

Lobe Sciences Provides Update For 2023 Milestones

Vancouver, British Columbia--(Newsfile Corp. - January 18, 2023) - Lobe Sciences Ltd. (CSE: LOBE) (OTCQB: LOBEF) ("Lobe" or the "Company"), a North American Biopharmaceutical company committed to discovering and developing patient focused psychedelic derived medicines for neurologic and brain disease today announced an updated overview for 2023.

Mr. Philip Young, Chairman and Chief Executive Officer of the Company, stated, "2022 was a productive year for Lobe Sciences. We increased our intellectual property portfolio with several new chemical entities (NCEs) derived from well-known psychedelic compounds, adding two of these, L-130 and L-131, to our development program. We solidified relationships with outstanding research and development teams, who affirmed their support for Lobe by taking an equity stake in the Company. Research collaborations with contract research organizations (CRO) were penned and we began work on a human Phase I Safety and Pharmacokinetics program to ascertain the bioavailability and metabolism of L-130. This trial will be the first of three similar trials that will determine the highest concentration of this NCE without an hallucinogenic effect. International Regulatory filings were completed and accepted in 2022. We expect to begin enrollment in early 2023."

The Company presented the following timeline for 2023:

L-130

- In January 2023, obtain cGMP clinical supplies and transfer these supplies to the international CRO for oral administration to humans in Phase I studies.
- In the first quarter of 2023, commence Phase I Safety and Pharmacokinetics Studies. Data is expected to be available in early in the second quarter of 2023.
- In the first quarter of 2023, commence USFDA required preclinical studies which are expected to be completed by the end of the second quarter of 2023. We have executed a contract with our international preclinical CRO and the active pharmaceutical ingredient (API) export license from US DEA is awaited. Our manufacturing partner has manufactured sufficient quantities of L-130 which will be shipped once required DEA export documents are approved.
- A pre-IND submission package will be filed to confirm that our entire regulatory pathway, which utilizes the 505(b)2 route to approval is appropriate.
- In anticipation of a successful identification of the highest dose having minimal or no hallucinogenic effect, the Company has begun preparation of the Phase II protocol which will utilize that dose. Initial designs for the study are being refined with a second international CRO (iNGenu).
- In the 2023, the Company anticipates a US IND filing.

L-131

- Synthesis of L-131 has produced sufficient material for preclinical investigation in a pediatric neurological orphan drug application.
- In the first half of 2023, an efficacy evaluation of L-131 utilizing a validated model of the orphan disease application will be initiated following receipt of the DEA export license the preclinical CRO.
- In the second half of 2023, an Orphan Drug Designation filing and a Priority Review Application (a pediatric application of L-131) will be submitted to US FDA following successful completion of the

preclinical investigation noted above.

- In the first half of 2023, a pre-IND filing to US FDA will occur to confirm the regulatory strategy being planned for L-131 and its orphan application.
- Preclinical safety and toxicokinetic studies will be initiated following the completion of preclinical pharmacology late in the first half or early in the second half of the year.

The Company expects to file an IND with the USFDA in the second half of the year. In a final comment, Mr. Young said, "Our plans for 2023 are ambitious but doable. By year end, we should have two active INDs, one of which may be designated as an orphan drug and an ongoing Phase II trial assessing L-130 as a therapeutic to treat a refractive neurological disorder. We will release details of each of these trials and the indication being treated as our patents are published."

About Lobe Sciences Ltd.

Lobe Sciences is a biopharmaceutical company focused on developing patient friendly practical psychedelic medicines. The Company, through collaborations with industry-leading partners, is engaged in drug research and development using sub hallucinatory doses of psychedelic compounds and the development of innovative devices and delivery mechanisms to improve mental health and wellness. Each of our New Chemical Entities; L-130 and L-131, are being developed to address unmet medical needs in neurological therapeutic applications. Refer to forward looking statements for information related to the compounds currently in development or under consideration for development.

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Forward-Looking Statements

This news release contains forward-looking statements relating to the future operations of the Company and other statements that are not historical facts. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expects" and similar expressions. All statements other than statements of historical fact included in this news release (including, without limitation, statements regarding the future plans and objectives of the Company, research and development using psychedelic compounds, and the development of innovative devices and delivery mechanisms to improve mental health and wellness) are forward-looking statements that involve risks and uncertainties. There can be no assurance that such statements will prove to be accurate, and actual results and future events could differ materially from those anticipated in such statements. Readers are cautioned that assumptions used in the preparation of the forward-looking statements may prove to be incorrect. Events or circumstances may cause actual results to differ materially from those predicted, as a result of numerous known and unknown risks, uncertainties, and other factors, many of which are beyond the control of the Company, including changes to the regulatory environment; that the Company's drug research and development activities may be unsuccessful; that drugs and medical devices produced by, or on behalf of, the Company, may not work in the manner intended or at all, and may subject the Company to product liability or other liability claims; that the Company may not be able to attain the Company's corporate goals and objectives; and other risk factors detailed in the Company's continuous disclosure filings from time to time, as available under the Company's profile at www.sedar.com. As a result, the Company cannot guarantee that any forward-looking statement will materialize and the reader is cautioned not to place undue reliance on any forward-looking information. Forward-looking statements contained in this news release are expressly qualified by this cautionary statement. The forward-looking statements contained in this news release are made only as of the date of this news release and the Company does not intend to update any of the included forward-looking statements except as expressly required by applicable Canadian securities laws.

The Company makes no medical, treatment or efficacy claims about its compounds currently in development or under consideration for development. The U.S. Food and Drug Administration, Health Canada or other global regulatory authorities have not evaluated claims regarding our psilocin compounds. The safety and efficacy of such products have not been confirmed by controlled clinical trials. There is no assurance that the use of our psilocin compounds will decrease the severity of, cure, or prevent disease. Geography specific preclinical research controlled clinical trials with validated endpoints are needed to be successfully completed in order to submit applications for potential regulatory clearance. Lobe has not conducted clinical trials for the use of its proposed products and references to. If Lobe cannot obtain the regulatory approvals or complete the research necessary to commercialize its psilocin compounds it may have a material adverse effect on Lobe's performance and operations. Lobe conducts all manufacturing and clinical research through licensed laboratories and CROs in the jurisdictions in which the CRO operates. These companies abide by all applicable regulations regarding the handling of psychedelic compounds and if applicable are regularly inspected by the applicable authorities in their respective geographies.



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