



Magdalena Biosciences, a Joint Venture Between Jaguar Health and Filament Health, Study Indicates Psychoactive Activity of Medicinal Plant Utilized for Centuries by Indigenous Peoples in Tropical Regions

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Magdalena aiming to submit Investigational New Drug application in 2024 to the FDA for this next-generation psychoactive prescription drug candidate for potential mental health indications such as ADHD, depression & anxiety

SAN FRANCISCO, CA / ACCESSWIRE / January 30, 2024 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#) today announced that a preclinical study in mice initiated in Brazil by [Magdalena Biosciences, Inc.](#) (Magdalena), the joint venture recently formed by Jaguar and [Filament Health Corp. \(OTCQB:FLHLE\)](#) ([NEO:FH](#)) ([ESE:7QS](#)) to develop novel, natural prescription medicines derived from plants for mental health indications, indicates psychoactive activity in a plant extract in a lead Magdalena botanical drug candidate. The botanical drug candidate is being evaluated for its potential use as a next-generation psychoactive prescription drug for treatment of mental health conditions such as attention-deficit/hyperactivity disorder (ADHD), depression, anxiety, and other possible neuropsychiatric conditions.

"Like Jaguar, Magdalena was formed to harness the power of ethnobotany and indigenous knowledge to identify and evaluate traditional medicines that have been utilized for hundreds or thousands of years to look for medications that are likely to be safe and effective - with a goal of bringing these novel therapies to a wider market as approved, sustainably derived prescription pharmaceuticals," said Steven King, Ph.D., Jaguar's chief sustainable supply and ethnobotanical research officer and an Advisor to Magdalena. "Earth's rainforests are often described as nature's largest medicine cabinets - and for good reason, as many of the world's important pharmaceutical medicines were discovered by studying the traditional medicine of indigenous peoples."

"So many companies evaluating plant-derived drugs for mental health disorders are chasing the same seven compounds or plants, and it's encouraging that a third-party organization recently submitted the first New Drug Application (NDA) to the FDA for a psychedelic drug - in this case, the MDMA drug midomafetamine for the treatment of post-traumatic stress disorder (PTSD). Magdalena is focused on identifying the *next* generation of psychoactive botanical drugs to treat mental health disorders, leveraging Jaguar's proprietary library of 2,300 highly characterized medicinal plants and 3,500 plant extracts, our team's extensive ethnobotanical expertise, and looking specifically at plants that have centuries of history of medicinal use in man by indigenous groups," Dr. King said.

The evaluation process for plants that have a history of traditional use by humans involves expanding traditional uses with exploratory studies in animals prior to initiating clinical trials in people. To this end, mice experiments with this extract of the Magdalena lead botanical drug candidate have shown increased brain metabolism that indicate its potential beneficial effect for several conditions where such areas show hypofunction, including ADHD, depression, and anxiety. Moreover, the connectivity analysis demonstrated that this plant extract appears to beautifully reshape the neuronal network. "In fact, this preclinical study identified effects that the team conducting the study do not frequently see - even with small molecule compounds they test for big pharmaceutical companies - meaning the extract induced a potentially significant increase in neuronal metabolism, lighting up several brain areas relevant to various mental conditions," said Dr. Elaine Elisabetsky, a consultant to both Magdalena and Jaguar who has general responsibility for coordinating resources and principal investigators for this project in Brazil and is one of the world's leading ethnopharmacologists.

"We are very excited with the result of this study and are especially encouraged that the analysis shows changes in neuronal connectivity with important implications for disease treatment which will be further studied in a clinical study," said Dr. Karen Brunke, Jaguar's EVP of Corporate and Business Development and Acting CEO of Magdalena. "Magdalena's goal is to identify effective, plant-based next-generation psychoactive drugs that are safe, can be taken at home, and can be used on a long-term basis. We aim to enter the clinic in 2024 with at least one botanical drug candidate after an IND (Investigational New Drug) application to the U.S. Food and Drug Administration (FDA) under FDA Botanical Guidance. Following activation of this IND by the FDA, Magdalena may be able to go directly into a Phase II clinical trial for the extract, with no need for a Phase I trial."

The Magdalena preclinical study consisted of radioactive fluorodeoxyglucose positron emission tomography (PET) scans performed by Dr. Daniella Faria, Faculdade de Medicina da Universidade de São Paulo (FMUSP), with the analysis done by Dr. Eduardo A. Zimmer through his consultancy.

The Growing Market for Medicines Derived from Psychoactive Plants

According to the World Health Organization, one in four people in the world will be affected by mental or neurological disorders at some point in their lives. Around 450 million people currently suffer from such conditions, placing mental disorders among the leading causes of ill-health and disability worldwide. Common mental health conditions include depression, PTSD, anxiety, addiction, bipolar disorder (formerly called manic-depressive illness or manic depression), and anorexia nervosa, and expand to include neuro-degenerative diseases such as Parkinson's, Alzheimer's disease, and ALS

(amyotrophic lateral sclerosis), among others. Substance use disorders occur when the recurring use of alcohol and/or drugs causes clinically significant impairment, including health problems, disability, and failure to meet major responsibilities at work, home, or school. The Lancet Commission, a group of experts in neuroscience, psychiatry, public health, and related fields, estimates that the cost of mental disorders, currently on the rise in every country, will reach \$16 trillion by 2030, including costs associated with lost productivity.

Jaguar's Library of 2,300 Medicinal Plants

The recent formation of Magdalena Biosciences allowed for the mobilization of a key asset Jaguar's team has generated over 30 years - a library of 2,300 highly characterized medicinal plants and 3,500 plant extracts from tropical regions, all from firsthand ethnobotanical investigation by Jaguar and members of the Scientific Strategy Team for Jaguar's mental health Entheogen Therapeutics Initiative (ETI), bridging the knowledge of traditional healers and Western medicine. Magdalena holds an exclusive license to plants and plant extracts in Jaguar's library, not including any sources of crofelemer or NP-300, for specific indications and focuses on identifying plant candidates in the library that may prove beneficial for addressing indications such as ADHD. A unique asset to drive drug discovery, Jaguar's plant collection was assembled over a decade by integrated ethnobotanist physician teams who conducted primary, first-hand field investigations and plant identification work in rainforest regions around the globe in addition to gathering data about traditional medicinal uses of plants from shamans and other Indigenous healer. The library contains plant specimens gathered from Central America, South America, Africa, and Southeast Asia, including a broad diversity of plant extracts from roots, shrubs, bark, leaves, fruits, and seeds.

Many members of the scientific strategy team that contributed to the development of Jaguar's plant library were trained by the late Dr. Richard Evans Schultes, who is often referred to as the father of modern ethnobotany. Dr. Schultes was the Jeffrey Professor of Biology and Director of the Botanical Museum of Harvard University. He conducted field studies for 48 years during his career, much of that time in the Colombian Amazon. He focused his research on medicinal, psychoactive plants and new sources of rubber, and investigated a wide diversity of psychoactive plants including but not limited to peyote, psilocybin mushrooms, viola snuffs, as well as Ayahuasca and its many admixtures.

About Filament Health

Filament Health (OTCQB:FLHLF)(NEO:FH (FSE:7QS) is a clinical-stage natural psychedelic drug development company. Filament believes that safe, standardized, naturally-derived botanical medicines can improve the lives of many, with a mission to see them in the hands of everyone who needs them as soon as possible. Filament's platform of proprietary intellectual property enables the discovery, development, and delivery of natural medicines, including psychedelic medicines, for clinical development. Filament is paving the way with the first-ever natural psychedelic drug candidates.

Learn more at www.filament.health and on [Twitter](#), [Instagram](#) and [LinkedIn](#).

About the Jaguar Health Family of Companies

Jaguar Health, Inc. (Jaguar) is a commercial stage pharmaceuticals company focused on developing novel proprietary prescription medicines sustainably derived from plants from rainforest areas for people and animals with gastrointestinal distress, specifically associated with overactive bowel, which includes symptoms such as chronic debilitating diarrhea, urgency, and bowel incontinence. Jaguar family company Napo Pharmaceuticals focuses on developing and commercializing human prescription pharmaceuticals for essential supportive care and management of neglected gastrointestinal symptoms across multiple complicated disease states. Napo Pharmaceuticals' crofelemer drug product candidate is the subject of the [OnTarget](#) study, a pivotal Phase 3 clinical trial for preventive treatment of chemotherapy-induced overactive bowel (CIOB) in adults with cancer on targeted therapy. Jaguar family company Napo Therapeutics is an Italian corporation Jaguar established in Milan, Italy in 2021 focused on expanding crofelemer access in Europe and specifically for orphan and/or rare diseases. Jaguar Animal Health is a Jaguar tradename. Magdalena Biosciences, a joint venture formed by Jaguar and Filament Health Corp. that emerged from Jaguar's [Entheogen Therapeutics Initiative](#) (ETI), is focused on developing novel prescription medicines derived from plants for mental health indications.

For more information about:

Jaguar Health, visit <https://jaguar.health>

Napo Pharmaceuticals, visit www.napopharma.com

Napo Therapeutics, visit napotherapeutics.com

Magdalena Biosciences, visit magdalenabiosciences.com

Visit Jaguar on LinkedIn: <https://www.linkedin.com/company/jaguar-health/>

Visit Jaguar on X: https://twitter.com/Jaguar_Health

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Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that the extract focused on in the PET scans study may have potential for use as a next-generation psychoactive prescription drug for treatment of mental health conditions such as ADHD, depression, anxiety, and other possible neuropsychiatric conditions, the expectation that this extract will be further studied in a clinical study, the expectation that Magdalena will enter the clinic in 2024 with at least one botanical drug candidate after an IND application to the FDA under FDA Botanical Guidance, and the expectation that Magdalena may be able to go directly into a Phase II clinical trial for the extract, with no need for a Phase I trial. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this release are only predictions. Jaguar has based these forward-looking statements largely on its current expectations and projections about future events. These forward-looking statements speak only as of the date of this release and are subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond Jaguar's control. Except as required by applicable law, Jaguar does not plan to publicly update or revise any forward-looking statements contained

herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Contact Info:

hello@jaguar.health

Jaguar-JAGX

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