Magdalena Biosciences, a Joint Venture Between Jaguar Health and Filament Health, to Present February 10th at BIO CEO & Investor Conference

February 6, 2025

Magdalena aiming to submit Investigational New Drug (IND) application in 2025 to the FDA for a next-generation psychoactive prescription drug candidate for potential mental health indications such as ADHD and schizophrenia, with 1-2 additional IND applications filed in late 2025/early 2026

SAN FRANCISCO, CA / ACCESS Newswire / February 6, 2025 / Jaguar Health, Inc. (NASDAQ:JAGX) today announced that Dr. Karen Brunke, Jaguar's EVP of Corporate and Business Development and Acting CEO of Magdalena Biosciences, Inc. (Magdalena), the joint venture formed by Jaguar and Filament Health Corp. (OTCQB:FLHLF) (CBOE CA:FH) (FSE:7QS) to develop novel, natural prescription medicines derived from plants for mental health indications, is presenting in person on Monday, February 10, 2025 at 2:30 PM Eastern at the BIO CEO & Investor Conference in New York City.

"I very much look forward to providing an overview of Magdalena at this conference and meeting with potential partners and investors at this event," Dr. Brunke said. "We expect Magdalena's lead botanical drug candidate, MB2500, to soon be IND-enabled for one of the following indications: cognitive deficit in schizophrenia or executive dysfunction in attention deficit hyperactivity disorder (ADHD). MB2500 may have the potential to serve as a first-ever treatment for the cognitive deficit that goes untreated in schizophrenia, which is a huge unmet medical need. Schizophrenia is a disease of cognitive deficit, a deficit which appears as much as a decade before onset of psychotic symptoms,[1] but no approved drug currently exists to treat cognitive deficit in schizophrenia patients."

MB2500 is derived from a well characterized plant that has been in use by local populations for centuries, and has been shown to have both neuroprotective and cognitive enhancing properties, but has never been put through the rigorous clinical testing required for FDA approval. One or two more Magdalena botanical drug candidates for mental health indications are planned to be IND-enabled in late 2025/early 2026.

ADHD, a $25 billion global market,[2] is a neurodevelopmental disorder characterized by the core symptoms of hyperactivity, inattentiveness, and impulsivity, and there is a growing need for safer ADHD treatments. Schizophrenia is a chronic, disabling mental illness that affects approximately one percent of the U.S. population.[3] The global schizophrenia market is projected to grow to $13.41 billion by 2032, according to a market research report by Market Research Future.[4]

The mission of Magdalena, which is currently approximately 40-percent owned by Jaguar, is to develop novel, safe, efficacious next-generation psychoactive FDA-approved plant-based drugs under FDA Botanical Guidance for mental health indications including schizophrenia, anxiety, depression, and ADHD. Botanical drug candidates have a long history of use by traditional psychiatrists and may have the potential to serve as a new class of plant-based psychoactive drugs which are safe for daily dosing.

"Our approach is paradigm-shifting in drug development as we expect to go from plant extract to proof-of-concept (POC) human studies in 12-24 months - a huge time and cost savings which also, based on the history of human medicinal use of the plants, has a higher probability of success," said Dr. Brunke.

About Botanicals Drugs

Botanicals drugs are defined by the U.S. Food and Drug Administration (FDA) as "products from plant materials, algae, macroscopic fungi, and combinations thereof." Many botanical drugs have a long history of safe use in traditional medicines, which may be documented and reviewed in scientific literature. Existing scientific literature on safety may accelerate the safety review process for a botanical drug, reducing the scope and financial burden for extensive safety studies. The FDA has established guidance on botanical drug development and recognizes the complexity of botanical drugs. Additionally, botanical drugs, by virtue of their complexity, have the added benefit of being difficult to genericize. Hence there are often multiple opportunities for creating 'trade-secrets,' as well as novel patents around a botanical drug substance, its processing, its formulation, and so forth.

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. Among children, ADHD is the most common psychiatric disorder, disrupting learning and social behaviors. 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.

About Filament Health (OTCQB:FLHLF) (CBOE CA:FH) (FSE:7QS)

Filament Health is a clinical-stage natural psychedelic drug development company. We believe that safe, standardized, naturally-derived psychedelic medicines can improve the lives of many, and our mission is 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 psychedelic medicines. We are paving the way with what we believe to be 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, bowel incontinence, and cramping pain. Jaguar family company Napo Pharmaceuticals (Napo) focuses on developing and commercializing human prescription pharmaceuticals for essential supportive care and management of neglected gastrointestinal symptoms across multiple complicated disease states. Napo's crofelemer is FDA-approved under the brand name Mytesi® for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral 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 the *Make Cancer Less Shitty* patient advocacy program on Bluesky, X, Facebook & Instagram

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that Magdalena management will present at the 2025 BIO CEO & Investor Conference, the expectation that MB2500 will soon be IND-enabled and ready to enter the clinic for the first of two indications, the expectation that MB2500 may have the potential to serve as a first-ever treatment for the cognitive deficit that goes untreated in schizophrenia, the expectation that Magdalena may submit an IND application in 2025 to the FDA for a next-generation psychoactive prescription drug candidate for potential mental health indications such as schizophrenia and ADHD, the expectation that 1-2 more additional Magdalena botanical drug candidates for mental health indications may be IND-enabled in late 2025/early 2026 and submitted as IND applications in late 2025/early 2026, the expectation that MB2500 may have the potential to be an effective treatment for ADHD or the cognitive deficit in schizophrenia, the expectation that botanical drug candidates may have the potential to serve as a new class of plant-based psychoactive drugs which are safe for daily at-home dosing, Magdalena's expectation that Magdalena may be able to go from plant extract to POC human studies within 12-24 months, and the expectation that human studies of Magdalena botanical drug candidates may have a higher probability of success based on the history of human medicinal use of the Magdalena botanical drug candidates. 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.

[1] JAMA Psychiatry. 2013;70(10):1107-1112. doi:10.1001/jamapsychiatry.2013.155

[2] https://finance.yahoo.com/news/attention-deficit-hyperactivity-disorder-adhd-220000543.html

[3] Bromet EJ, Dew MA, Eaton W. Epidemiology of psychosis with special reference to schizophrenia. In: Tsuang MT, Tohen M, Zahner GEP, eds. Textbook in psychiatric epidemiology. New York: John Wiley, 1996:283-300

[4] https://www.marketresearchfuture.com/reports/schizophrenia-market-1625

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