OKYO Pharma Limited (LSE: OKYO) a biopharmaceutical company developing next-generation therapeutics to improve the lives of patients with inflammatory eye diseases and chronic pain today announces its interim results for the six months ended 30 September 2021.

Financial Highlights:

- Total assets decreased to £4.2 million (31 March 2021: £5.1 million)
- Cash on hand of £3.8 million (31 March 2021: £5.0 million)
- During the financial period under review, the Company reported a total comprehensive loss of £1.8 million (restated 30 September 2020: total comprehensive loss £0.5 million).

Group Focus:

The Group's focus is to develop drugs for inflammatory dry eye diseases and ocular pain by targeting G- protein-coupled receptors (GPCRs). GPCRs comprise the single largest family of membrane proteins and are involved in a variety of biological processes. Identifying and developing molecules that target GPCRs has proven to be a highly successful approach to the discovery and development of a wide range of drugs to treat cardiovascular disease, cancer and diabetes. Approximately one third of all Food and Drug Administration (FDA) approved drugs target members of this family.

OK-101 Project:

During the past six months the Group's primary focus has been centered around the decision to move OK-101 forward for the filing of an investigational new drug (IND) application with the FDA to treat dry eye disease (DED). The intention is to focus the Company on rapid clinical development of OK-101 to treat DED. To do this, on 29 June 2021, the Group announced that it has retained the services of Ora, Inc., a world-class ophthalmology contract research organization, to guide the company's upcoming product development and lead the regulatory strategy of OK-101 for the treatment of dry eye. OK-101, OKYO's lead pre-clinical drug candidate is a novel long-acting GPCR-based anti-inflammatory drug candidate.

In the Annual Report and Financial Statements for the year ended 31 March 2021, the company stated that based on the results from the DED animal model and ocular tolerance studies, the company would put in place plans to file an IND on OK-101 to treat DED in the third quarter of 2022. This would enable the company to begin clinical trials with OK-101 as early as one month after submission of the IND to the FDA. To support this work, we signed an agreement in June 2021 with Ora, Inc. which specializes in ophthalmic drug development and who will be providing the following services:

- Providing quality oversight for development of topical formulation for OK-101;
- Providing quality oversight for development and qualification of a drug stability analysis method for OK-101 along with conducting stability studies to establish formulated drug product is stable for at least 90 days;
- Support for completing animal toxicology studies in two animal species;
- Preparation of the OK-101 Pre-IND briefing document;
- Support in requesting and preparing for the OK-101 Pre-IND meeting with FDA; and
- Support for regulatory publishing and submission of IND..

During the months of April through September 2021, the Group began the development of a formulation of OK-101 drug product to be used in future clinical studies, along with initiating a myriad of other necessary elements needed for filing the IND. This includes: 1) development of analytical methods to support clinical trials, 2) toxico-kinetics method development, 3) OK-101 toxicology studies, 4) initiation of scale-up of clinical batch manufacturing of OK-101 required for clinical studies, and 5) batch manufacture of sufficient OK-101 needed to initiate the above IND-enabling studies. To this end, we completed the manufacture of a 200-gram batch of OK-101 drug substance in April 2021 which was needed for initiating the IND-enabling studies.

**OK-201 Project:**

On 2 February 2018, the company obtained a license agreement from Tufts Medical Center for the right to exploit all the intellectual property claimed in patent application PCT/US2016/0611101 'Lipidated BAM8-22 and methods of using same' including claims covering composition-of-matter and methodology for treating symptoms of neuropathic chronic pain, ocular pain and uveitis-associated pain. The Group has been exploring BAM8-22 analogs that have potential to ameliorate inflammation and neuropathic pain. OK-201 is the lead compound from the license agreement with Tufts Medical Center and was the focus of the company's efforts to develop a lipidated BAM8-22 analogue to treat neuropathic pain.

On 6 August 2019, a collaborative agreement was signed with Pedram Hamrah, MD, Professor of Ophthalmology at Tufts University School of Medicine, Boston, MA to evaluate the Group's BAM8-22 analogues, including OK-201, as non-opioid analgesics to suppress corneal neuropathic pain using a mouse ocular pain model developed in Dr. Hamrah's laboratory. Neuropathic corneal pain is a severe, chronic and debilitating disease with no FDA approved commercially available treatments currently available for this condition.

On 28 April 2021 the company announced positive results of OK-201, a non-opioid analgesic drug candidate delivered topically in Dr. Hamrah's mouse neuropathic corneal pain model, as a potential drug to treat acute and chronic ocular pain. Importantly, OK-201 demonstrated a reduced corneal pain response equivalent to that of gabapentin, a commonly used oral drug for neuropathic pain. These observations demonstrated preclinical 'proof-of-concept' for the topical administration of OK-201 as a potential non-opioid analgesic for ocular pain. Current treatments for corneal pain are limited to short term NSAIDs, steroids, and oral gabapentin and opioids in severe cases.

Although the results with OK-201 were encouraging, due to subsequent success obtained with OK-101 in follow-on animal model studies utilizing the same mouse neuropathic corneal pain model, the company has decided to stop further development of OK-201 to treat ocular neuropathic pain, and to turn its full attention to the development of OK-101 to treat DED.

Enquiries:

| | | |
|---|---|---|
| OKYO Pharma Limited | Gary Jacob | +44 (0)20 7495 2379 |
| Optiva Securities Limited | | +44 (0)20 7408 4050 |

**About OKYO**

OKYO Pharma Limited (LSE: OKYO; OTCQB: EMMLF) is a life sciences and biotechnology company admitted to listing on the standard segment of the Official List of the UK Financial Conduct Authority and to trading on the main market for listed securities of London Stock Exchange plc. OKYO is focusing on the discovery and development of novel molecules to treat inflammatory dry eye diseases and ocular pain.

Website: www.okyopharma.com