



atai Life Sciences Announces Strategic Investment in Beckley Psytech to Accelerate the Clinical Development of Short-Duration Psychedelics

January 4, 2024

- *Strategic investment in Beckley Psytech reinforces atai's position as the biopharmaceutical company with the largest and most diverse portfolio of clinical-stage psychedelic candidates*
- *Two patent-protected, clinical-stage programs BPL-003 (intranasal 5-MeO-DMT) and ELE-101 (intravenous psilocin) complement atai's existing drug development programs*
- *Multiple clinical readouts anticipated from this investment in Beckley Psytech within next 12 months, including a Phase 2b readout of BPL-003 in Treatment Resistant Depression in 2H24*
- *BPL-003 has the potential to become a first-in-class short-duration psychedelic treatment with rapid acting and durable antidepressant effects*
- *Anticipated synergies through collaborating on digital therapeutics, commercial and market access activities in preparation for potential future commercialization*
- *atai to hold conference call & webcast on Thursday, January 4, 2024 at 8:00 a.m. ET*

NEW YORK and BERLIN, Jan. 04, 2024 (GLOBE NEWSWIRE) -- [atai Life Sciences](#) (NASDAQ: ATAI) ("atai" or "Company"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, today announced a strategic investment in Beckley Psytech Limited ("Beckley Psytech"), a private clinical-stage biotechnology company dedicated to transforming short-duration psychedelics into effective and rapid-acting medicines for neuropsychiatric conditions.

This strategic investment and collaboration aims to accelerate the development of Beckley Psytech's two clinical-stage, patent-protected, short-duration psychedelic candidates, BPL-003 and ELE-101, by adding them to atai's mental health innovation platform. BPL-003 is a novel, short-duration, intranasal formulation of 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT also known as Mebufotenin), and ELE-101 is a novel intravenous formulation of psilocin, the primary moiety of psilocybin.

"This transaction underscores our conviction in the potential of psychedelics as groundbreaking treatments for people living with mental health disorders. Short-duration psychedelics have the potential to offer similar clinical benefit to longer-acting psychedelics, in a more efficient and scalable way, which could lead to increased patient access. By including BPL-003 and ELE-101 in the atai platform, we are building the largest portfolio of psychedelic compounds with prior clinical evidence," said atai Founder and Chairman, Christian Angermayer.

Beckley Psytech's CEO, Cosmo Feilding Mellen said: "Beckley Psytech and atai Life Sciences share a vision for the future of mental health treatment, and we are excited to join forces on the journey to develop effective, accessible, rapid-acting psychedelic medicines for people in need. Alongside the financial investment, we are optimistic about the numerous possible synergies of this collaboration, especially in developing digital tools to optimize patient support and planning for future commercialization. We look forward to exploring these in the coming months."

BPL-003 is currently in development for two indications: Treatment Resistant Depression (TRD) and Alcohol Use Disorder (AUD), with three clinical trials underway. The first trial is a global, multi-site, double-blind, randomized Phase 2b study in people living with TRD, evaluating the effects of a medium and high dose of BPL-003 against an active placebo comparator in 225 patients with moderate-to-severe TRD. Medium and high dosages were found to reliably induce profound psychedelic experiences in a completed Phase 1 trial, with a rapid onset of psychedelic effects within minutes and the resolution of all perceptual effects within 60-90 minutes. In addition to the Phase 2b study in TRD that is anticipated to read out in the second half of 2024, BPL-003 is also being investigated in two small Phase 2a open-label studies in TRD and AUD, with data expected in the first half of 2024 and mid 2024 respectively.

Beckley Psytech's second candidate ELE-101 is being developed for the treatment of Major Depressive Disorder (MDD). This compound has the potential to offer the therapeutic benefits of psilocybin, which has demonstrated significant antidepressant effects in multiple clinical studies, in a more consistent, controllable, and shorter treatment paradigm of less than 2 hours. Initial results from the current ELE-01 Phase 1/2a study are anticipated in the first half of 2024.

atai Co-founder and Chief Executive Officer, Florian Brand added: "When it comes to mental health, there is no one-size-fits-all solution, and the diverse pharmacology of our drug candidates acknowledges the heterogeneity of neuropsychiatric patient populations. Looking ahead to the next 12 months, adding to our already strong pipeline of potential catalysts, we anticipate this investment will lead to several additional meaningful clinical readouts, including topline results from the BPL-003 Phase 2b study, expected in the second half of 2024."

Under the terms of the investment Beckley Psytech will remain an independent, privately-owned company and atai will own 35.5% of Beckley Psytech. This is based on a \$50m total investment, with a \$40m direct investment into the company to fund ongoing research programs, and an additional \$10m in secondary share purchases from existing shareholders. Upon closing, atai will receive 1:1 warrant coverage at a 30% premium on the primary issuances. atai will also have the right to appoint and hold 3 of the 9 seats in Beckley Psytech's Board of Directors, and will hold a time-limited right of first refusal on a future sale of the company, asset sales or other transfer of commercial rights, as well as an indefinite right of first negotiation for BPL-003 and ELE-101.

Conference Call Information

atai Life Sciences will host a conference call and live webcast on Thursday January 4, 2024 at 8:00 a.m. ET. The conference call can be accessed on the Investors section of atai Life Sciences' website under News, Events & Presentations, via the following link: <https://ir.atai.life/news-events/events>. The presentation and an archived replay of the webcast will be available in the same section of the website for a minimum of 30 days following the event.

About Beckley Psytech

Beckley Psytech Ltd is a private, clinical stage biotechnology company dedicated to improving the lives of people suffering from neuropsychiatric disorders by transforming psychedelics into effective and rapid-acting clinical medicines. The company's most advanced programs are focused on the development of psychedelic-based medicines to treat people with TRD and MDD. Founded in 2019 and underpinned by more than two decades of pioneering scientific research from the Beckley Foundation, Beckley Psytech combines world-leading psychedelic science with extensive drug development expertise in order to optimize patient outcomes, improve treatment opportunities and ease the burden neuropsychiatric conditions have on individuals, healthcare systems and society.

About atai Life Sciences

atai is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders and was founded as a response to the significant unmet need and lack of innovation in the mental health treatment landscape. atai is dedicated to efficiently developing innovative therapeutics to treat depression, anxiety, addiction, and other mental health disorders. By pooling resources and best practices, atai aims to responsibly accelerate the development of new medicines to achieve clinically meaningful and sustained behavioral change in mental health patients. atai's vision is to heal mental health disorders so that everyone, everywhere can live a more fulfilled life. For more information, please visit www.atai.life.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "could," "would," "project," "plan," "potentially," "preliminary," "likely," and the negative of these terms and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions. All statements contained in this press release other than statements of historical fact should be considered forward-looking statements, including statements concerning our expectations and projections regarding any or all of the following: statements concerning the terms and benefits of the strategic investment with Beckley Psytech; the timing of clinical and regulatory developments related to BPL-003 and ELE-101; our future operating results and financial position; the success, cost, and timing of development of our other product candidates, including the progress of preclinical studies and clinical trials and related milestones; the commercialization of our product candidates and any other product candidates we may identify and pursue, if approved; the timing for announcing our study results and development plans including our clinical trials for RL-007, VLS-01, DMX-1002, EGX-121 and EMP-01; the timing of our communications with regulatory authorities to discuss future studies and trials or ability to obtain and maintain regulatory approvals; the scope and breadth of our existing and future intellectual property and protection thereof; our business strategy and plans; the sufficiency of our cash position to fund our operations and the length of time it may do so; the plans and objectives of management for future operations and capital expenditures; and our participation in upcoming events and conferences.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. Because forward-looking statements are subject to known and unknown risks, uncertainties, and assumptions, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks, uncertainties, and assumptions include, among others: our limited operating history, historical losses, and anticipation that we will continue to incur significant losses for the foreseeable future; we will require substantial additional funding to achieve our business goals, including the development and any commercialization of our product candidates; we have never generated revenue and may never be profitable; our product candidates contain controlled substances, the use of which may generate public controversy; clinical and preclinical development is uncertain, and our programs may experience delays or may never advance to clinical trials; our reliance on third parties to assist in conducting our clinical trials and impact to such trials based on factors including failure by third parties to meet trial or testing deadlines; our reliance on qualified therapists working at third-party clinical trial sites to administer certain of our product candidates and failure to recruit and retain a sufficient number of therapists; the timing and outcome of regulatory review and/or approvals, which are necessary prior to commercialization; research and development of drugs targeting the central nervous system, or CNS, is particularly difficult, and it can be difficult to predict and understand why a drug has a positive effect on some patients but not others; significant competition; obtaining, maintaining and protecting our intellectual property; restricted operating activity as a result of covenants in any financing arrangements, including our loan agreement with Hercules Capital, Inc.; our aggregate tax burden based on our management and operational activity. These forward-looking statements are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the risks, uncertainties, and assumptions described in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission ("SEC") on March 30, 2023, and as any such factors may be updated from time to time in our other filings with the SEC.

Any forward-looking statements made herein speak only as of the date of this press release. Except as required by applicable law, we undertake no obligation to update any of these forward-looking statements for any reason after the date of this press release or to conform these statements to actual results or revised expectations.

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