



atai Life Sciences Launches Invyxis to Accelerate Discovery of Next-Generation Mental Health Treatments

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Invyxis will add proven medicinal chemistry and comprehensive biological evaluation capabilities to grow atai's portfolio of new chemical entities (NCEs)

Early focus will be on designing unique, novel compounds aimed at the serotonin 5-HT2A receptor with other central nervous system (CNS) targets to follow

This new platform company is a further step-up in atai's commitment to next-generation treatments, complementing its machine learning-powered computational chemistry with EntheogeniX and biosynthesis-based drug discovery approaches with TryptageniX

NEW YORK and BERLIN, Jan. 27, 2022 (GLOBE NEWSWIRE) -- atai Life Sciences N.V. (Nasdaq: ATAI) ("atai"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, today launched Invyxis, a new, wholly owned platform company committed to developing new chemical entities (NCEs) and to further pioneering next-generation mental health treatments. Invyxis will bring proven medicinal chemistry tools and comprehensive biological screening approaches to atai's growing enterprise of drug discovery and design.

The launch of Invyxis is a further step-up in atai's growth and commitment to innovation in the treatment of mental health disorders. The new atai platform company has entered into a strategic collaboration with Dalriada Drug Discovery, specialists in the discovery of small molecule therapeutics. Invyxis will harness a broad array of methods including structure-based design, synthetic chemistry, high-throughput screening, and in vivo characterization.

Invyxis' goal will be to discover new agents with potential in treating mental health disorders, generating NCEs to progress into atai's research & development pipeline of psychedelic and non-psychedelic compounds. The platform company will initially focus on agonists at the 5-HT2A receptor, recognizing the importance of this key serotonin receptor system in treating a range of mental health disorders.

Expanding intellectual property (IP) has been essential to atai's strategy since inception, with key investments made to unlock NCEs. In 2019, atai launched EntheogeniX to pursue novel compounds using machine learning-based drug discovery, and the recent launch of TryptageniX added biosynthetic capabilities to atai's discovery efforts. ^{1,2} atai has already made substantial progress in its drug discovery efforts to date, synthesizing and screening approximately 300 compounds and identifying novel scaffolds that display potential in targeting mental health disorders.

"The global mental health crisis continues to escalate at an alarming rate and many patients do not find sufficient relief from currently available treatments. We urgently need newer, better options and innovative drug discovery is integral to this," said Florian Brand, Chief Executive Officer and Co-Founder of atai Life Sciences. "With the addition of Invyxis, atai is now even more equipped to bring forward revolutionary new treatments and optimize next-generation therapies to better meet patient needs."

"Expanding IP and growing our library of NCEs has been essential to our strategy since our inception," said Srinivas Rao, Chief Scientific Officer and Co-Founder of atai Life Sciences. "By establishing differentiated potential treatments, with near, middle, and long-term developmental timelines, we add value and sustainability to our extensive pipeline of novel compounds with potential in targeting mental health indications. We are uniquely positioned, as a leading developer of psychedelic therapeutics, with the resources necessary to commit to and deliver this forward-looking strategy."

"The use of psychedelic compounds to create improved next-generation mental health therapies is a highly promising and emerging field," said Diana Kraskouskaya, Dalriada Chief Executive and Co-Founder. "We're delighted to be partnering with atai to make an impact in this area. This creation of Invyxis brings together Dalriada's ability to provide a rapid set-up and advancement of NCE discovery pipelines and atai's expertise in the preclinical and clinical development of psychedelic therapeutics."

Mental health disorders impact over 1 billion people around the world, representing a growing global crisis, but medical innovation has failed to offer recent novel solutions.³ Only 7 treatments have been approved by the FDA for psychiatry disorders since 2015; a time in which approximately 100 have been advanced in oncology.⁴ atai Life Sciences is proud to be a driving force in mental health innovation and to make Invyxis the latest addition to its diversified platform, to develop new therapeutic options in key areas of patient unmet need.

References:

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2. atai Life Sciences launches TryptageniX to further expand atai's robust intellectual property portfolio and strengthen atai's supply chain. [Press release] <https://ir.atai.life/news-releases/news-release-details/atai-life-sciences-launches-tryptagenix-further-expand-atais>. Published December 9, 2021. Accessed January 18, 2022.
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4. U.S. Food and Drug Administration. New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products. Accessed January 5, 2022. <https://www.fda.gov/drugs/development-approval-process-drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products>.

About atai Life Sciences

atai is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders. atai was founded in 2018 as a response to the significant unmet need and lack of innovation in the mental health treatment landscape. atai is dedicated to acquiring, incubating and efficiently developing innovative therapeutics to treat depression, anxiety, addiction, and other mental health disorders.

atai's business model combines funding, technology, scientific and regulatory expertise with a focus on psychedelic therapy and other drugs with differentiated safety profiles and therapeutic potential. By pooling resources and best practices, atai aims to responsibly accelerate the development of new medicines across its companies, seeking to effectively treat and ultimately heal mental health disorders.

atai's vision is to heal mental health disorders so that everyone, everywhere can live a more fulfilled life. atai has offices in New York, London, and Berlin. 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, as amended. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "initiate," "could," "would," "project," "plan," "potentially," "preliminary," "likely," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements include express or implied statements relating to, among other things: statements regarding Invyxis and NCE development, the success, cost and timing of development of our product candidates, including the progress of preclinical and clinical trials and related milestones; our business strategy and plans; potential acquisitions; and the plans and objectives of management for future operations and capital expenditures. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond our control and which could cause actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these forward-looking statements.

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. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including without limitation: we are a clinical-stage biopharmaceutical company and have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future; we will require substantial additional funding to achieve our business goals, and if we are unable to obtain this funding when needed and on acceptable terms, we could be forced to delay, limit or terminate our product development efforts; our limited operating history may make it difficult to evaluate the success of our business and to assess our future viability; 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 preclinical programs may experience delays or may never advance to clinical trials; we rely on third parties to assist in conducting our clinical trials and some aspects of our research and preclinical testing, and those clinical trials, including progress and related milestones, may be impacted by several factors including the failure by such third parties to meet deadlines for the completion of such trials, research, or testing, changes to trial sites and other circumstances; we currently rely on qualified therapists working at third-party clinical trial sites to administer certain of our product candidates in our clinical trials and we expect this to continue upon approval, if any, of our current or future product candidates; if third-party sites fail to recruit and retain a sufficient number of therapists or effectively manage their therapists, our business, financial condition and results of operations would be materially harmed; we cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized; 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; we face significant competition in an environment of rapid technological and scientific change; third parties may claim that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent or delay our development and commercialization efforts; a change in our effective place of management may increase our aggregate tax burden; we identified material weaknesses in connection with our internal control over financial reporting; and a pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect our business, including our preclinical studies, clinical trials, third parties on whom we rely, our supply chain, our ability to raise capital, our ability to conduct regular business and our financial results. Other risk factors include the important factors described in the section titled "Risk Factors" in our final prospectus, dated June 17, 2021, filed with the Securities and Exchange Commission ("SEC") pursuant to Rule 424(b) under the Securities Act, and in our other filings with the SEC, that may cause our actual results, performance or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements.

Any forward-looking statements made herein speak only as of the date of this press release, and you should not rely on forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, performance, or achievements reflected in the forward-looking statements will be achieved or will occur. 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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