



Press Release

Poxel Reports Cash and Revenue for the Third Quarter and Nine Months 2024 and Provides Corporate Update

- TWYMEEG[®] sales continue to increase in Japan for the last quarter (July-September) by 5% over the prior quarter and by 23% over the 3rd quarter 2023
- Poxel expects TWYMEEG[®] net sales in Japan in the near term to reach at least JPY 5 billion (EUR 30.6 million)¹ entitling the Company to receive 10% royalties on all TWYMEEG[®] net sales and a sales-based payment of JPY 500 million (EUR 3.1 million)¹
- Continued discussions with potential partners in parallel of reviewing the clinical development strategy for PXL770 and PXL065 for the treatment of multiple rare diseases
- As of September 30, 2024, cash and cash equivalents were EUR 13.1 million (USD 14.7 million)²
- Following the non-dilutive financing agreement with OrbiMed, cash runway extension until end of 2025, including the full residual drawdown of the equity-linked financing facility put in place with IRIS

LYON, France, November 6, 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 provided a corporate update and announced its cash position and revenue for the third quarter and the nine months ended September 30, 2024.

"We are pleased to see the good sales trajectory for TWYMEEG[®] in Japan, which should lead to the achievement of JPY 5 billion net sales in the coming months, at which point, Poxel will be entitled to 10% royalties on all TWYMEEG[®] net sales and a sales-based payment of JPY 500 million (EUR 3.1 million)¹. These amounts, based on our recent royalty monetization agreement, will serve to start repayment of bonds to OrbiMed. Additionally, Poxel will benefit from the residual amount of the reserve deposit made under the terms of the agreement with OrbiMed, in addition to the USD 42.5 million proceeds received upon closing. This deposit amount will be used to further reduce our debt obligations towards IPF Partners," stated **Thomas Kuhn, Chief Executive Officer of Poxel.**

¹ Converted at the exchange rate as of March 31, 2024

² Converted at the exchange rate as of September 30, 2024.



TWYMEEG® (Imeglimin)

- For the quarter ended September 2024, TWYMEEG® gross sales in Japan increased by 5% to JPY 1.8 billion (EUR 11.4 million)² over the prior quarter sales of JPY 1.7 billion (EUR 10.1 million)³ as reported by Sumitomo Pharma.
- During Sumitomo Pharma FY 2024, Poxel expects TWYMEEG® net sales in Japan to reach at least JPY 5 billion (EUR 30.6 million)¹, entitling Poxel to receive 10% royalties on all TWYMEEG® net sales and a sales-based payment of JPY 500 million (EUR 3.1 million)¹. Based on the recent royalty monetization agreement with OrbiMed, these proceeds for FY2024, net of Poxel's obligation to Merck Serono, will be directed to the reimbursement of the bonds issuance. Beyond 2024, Poxel expects to receive escalating double-digit royalties as well as additional sales-based payments upon achievement of contractually based sales thresholds.
- Sumitomo Pharma has announced an early retirement program in Japan that could impact their organization, including Sales & Marketing division. However, to support TWYMEEG® sales trajectory, Sumitomo Pharma is implementing measures to minimize potential impact from this program.
- As announced on August 7, 2024, topline results obtained from the post-marketing clinical study, TWINKLE (TWYMEEG® in diabetic patients with renal impairment: A post-marketing long-term study) conducted by Sumitomo Pharma in Japanese type 2 diabetic patients with renal impairment confirmed TWYMEEG®'s safety and tolerability profile, which is consistent with prior clinical studies in the general type 2 diabetes population. Based on these results, Sumitomo Pharma has initiated discussions with the regulatory authorities in Japan for revising TWYMEEG® package insert for patients with renal impairment with eGFR (estimated glomerular filtration rate) less than 45 mL/min/1.73m².
- In parallel of the non-dilutive financing agreement with OrbiMed announced on September 30, 2024, Poxel recovered the Imeglimin rights for Asian countries other than Japan⁴ from Sumitomo Pharma. The Company has already initiated discussions to develop and market Imeglimin in China, the world's second largest type 2 diabetes market.

³ Converted at the exchange rate as of June 30, 2024.

⁴ China, South Korea, Taiwan, Indonesia, Vietnam, Thailand, Malaysia, The Philippines, Singapore, Republic of the Union of Myanmar, Kingdom of Cambodia and Lao People's Democratic Republic.



Third Quarter and Nine Months Ended September 30, 2024, Revenue and Cash

Revenue

Poxel reported revenues of EUR 854 thousand for the third quarter 2024, bringing the revenues for the nine months ended September 30, 2024, to EUR 2,016 thousand as compared to EUR 1,619 thousand during the corresponding period in 2023.

Revenue for the first nine months of 2024 mostly reflects the JPY 328 million (EUR 2,016 thousand)² of royalty revenue from Sumitomo Pharma which represents 8% of TWYMEEG[®] net sales in Japan. Based on the current forecast, Poxel expects to receive 10% royalties on TWYMEEG[®] net sales in Japan through the Sumitomo Pharma fiscal year 2024 and a sales-based payment of JPY 500 million (EUR 3.1 million)¹. As part of the Merck Serono licensing agreement, Poxel will pay Merck Serono a fixed 8% royalty based on the net sales of Imeglimin, independent of the level of sales. According to the Royalty Monetization agreement with OrbiMed, the positive net Royalties will be fully dedicated to the repayment of the bonds.

EUR (in thousands)	Sept. 2024 9 months	Q3 2024 3 months	H1 2024 6 months	Sept. 2023 9 months	Q3 2023 3 months	H1 2023 6 months
Sumitomo Pharma Agreement	2,016	854	1,162	1,619	664	955
Other	-	-	-	-	-	-
Total revenues	2,016	854	1,162	1,619	664	955

Unaudited data

Cash and cash equivalents

As of September 30, 2024, total cash and cash equivalents were EUR 13.1 million (USD 14.7 million)², as compared to EUR 2.8 million as of June 30, 2024.

EUR (in thousands)	Q3 2024	Q2 2024	Q1 2024	Q4 2023
Cash	13,149	2,812	2,460	2,341
Cash equivalents	-	-	-	-
Total cash and cash equivalents	13,149	2,812	2,460	2,341

Unaudited data



Following the non-dilutive financing agreement with OrbiMed, and according to Poxel's current forecasts, including in particular:

- (i) The Company's cash position as of September 30, 2024, at EUR 13.1 million;
- (ii) the partial redemption of the PGE loans for a total amount of EUR 2.8 million;
- (iii) the advisory fees linked to the transaction;
- (iv) the full residual drawdown of the equity-linked financing facility put in place with IRIS⁵; and
- (v) the anticipated business plan including strict control of its operating expenses;

the Company expects that its resources will be sufficient to finance its operations and capital expenditures until the end of 2025.

Next Financial Press Releases:

- First Half Results, on December 9, 2024
- Fourth Quarter 2024 Cash and Revenue update, on February 12, 2025

⁵ Since March 31, 2023, 15 additional tranches have been drawn down for a total of EUR 7.8 million. 5 tranches are currently secured for a total of EUR 2.5 million, and an additional amount of 1.2 million euros could be drawn down by the Company depending on the liquidity and exposure conditions under the contract.



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.