



Press release

Poxel Announces Agreement with OrbiMed to Monetize a portion of TWYMEEG[®] Royalties for USD 50 million

- One time cash payment of USD 50 million in the form of bonds issuance from OrbiMed
- In return OrbiMed to obtain the royalties received by Poxel from sales by Sumitomo Pharma of TWYMEEG[®] in Japan for a total amount of USD 100 million
- Rights to royalty payments returned to Poxel once OrbiMed receives an aggregate payment of USD 100 million
- Proceeds from the OrbiMed's bonds issuance will be used to (i) reduce the Company's debt towards IPF Partners and the PGE banks, after amendment of the loan agreements, to a total remaining amount of EUR 15,3 million and (ii) to support its strategic plan in rare diseases, while pursuing partnership discussions for its products
- Return of Imeglimin rights for countries covered by the agreement with Sumitomo Pharma other than Japan¹, as Sumitomo Pharma intends to focus its efforts on TWYMEEG[®] commercialization in its domestic market, Japan
- Ongoing partnering discussions to develop and market Imeglimin in China, the world's second-largest type 2 diabetes market
- Cash runway extension until end of 2025 including the full residual drawdown of the equity-linked financing facility put in place with IRIS

The management team will host webinars today, on September 30, 2024, at:

- **1:00 pm CEST, Paris time** (7:00 am ET) in **French** and
- **8:45 am ET, New York time** (2 :45 pm CEST) in **English**.

A presentation will be available on Poxel's website in the [Investor section](#).

To register for the webinar in **French**:

<https://app.livestorm.co/newcap-1/poxel-presentation-de-laccord-de-monetisation-des-redevances-issues-des-ventes-de-twymeeg-r-conclu-avec-orbimed?type=detailed>

To register for the webinar in **English**:

<https://app.livestorm.co/newcap-1/poxel-presentation-of-the-royalty-monetization-agreement-based-on-twymeeg-r-sales-with-orbimed?type=detailed>

¹ 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.



LYON, France, September 30, 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 announces that it entered into a non-dilutive financing agreement with OrbiMed for USD 50 million to monetize a portion of Poxel's future royalties and sales-based payments from TWYMEEG[®] sales by Sumitomo Pharma in Japan. Poxel intends to use the proceeds of the transaction to pursue its activities in the field of rare diseases, reduce the Company's debt towards IPF Partners and the PGE banks, and finance general corporate purposes. TWYMEEG[®] is Poxel's first-in-class product marketed for the treatment of type 2 diabetes in Japan.

"This transaction with OrbiMed, a leading healthcare investment firm, reflects the significant value of TWYMEEG[®] in Japan, based on our strategic partnership with Sumitomo Pharma. We are pleased that this transaction strengthens our balance sheet and provides non-dilutive financing to continue our strategic plan in rare diseases and reduce the Company's debt towards IPF Partners and the PGE banks. We aim to finalize our ongoing advanced discussions with several potential partners for each of our products, before finalizing our investment decisions and executing our development plans for PXL770 and PXL065," stated **Thomas Kuhn, Chief Executive Officer of Poxel.**

"We are delighted to partner with Poxel to provide a non-dilutive source of financing that aligns with our mission to accelerate innovation in the biopharmaceutical industry," added **Matthew Rizzo, General Partner of OrbiMed.**

Royalty monetization agreement based on TWYMEEG[®] sales with OrbiMed

Under the terms of the agreement, Poxel received a gross upfront payment of USD 50 million from the OrbiMed funds in exchange for an issuance of its bonds in the same aggregate amount. From such proceeds, a deposit of USD 7.5 million has been made by the Company into a deposit account, from which USD 1.25 million will be withdrawn quarterly and paid in partial repayment of the bonds issued to OrbiMed, until net sales of TWYMEEG[®] reach JPY 5 billion (USD 31.5 million²), at which point OrbiMed will begin to receive sales-based payments and royalties (anticipated in early 2025, based on the expected achievement of this sales threshold by the end of 2024³). The residual amount of the deposit will then be available to the Company, in addition to the USD 42.5 million deposit received upon signature of the agreement.

For the bonds issued by Poxel, the OrbiMed funds will receive (i) royalties payable

² Converted at the exchange rate on September 27, 2024

³ Sumitomo Pharma fiscal year 2024 ends March 31, 2025



by Sumitomo Pharma on net sales of TWYMEEG® in Japan, net of Poxel's obligation to Merck, (ii) sales-based payments due by Sumitomo Pharma in connection with the commercialization of TWYMEEG® in Japan, and (iii) a portion of the cash flows received by the Company, in the event of partnership for the development and commercialization of Imeglimin in Asian countries other than Japan¹, and for which Poxel just recovered the rights from Sumitomo Pharma^{4,5}. The Company has initiated discussions to develop and market Imeglimin in China, the world's second largest type 2 diabetes market.

The agreement will expire, and the bonds be deemed repaid once OrbiMed receives a capped return equivalent to 2 times its investment, i.e. USD 100 million, plus specified expenses, if any. Upon such repayment, Poxel will regain full rights to TWYMEEG® royalties in Japan and to any sales-based commercial payments and will use the majority of these proceeds to repay the outstanding amount owed to IPF Partners.

Besides usual recourses in case of breaches of representations, warranties and covenants, the financing provided by OrbiMed is non-recourse to Poxel, except for additional quarterly payments of USD 1,25 million and up to a total of USD 5 million to the extent that the deposit account is exhausted and the JPY 5 billion TWYMEEG® net sales level is not reached.

Part of the bonds issuance amount from this transaction was used to reduce the Company's debt towards IPF Partners and the PGE banks:

- (i) EUR 23.7 million for partial repayment of IPF debt, reducing it to EUR 12.3 million; and
- (ii) EUR 2.8 million for partial repayment of the debt to the banks that granted the PGE Loan, reducing it to EUR 3 million.

Consequently, the Company amended its agreements respectively with IPF Partners and the banks that granted a PGE loan for the repayment of the outstanding principal of each of these debts.

Amendment to the bond loan contracted with IPF Partners

The revised financing arrangement with IPF Partners is as follows:

- From the proceeds of the OrbiMed transaction, Poxel will repay IPF Partners EUR 23.7 million, broken down as follows:

⁴ In accordance with the Sumitomo Pharma license agreement, Poxel is entitled to receive escalating royalties of 8 - 18% on net sales of TWYMEEG®

⁵ As part of the Merck licensing agreement, Poxel will pay Merck Santé (designated as Merck hereafter) a fixed 8% royalty based on the net sales of Imeglimin, independent of the level of sales.



- Full reimbursement of Tranche A bonds for an amount of EUR 6.4 million
- Full reimbursement of Tranche B bonds for an amount of EUR 10.4 million
- Partial reimbursement of Tranche C bonds for an amount of EUR 4.7 million
- Early repayment fees of EUR 2.2 million
- Remaining debt owed on Tranche C, of EUR 12.3 million
- The Company and IPF Partners agreed to restructure the repayment terms of the remaining debt, the main features of which are as follows:
 - Cash interest rate decreased to 0% (from 6.5% previously)
 - Capitalized interest rate (PIK Interests) increased to 27% (from 11% previously), which may be reduced to 25% in the event of partnerships for the development and commercialization of, *inter alia*, Imeglimin in the rest of the world
 - Existing exit commissions of EUR 4.1 million maintained
- Reimbursement of the remaining debt and exit fees mainly paid as follows:
 - 100% of the residual amount from the USD 7.5 million deposit as part of the transaction with OrbiMed
 - 75% of TWYMEEG[®] royalties in Japan, following the OrbiMed funds receipt of its full return
- The terms & conditions also plan for additional sources of debt repayment:
 - 75% of cash flows received by the Company, in the event of a partnership for the development and commercialization of Imeglimin in the rest of the world, pro rata to receivables held by IPF Partners and by the PGE lenders
 - 50% of drawdowns under the structured finance facility with IRIS
- Financial covenants removed, with the exception of the requirement to maintain, at any time, a cash position in excess of EUR 500,000,
- Release of all the security package previously granted to IPF Partners in respect of the initial bond loan, and
- Waiver, by IPF Partners, of any recourse against Poxel from an additional partial repayment of EUR 2.7 million (expected beginning of 2025 through the repayment of the remaining amount from the OrbiMed deposit account after reaching the TWYMEEG[®] net sales JPY 5 billion level)

The terms and conditions of the existing warrants held by IPF Partners, which were attached to the Tranches A, B and C bonds, entitling their holders to subscribe for 630,804 shares at respectively EUR 7.37, EUR 7.14 and EUR 6.72 per warrant for each tranche, remain unchanged and therefore do not entail any potential additional dilution.

The agreement with IPF Partners also introduces the ability for the Company to draw down an additional Tranche D of the IPF bond loan with warrants for a maximum amount of EUR 6.250 million, available only if the Company's cash position would fall below EUR 1 million, so as to guarantee the Company's long-



term viability until full repayment of the remaining debt to IPF Partners. Such drawdowns would be combined with a new savings plan aimed at reducing the drawdowns of Tranche D bonds. These Tranche D bonds have the same conditions as Tranche C bonds⁶.

Once all IPF bonds and associated exit fees are fully repaid, Poxel will regain full rights on royalties from TWYMEEG[®] sales in Japan and on potential sales-based commercial payments and cash flows in the event of a partnership for the development and commercialization of Imeglimin in the rest of the world.

As a security for the payment of the royalty streams to OrbiMed and IPF Partners and in consideration for a release of all the security interests held by IPF Partners, the Company set up three security trusts into which several assets (including patents, license agreements, future cash flows and receivables) are transferred.

Trust 1:

A trust agreement has been signed between (i) Poxel, as grantor and beneficiary, (ii) Merck and the OrbiMed funds, as first-ranking beneficiaries, (iii) IPF Partners, as second-ranking beneficiary, and (iv) Pristine, as the trustee. The main purpose of this agreement, and the other transaction agreements concurrently entered into, is to regulate the transfer of assets related to Imeglimin in Japan and to distribute the royalties received by Poxel under the partnership with Sumitomo Pharma among the various beneficiaries of the trust. Once the OrbiMed funds and IPF Partners have been fully repaid, all the assets held in the trust will be recovered by the Company.

Trust 2:

A trust agreement has been signed between (i) Poxel, as grantor and beneficiary, (ii) Merck and IPF Partners, as first-ranking beneficiary, (iii) the OrbiMed funds, as second-ranking beneficiary and (iv) Pristine, as the trustee. The main purpose of this agreement, and the other transaction agreements concurrently entered into, is to regulate the transfer of assets related to Imeglimin in the rest of the world and to distribute the potential royalties to be received by Poxel under future partnerships among the various beneficiaries of the trust and the PGE banks. Once IPF Partners and the OrbiMed funds have been fully paid, all the assets held in the trust will be recovered by the Company.

Trust 3:

A trust agreement has been signed between (i) Poxel, as grantor and beneficiary, (ii) IPF Partners, as first-ranking beneficiary, and (iii) Pristine, as the trustee. The main purpose of this agreement is to regulate the transfer of Poxel's other intellectual property rights (including the transfer of the PXL770 and PXL065 assets) on the understanding that Poxel will benefit from 100% of the financial flows in the event of a partnership for PXL770 and PXL065. Once IPF Partners have

⁶ It should be noted that the Company's financing horizon to the end of 2025 does not include the drawdown of this tranche D.



been fully repaid, all the assets held in the trust will be recovered by the Company.

Amendment to the PGE loan agreement

- Partial reimbursement of EUR 2.8 million corresponding to the amount due at that date, under the initial PGE loan schedule agreed prior to the March 2023 restructuring
- Outstanding capital amounting to EUR 3 million
- Amendment of the repayment schedule for the remaining balance due with a quarterly repayment schedule with linear maturities
- Similar interest rate as for the March 2023 agreement

Following this transaction, and according to Poxel's current forecasts, including in particular:

- (i) the Company's cash position estimated, as of August 31st, 2024, at EUR 2.9 million
- (ii) the net upfront payment of USD 42.5 million (EUR 38,1 million⁷) from the monetization of royalties from TWYMEEG[®] sales
- (iii) the partial redemption of the IPF Partners bond loan and the PGE loans for a total amount of EUR 26,5 million
- (iv) the advisory fees linked to the transaction
- (v) the full residual drawdown of the equity-linked financing facility put in place with IRIS[®]; and
- (vi) 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.

Morgan Stanley & Co. LLC acted as Poxel's sole structuring agent for the transaction. Dechert LLP advised Poxel. Covington & Burling LLP and Bryan Cave Leighton Paisner LLP acted as legal advisors to OrbiMed.

⁷ Converted at the exchange rate on September 27, 2024

⁸ Since March 31, 2023, 14 additional tranches have been drawn down for a total of EUR 7.3 million. 6 tranches are currently secured for a total of EUR 3 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 **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. 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

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About OrbiMed

OrbiMed is a leading healthcare investment firm, with approximately \$17 billion in assets under management. OrbiMed invests globally across the healthcare industry, from start-ups to large multinational corporations, through private equity funds, public equity funds, and royalty/credit funds. OrbiMed seeks to be a capital provider of choice, providing tailored financing solutions and extensive global team resources to help build world-class healthcare companies. OrbiMed's team of over 100 professionals is based in New York City, London, San Francisco, Shanghai, Hong Kong, Mumbai, Herzliya, and other key global markets. For more information, please visit www.orbimed.com.

Forward-looking statements

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.

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 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
 - 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 licensing agreement, Poxel will pay Merck 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 the 8% level are considered 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.