atai Life Sciences Reports Second Quarter 2023 Financial Results and Operational Highlights, and Announces Clinical Data from the Phase 1 Study of DMX-1002 (Ibogaine)

August 10, 2023

- *Advanced multiple clinical stage assets in development, including the on-going Phase 2b study of RL-007 in patients with Cognitive Impairment Associated with Schizophrenia*
- *DMX-1002 (Ibogaine) Phase 1 results enable discussions with regulatory authorities to assess progressing into proof-of-concept study in patients with Opioid Use Disorder*
- *The Company's $227M cash position and committed term loan funding is expected to fund operations into 1H 2026*

NEW YORK and BERLIN, Aug. 10, 2023 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) ("atai"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, reported second quarter 2023 financial results and provided corporate updates.

"We continue to focus on our vision to heal mental health disorders so that everyone, everywhere can live a more fulfilled life," said Florian Brand, CEO and Co-Founder of atai. "Looking ahead to the second half of 2023 and beyond, we believe we are well positioned to continue advancing our key clinical programs. We are especially encouraged by the progress our team has made in advancing RL-007 in the on-going randomized, placebo-controlled Phase 2b study as well as further evaluating VLS-01 in Part 3 of the on-going Phase 1 study. Today, we are pleased to report data from the Phase 1 trial of DMX-1002 (Ibogaine)."

"Current treatment options for Opioid Use Disorder (OUD) patients are not highly effective, with approximately 75% of patients undergoing therapy experiencing relapse within one year," said Srinivas Rao, CSO and Co-Founder. "DMX-1002 has the potential to be a disease modifying treatment for this vulnerable patient population seeking to end their intractable cycle of drug dependence."

"The results from this trial are consistent with the known side-effect profile of ibogaine, the active moiety in DMX-1002," said Dr. Marek Malik, Professor Emeritus of Cardiac Electrophysiology, Imperial College, London and clinical advisor for the DMX-1002 development program. "Ibogaine is known to cause prolongation of the electrocardiographic QT interval. Drug-induced prolongation of the QT interval is a phenomenon that has been, with many but not all drugs, associated with cardiac arrhythmias. The QT-related side effect of ibogaine is anticipated to be manageable in a controlled setting with appropriate cardiac monitoring and safety protocols. In severe patient populations, like those living with OUD, ibogaine treatment administered in such a setting has a potential to be a paradigm shift for patients."

DMX-1002 (Ibogaine) Phase 1 Results and Program Update:

Today, the company announced results from the Phase 1 study of DMX-1002, a cholinergic, glutamatergic and monoaminergic receptor modulator being developed for the treatment of OUD.

The single-blinded Phase 1 study assessed the safety, tolerability and pharmacokinetics of single-ascending doses of DMX-1002 in healthy volunteers. Oral doses of 3 mg/kg, 6 mg/kg & 9 mg/kg were evaluated in 20 participants. Results of the Phase 1 trial demonstrated that oral doses of DMX-1002 at 9 mg/kg achieved plasma concentrations in line with those described in previous studies[1,2] in which subjects reported psychedelic experiences and obtained therapeutic benefit in OUD.

The treatment-related adverse events (AEs) were similar to those observed in prior trials of DMX-1002, and nearly all (>94%) were rated mild-to-moderate in severity. There were no serious adverse events reported.

In one of the two participants who received 9 mg/kg of DMX-1002, QTc prolongation reached levels near those seen at the 10 mg/kg dose in the published literature[3] (median change: 95ms). In this participant, a QTcF prolongation of 90-94ms was observed with a QTcF interval of 493-501ms. The patient was asymptomatic, with no cardiac arrythmias, and the QTc change resolved without intervention or sequalae.

During the study the company closely worked with cardiology experts who concluded that while QT prolongation of this order is a clinical risk, monitoring can help mitigate the risk to ensure the safety of patients, especially in a medical setting. The benefit of the drug will need to be defined in efficacy trials and will need to be weighed against the risks that have been defined.

The company plans to engage regulatory authorities to assess progressing DMX-1002 into an efficacy study in patients with OUD.

Recent Developments:

RL-007 (Pro-Cognitive Neuromodulator for Cognitive Impairment Associated with Schizophrenia)

- The on-going Phase 2b study is a randomized, placebo-controlled, double-blind, study of 6 weeks duration evaluating 20mg and 40mg of RL-007 vs placebo.
- The primary endpoint of the study is the change from baseline in the MATRICS Consensus Cognitive Battery (MCCB) neurocognitive composite score, a well-established regulatory endpoint.
- The company expects to report topline results from this study in the 2nd half of 2024.

VLS-01 (N,N-dimethyltryptamine [DMT] for Treatment-Resistant Depression (“TRD”))

- The on-going Phase 1 study is designed to evaluate the safety, tolerability, PK and PD of VLS-01 delivered by intravenous (IV) infusion and using our proprietary oral transmucosal film (OTF) formulation.
- In Part 1 (IV) and Part 2 (OTF), VLS-01 was well-tolerated, with no dose-limiting toxicity and a favorable safety profile. VLS-01 produced generally dose-dependent increases in exposure, and administration resulted in subjective psychedelic experiences in the majority of subjects. Part 3 is exploring further optimization of PK and PD of our proprietary OTF formulation, including further dose ranging.
- The company expects to report additional clinical data in Q3 2023.

PCN-101 (R-Ketamine for TRD)

- The company recently announced completion of the Phase 1 open-label bridging study designed to assess the safety, tolerability, and pharmacokinetic profile of 60mg, 90mg and 120mg of PCN-101 delivered subcutaneously (SQ) as compared to 60mg of PCN-101 delivered IV.
- Pharmacokinetic (PK) analysis indicates that 120mg of PCN-101 delivered SQ resulted in an approximate doubling of drug exposure (AUC) while maintaining approximately the same maximum concentration (Cmax) as the 60mg IV dose.
- At the highest SQ dose of 120mg, rates of sedation (defined as MOAA/S score <5) and dissociation (defined as CADSS total score >4 and change from baseline >0) were each 14%. Overall, the data support testing the concept of at-home use of PCN-101 in future studies.
- The company continues to work with Perception Neuroscience to explore strategic partnership options.

EMP-01 (3,4-methylenedioxy-methamphetamine [MDMA] derivative for Post-Traumatic Stress Disorder (“PTSD”))

- The Phase 1 study is designed to evaluate the safety and tolerability of single-ascending doses of EMP-01 in healthy adult participants.
- Enrollment has been recently completed and the company expects to report initial clinical data in Q4 2023.

COMP360 (Psilocybin Therapy for TRD, Anorexia Nervosa and PTSD)

- COMPASS Pathways is currently conducting a Phase 3 program composed of two pivotal trials, each of which will have a long-term follow-up component. Topline data from Pivotal Trial 1 (COMP005) is expected in the summer 2024. The primary endpoint in both pivotal trials is the change from baseline in MADRS total score at week 6.
- The American Medical Association recently released the language of its new Current Procedural Terminology (CPT®) III code for Continuous In-Person Monitoring and Intervention During Psychedelic Medication Therapy. The code will go into effect and will be published in the CPT manual on January 1, 2024. Once effective, the new code will provide a mechanism to track and report the delivery of psychedelic treatments.

Consolidated Financial Results

Cash, Cash Equivalents, and Short-term investments: Cash, cash equivalents and short-term investments totaled $227.5 million as of June 30, 2023, compared to $273.1 million as of December 31, 2022. The decrease of $45.6 million was primarily driven by net cash used in operating activities of $43.7 million and $3.0 million of loans to related parties. The Company expects its cash position and committed term loan funding will be sufficient to fund operations into 1H 2026.

Research and Development (R&D) Expenses: Research and development expenses for the three months ended June 30, 2023 were $15.5 million, including $3.3 million of stock-based compensation compared to $17.9 million, including $3.9 million of stock-based compensation for the three months ended June 30, 2022. The decrease of $2.4 million was primarily attributable to a $1.8 million decrease of costs related to our non-clinical activities and $0.6 million decrease in contract research organization expenses.

General and Administrative (G&A) Expenses: General and administrative expenses were $16.6 million, including $5.4 million of stock-based compensation for the three months ended June 30, 2023 compared to $17.2 million, including $5.7 million of stock-based compensation for the three months ended June 30, 2022. The decrease of $0.6 million was largely attributable to a decrease of $0.4 million in personnel related costs and $0.2 million net decrease in public company administrative costs.

Net Loss: Net loss attributable to shareholders for the three months ended June 30, 2023, was $33.1 million (including non-cash share-based compensation expense of $8.8 million) as compared to $36.6 million (including non-cash share-based compensation expense of $9.5 million) for the comparable prior year period.

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.

References:

1. DC Mash et. al. [1998]
2. DC Mash et. al. [2018]
3. T Knuijver et al. [2021]

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 similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include but are not limited to statements concerning our expectations and projections regarding any or all of the following: our future operating results and financial position; the success, cost, and timing of development of our product candidates, including the progress of preclinical studies and clinical trials and related milestones; the timing for announcing our study results and development plans, including our clinical trials for RL-007, VLS-01, DMX-1002, PCN-101 and EMP-01; the timing of and our ability to obtain and maintain regulatory approvals; our business strategy and plans, including the benefits of our corporate restructuring; potential acquisitions, partnerships and other strategic arrangements; the sufficiency of our cash and cash equivalents to fund our operations; available funding under the Hercules Capital, Inc. loan facility; the plans and objectives of management for future operations and capital expenditures; and our participation in upcoming events and conferences.

Because forward-looking statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties 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 Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission ("SEC") and our quarterly reports on Form 10-Q, as may be updated by other filings we file with or furnish to 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.

ATAI LIFE SCIENCES N.V.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
License revenue	$ 172	$ 170	$ 209	$ 170
Operating expenses:				
Research and development	15,476	17,949	34,757	33,409
Acquisition of in-process research and development	—	357	—	357
General and administrative	16,558	17,221	30,529	35,203
Total operating expenses	32,034	35,527	65,286	68,969
Loss from operations	(31,862)	(35,357)	(65,077)	(68,799)
Other income (expense), net	204	4,551	263	6,072
Loss before income taxes	(31,658)	(30,806)	(64,814)	(62,727)
Provision for income taxes	(185)	(51)	(351)	(92)
Losses from investments in equity method investees, net of tax	(1,928)	(6,652)	(2,961)	(12,248)
Net loss	(33,771)	(37,509)	(68,126)	(75,067)
Net loss attributable to noncontrolling interests	(729)	(891)	(1,948)	(1,580)
Net loss attributable to ATAI Life Sciences N.V. stockholders	$ (33,042)	$ (36,618)	$ (66,178)	$ (73,487)

Net loss per share attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	$ (0.21)	$ (0.24)	$ (0.42)	$ (0.48)
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	155,792,490	153,971,202	155,793,323	153,751,456

ATAI LIFE SCIENCES N.V.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands)

	June 30 2023 (unaudited)	December 31, 2022 (1)
Assets		
Cash and cash equivalents	$ 141,090	$ 190,613
Securities carried at fair value	86,402	82,496
Prepaid expenses and other current assets	6,257	14,036
Short term notes receivable - related parties, net	9,021	—
Property and equipment, net	1,043	928
Operating lease right-of-use asset, net	1,367	226
Other investments	3,991	6,755
Long term notes receivable - related parties, net	1,157	7,262
Other assets	3,267	3,125
Total assets	$ 253,595	$ 305,441
Liabilities and Stockholders' Equity		
Accounts payable	3,859	2,399
Accrued liabilities	12,855	17,306
Current portion of lease liability	322	180
Other current liabilities	890	12
Non-current portion of contingent consideration liability - related parties	842	953
Non-current portion of lease liability	1,095	44
Convertible promissory notes - related parties, net of discounts and deferred issuance costs	420	415
Long-term debt, net	14,868	14,702
Other liabilities	2,807	3,664
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders	212,550	260,740
Noncontrolling interests	3,087	5,026
Total liabilities and stockholders' equity	$ 253,595	$ 305,441

(1) The condensed consolidated financial statements as of and for the year ended December 31, 2022 are derived from the audited consolidated financial statements as of that date.

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