Net royalties will therefore be positive for Poxel when TWYMEEG net sales exceed JPY 5 billion in a fiscal year and royalties reach 10% and above.