



Press Release

Poxel Reports Revenue for the Second Quarter and First Half 2024 and Provides Corporate Update

- TWYMEEG[®] sales in Japan for Q2 (April-June) increased 62% vs. the prior quarter (January-March)
- Exclusive discussions being finalized with a leading investor to monetize royalties from sales of TWYMEEG[®] (Imeglimin) in Japan
- As of June 30, 2024, cash and cash equivalents amounted to EUR 2.8 million (USD 3 million¹)
- Cash horizon estimated to be sufficient until the completion of the contemplated transaction on monetization of royalties, including only the tranches already drawn down or fully available under the equity-linked financing facility with IRIS

LYON, France, September 9, 2024 – [POXEL SA](#) (Euronext: POXEL - FR0012432516), a clinical stage biopharmaceutical company developing innovative treatments for chronic serious diseases with metabolic pathophysiology, including non-alcoholic steatohepatitis (NASH) and rare metabolic disorders, today provided a corporate update and announced its revenue for the second quarter and first half of 2024.

Thomas Kuhn, Chief Executive Officer of Poxel, stated: *"As our exclusive discussions to monetize royalties from sales of TWYMEEG[®] in Japan are finalizing, the topline results recently obtained by our partner Sumitomo Pharma from the TWINKLE post-marketing clinical study confirm the profile of the product for type 2 diabetic patients with renal impairment. These results provide a basis for our partner to conduct discussions with the regulatory authorities in Japan on revising TWYMEEG[®] 's package insert and, on the appropriateness, to recommend TWYMEEG[®] to Japanese type 2 diabetic patients with renal impairment."*

¹ Converted at the exchange rate on June 30, 2024



TWYMEEG® (Imeglimin)

Commercial update, clinical development, intellectual property and scientific publications

- For the quarter ended June 2024, TWYMEEG® gross sales in Japan increased 62% to JPY 1.7 billion (EUR 10.1 million)¹ over the prior quarter sales of JPY 1.1 billion (EUR 6.6 million)² as reported by Sumitomo Pharma.
- For its FY 2024³, Sumitomo Pharma forecasts⁴ gross sales for TWYMEEG® of JPY 11.3 billion (EUR 69.1 million)² which would represent a 150% increase over FY 2023 TWYMEEG® gross sales.
- During Sumitomo Pharma FY 2024³, Poxel expects TWYMEEG® net sales in Japan to reach at least JPY 5 billion (EUR 30.6 million)² entitling Poxel to receive 10% royalties on all TWYMEEG® net sales and a sales-based payment of JPY 500 million (EUR 3.1 million)². Based on this FY 2024 forecast, TWYMEEG® net sales could also reach JPY 10 billion (EUR 61.2 million)² entitling Poxel to receive 12% royalties on all TWYMEEG® net sales and a second sales-based payment of JPY 1 billion (EUR 6.1 million)². Beyond 2024, Poxel expects to receive escalating double-digit royalties as well as additional sales-based payments upon achievement of contractually based sales thresholds.
- Several scientific presentations on TWYMEEG®'s innovative mechanism of action and potential additional benefits, in addition to its anti-diabetic activity were shared at the 67th Annual Meeting of the Japanese Diabetes Society (JDS), held in Tokyo, Japan, from May 17 to 19, 2024, and at the 84th Scientific Sessions of the American Diabetes Association in Orlando, Florida. New preclinical and clinical data will be presented at the 60th Annual Congress of the European Association for the Study of Diabetes (EASD).
- On May 29, 2024, the Japanese Patent Office approved the remaining two Patent Term Extension (PTE) applications, granting Poxel an extension to patents n°5542066 and n°5758010, protecting Imeglimin's synthesis process. As a result of this approval, it extends the product patent life until 2036.
- As announced on August 7, 2024, topline results obtained from the open-label, uncontrolled, long-term 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 is planning to conduct discussions

² Converted at the exchange rate on March 31, 2024

³ Sumitomo Pharma fiscal year 2024 ends March 31, 2025

⁴ As per Sumitomo Pharma FY2024 forecast published on May 14, 2024



with the regulatory authorities in Japan during its FY 2024³, on revising TWYMEEG[®] package insert in fiscal 2024 for patients with renal impairment with eGFR (estimated glomerular filtration rate) less than 45 ml/min/1.73m².

Second Quarter and First Half 2024 Revenue

Poxel reported revenue of EUR 1,162 thousand (unaudited data) for the six months ended June 30, 2024, as compared to EUR 955 thousand revenue during the corresponding period in 2023.

Revenue for the first half of 2024 reflects JPY 199 million (EUR 1,162 thousand)¹ of royalty revenue from Sumitomo Pharma which represents 8% of TWYMEEG net sales in Japan. Based on the current forecast, Poxel expects to receive at least 10% royalties on TWYMEEG[®] net sales in Japan through the Sumitomo Pharma fiscal year 2024³. 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.

<i>EUR (in thousands)</i>	Q1	Q2	H1	Q1	Q2	H1
	2024	2024	2024	2023	2023	2023
	3	3	6	3	3	6
	months	months	months	months	months	months
Sumitomo Pharma Agreement	449	713	1,162	449	506	955
Other	-	-	-	-	-	-
Total revenues	449	713	1,162	449	506	955

Unaudited data

Second Quarter and First Half 2024 Cash and Cash equivalents

As of June 30, 2024, total cash and cash equivalents amounted to EUR 2.8 million (USD 3 million¹), compared with EUR 2.3 million (USD 2.6 million⁵) as of December 31, 2023 (unaudited data). Net financial debt (excluding IFRS16 impacts and derivative debts) amounted to EUR 46.6 million as of June 30, 2024, compared with EUR 45.6 million as of December 31, 2023 (unaudited data).

<i>EUR (thousands)</i>	Q2 2024	Q4 2023
Cash	2,812	2,341
Cash equivalents	-	-
Cash and cash equivalents	2,812	2,341

Unaudited data.

⁵ Converted at the exchange rate on December 31, 2023



Finalization of exclusive discussions with a leading investor to monetize royalties from sales of TWYMEEG[®] (Imeglimin) in Japan and cash runway

With the priority objective of relaunching its R&D activities and executing its strategic plan in rare diseases, the Company has focused in recent months on securing additional financing, in particular non-dilutive solutions. In this context, the Company is currently finalizing exclusive negotiations initiated several months ago with a leading investor to monetize royalties from TWYMEEG[®] (Imeglimin) sales in Japan. In addition, the Company is in advanced discussions – in some cases on an exclusive basis – with several potential partners for each of its three products: Imeglimin, for several countries not covered by its agreement with Sumitomo Pharma, PXL065 and PXL770.

Based on:

- (i) its cash position on June 30, 2024,
- (ii) tranches already drawn⁶ or fully available as of the date of this press release under the equity-linked financing facility with IRIS,
- (iii) no research and development expenses, and
- (iv) a strict control of operating expenses,

Poxel expects that its resources, including funds available to it, will be sufficient to maintain its operations and capital expenditure until completion of the current process underway to monetize royalties from sales of TWYMEEG[®] (Imeglimin) in Japan.

Rescheduling of the 2024 Annual General Meeting

In view of the importance of the transaction to monetize royalties, which is key for the Company to continue its operations, and which will be taken into consideration for the closing of the Company's social and consolidated financial statements for the year ending December 31, 2023, Poxel requested and received confirmation from the Lyon Commercial Court of the rescheduling of its Annual General Meeting, which must be held on December 31, 2024 at the latest.

Once its social and consolidated financial statements are approved by the Board of Directors, Poxel will inform the market and its shareholders, and will publish its Universal Registration Document, including its 2023 annual financial report and its new financial calendar for 2024, including the new date set of its General Meeting.

⁶ Since March 31, 2023, 13 additional tranches have been drawn for a total amount of EUR 6.8 million.



Planned Presentations and Participations of the Company at the Following Upcoming Events

European MidCap Event, October 1st and 2nd, 2024 (in-person)

- Thomas Kuhn, CEO, will be available for one-on-one in-person meetings.

H.C. Wainwright 8th Annual MASH⁷ Virtual Conference, October 7, 2024 (virtual)

- Thomas Kuhn, CEO, will be available for one-on-one meetings.

⁷ Metabolic dysfunction-associated steatohepatitis also called NASH.



About Poxel SA

Poxel is a **clinical stage biopharmaceutical company** developing **innovative treatments for chronic serious diseases with metabolic pathophysiology**, including **non-alcoholic steatohepatitis (NASH)** and rare disorders. For the treatment of NASH, **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 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, China, and eleven other Asian countries. 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.

Contacts - Investor relations / Media

NewCap

Nicolas Fossiez, Aurélie Manavarere / Arthur Rouillé

investor@poxelpharma.com

+33 1 44 71 94 94





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 from April to March. As an example, Fiscal Year 2023 is April 1, 2023, through March 31, 2024.
- **TWYMEEG[®] royalties:** As per the Sumitomo Pharma's agreement, Poxel is entitled to receive royalties from the sales of TWYMEEG[®] (Imeglimin) in Japan
 - TWYMEEG[®] royalties are calculated on net sales, while Sumitomo Pharma communicates only TWYMEEG[®] gross sales.
 - Poxel entitled to receive escalating royalties of 8-18% on TWYMEEG[®] net sales from Sumitomo Pharma.
- **Positive net royalties:** refers to royalties Poxel receives from TWYMEEG[®] net sales after paying Merck Serono the first 8%, once Poxel starts to receive 10% royalties upon TWYMEEG[®] net sales exceeding JPY 5 billion in a fiscal year.