April 1, 2016

Poxel Reports Results for Fiscal Year 2015 and Provides Corporate Update

The Company Advanced its Two Lead Programs in Type 2 Diabetes and Completed Two Major Financing Events

LYON, France--(BUSINESS WIRE)-- POXEL SA (Euronext – POXEL - FR0012432516), a clinical-stage biopharmaceutical company focused on the development of novel treatments for type 2 diabetes and metabolic disease, today announced the results for its fiscal year ended December 31, 2015 and provided a corporate update. As of year-end, the cash and cash equivalents amounted to €42.4 million.

“We achieved significant clinical, regulatory, financial and corporate milestones during 2015, including additional mechanistic and Phase 2 efficacy and safety data for Imeglimin, which were presented to key regulatory authorities in anticipation of launching our Phase 3 programs. We also broadened our clinical portfolio in type 2 diabetes by advancing our direct AMPK activator, PXL770, into a Phase 1 study,” said Thomas Kuhn, CEO of Poxel. “Additionally, we have continued to build a strong management team and board of directors, and strengthened our balance sheet by completing two major financing events. We look forward to 2016 as we continue to advance the Company and the development of our two first-in-class drug candidates.”

Highlights 2015:

Imeglimin

- Over the course of 2015, Imeglimin, Poxel’s lead drug candidate successfully completed several Phase 2 and Phase 2b clinical trials, further supporting Imeglimin’s favorable safety profile and providing additional efficacy data. The results of these trials were presented at major medical meetings, supporting the competitive profile of this novel first-in-class oral drug candidate for the treatment of type 2 diabetes. These results were also presented to key regulatory authorities, including the United States Food and Drug Administration (FDA) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), providing the Company with additional visibility into the design of Phase 3 programs to support future regulatory submissions in the US and Japan.
- The clinical data as well as additional preclinical data presented in 2015 further demonstrated Imeglimin’s dual mechanism-of-action, increasing insulin secretion in response to glucose and improving insulin action.
    - During clinical trials, Imeglimin was observed to restore the mitochondria respiratory chain dysfunction resulting in the improvement of insulin and glucose

sensing in the target tissue.
    - During a Phase 2b trial a statistically significant reduction was observed in glycated hemoglobin levels, indicating a promising risk/benefit ratio.
- The Company achieved several important milestones in developing Imeglimin for the Asian market.
    - During a Phase 1 trial in Japanese subjects, Imeglimin was observed to be safe and well-tolerated with a pharmacokinetic profile that was comparable to results shown in Caucasians, enabling the potential for accelerated development of Imeglimin in Asia.
    - Poxel initiated a Phase 2b trial, which is being supported by a Japanese Scientific Advisory Board, helping to guide the ongoing regulatory interactions and clinical development plans.

PXL770

- Poxel made significant progress with its direct AMPK activator drug candidate, PXL770, during 2015. PXL770 directly activates AMPK, an enzyme that acts as an energy sensor and regulator, maintains cellular homeostasis, and therefore has the potential to play an important role in the management of diabetes. In November 2015, Poxel presented the first preclinical data for PXL770 at the World Congress on Insulin Resistance, Diabetes and Cardiovascular Diseases in Los Angeles.
    - In an obese type 2 diabetes mouse model, PXL770 was observed to improve glucose tolerance and normalized plasma and liver triglycerides.
    - The data showed that increased AMPK activity could be measured in both liver and muscle, further demonstrating target engagement *in vivo*.
    - Together, the results elucidate PXL770's mechanism-of-action and demonstrate its potential as a novel oral agent for the treatment of type 2 diabetic patients with added benefits on lipid abnormalities.
- In early 2016, the Company initiated a Phase 1 study in healthy volunteers. The single ascending dose trial will enroll healthy male subjects who will receive placebo or one of the eight planned dose levels of PXL770. The study is on track and over a third of the subjects have been enrolled.
- Most recently, Poxel announced that the U.S. Patent and Trademark Office (USPTO) has granted the patent (US patent number US-9,284,329) filed by Poxel covering direct AMPK activators. This patent includes Poxel's second lead product candidate PXL770 for the treatment of type 2 diabetes as well as other indications.

Corporate

- Poxel raised €26.8 million through its IPO on the Euronext Paris in February 2015.
- The Company raised an additional €20 million through a successful international private placement in July 2015, which included predominantly healthcare-focused investors based in the United States and Europe.
- Poxel signed a licensing agreement with ENYO Pharma, a biopharmaceutical company focused on developing treatments for acute and chronic viral infections. Under the terms of the agreement, ENYO will have access to Poxel's FXR (farnesoid X receptor) agonist compounds for infectious disease with therapeutic indications such as hepatitis B, while Poxel retains rights for other indications including cardiovascular and metabolic diseases.

- The Company further strengthened its management team through the appointment of Noah D. Beerman as Executive Vice President, Business Development and President of Poxel's US Operations and Dr. Yohjiro Itoh to lead clinical and regulatory operations in Asia. The Company also welcomed Jonae R. Barnes as Senior Vice President, Investor Relations and Public Relations, based in the US.
- The Company expanded its Board of Directors by appointing four new independent Board members welcoming Richard Kender (US), Pascale Boissel (France), Janice Bourque (US) and Pierre Legault (US).

Financial Statements for Fiscal Year 2015 (IFRS standards)
Poxel's revenues for 2015 were €59 thousand (2014: no revenues). Poxel devotes the bulk of its resources to research and development (R&D). The corresponding R&D costs presented below are net of the R&D Tax Credit (CIR) that resulted in income of €1.9 million in 2015. The variance from 2014 to 2015 is mainly driven by the increased R&D costs for PXL770 (approximately €1.3 million), as well as clinical activities in respect to Imeglimin, particularly in Japan. The increase in general and administrative (G&A) costs mainly resulted from non-recurrent costs directly related to the Euronext IPO and increased personnel costs related to the Company's ongoing R&D programs, particularly in Japan and in the US. In 2015, financial charges were mainly driven by interest expenses linked to the venture loan, whereas 2014 was impacted by the fair value of Merck Serono debt. This Merck Serono debt has now been offset against a dedicated share capital increase at the IPO in February 2015. The net result for the financial period ending December 31, 2015 showed a net loss of €12.2 million, as expected, compared to a net loss of €14.1 million in the previous year. On December 31, 2015, the cash and cash equivalents amounted to €42.4 million (compared to €10.3 million on December 31, 2014).

Condensed Income Statement (consolidated)

In thousand €

	31 Dec 2015	**31 Dec 2014**
Turnover	**59**	**-**
Net research and development expenses	(7 319)	(5 017)
General and administrative expenses	(4 462)	(1 878)
Operating loss	**(11 721)**	**(6 895)**
Financial expenses	(909)	(7 258)
Financial income	388	72
Net loss	**(12 242)**	**(14 081)**

Number of shares and voting rights as of December 31, 2015:

Month	Date	Total number of shares outstanding	Total of theoretical voting rights (1)	Total of exercisable voting rights (2)
December	12/31/2015	19,482,394	19,482,394	19,476,043

(1) The total number of theoretical voting rights (or “gross” voting rights) is used as the basis for calculating the crossing of shareholding thresholds. In accordance with Article 223-11 of the AMF General Regulation, this number is calculated on the basis of all shares to which voting rights are attached, including shares whose voting rights have been suspended.

(2) The total number of exercisable voting rights (or “net” voting rights) is calculated without taking into account the shares with suspended voting rights, in this case, shares held by the Company in the context of a liquidity contract agreement with ODDO.

Next financial press release: Q1-turnover and cash position May 5, 2016

About Poxel
Poxel uses its development expertise in metabolism to advance a pipeline of drug candidates focused on the treatment of type 2 diabetes. We have successfully completed our Phase 2 trials for our first-in-class lead product, Imeglimin, which targets mitochondrial dysfunction, in the U.S. and EU and have entered Phase 2b clinical development in Japanese patients. We are advancing our second program, PXL770, a direct AMPK activator. We intend to generate further growth through strategic partnerships and pipeline development. (Euronext: POXEL, www.poxel.com)

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