atai Life Sciences Reports Third Quarter 2023 Financial Results and Pipeline Highlights

November 14, 2023

- *Phase 2b study of RL-007 in CIAS patients continues to be on track to report data in 2H 2024 and data from the EMP-01 (MDMA derivative) Phase 1 study is anticipated to report out later this year.*
- *Phase 1 data of VLS-01 (a proprietary oral transmucosal film formulation of DMT) demonstrated that 160mg of VLS-01 reached exposure levels comparable to 30mg of IV DMT.*
- *Acceptance of three non-clinical poster presentations at upcoming medical meetings, including non-clinical data for RL-007 and two novel 5-HT2A receptor agonists, EGX-A and EGX-B.*
- *The Company's $209M cash position and committed term loan funding is expected to fund operations into 1H 2026.*

NEW YORK and BERLIN, Nov. 14, 2023 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) ("atai"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, reported third quarter 2023 financial results and provided corporate updates.

"As the burden of unmet medical needs in mental health care continues to grow, our team remains highly focused on pioneering the development of innovative neuropsychiatric treatments," said Florian Brand, CEO and Co-Founder of atai. "With a strong cash balance of $209M, we are well positioned to continue advancing our clinical programs towards key data milestones, including the Phase 2b readout of RL-007 expected in the second half of 2024. Last month, we were pleased to report Phase 1 results from our VLS-01 study, which demonstrated that 160mg of VLS-01 reached exposure levels comparable to 30mg of intravenous DMT. Next to our steady clinical progress, we are encouraged by our team's preclinical and drug discovery work, such as on EGX-A and EGX-B, that demonstrate our holistic drug development capabilities and commitment to groundbreaking mental health innovation."

Recent Pipeline Highlights:

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

- RL-007 is an orally bioavailable compound that has consistently demonstrated pro-cognitive effects in multiple pre-clinical and clinical studies, including two Phase 1 and two Phase 2 trials.
- The on-going Phase 2b study will evaluate 20mg and 40mg of RL-007 vs. placebo in patients with CIAS, with topline results expected in 2H 2024.
- The company announced the acceptance of a non-clinical poster presentation titled "*RL-007, a Novel Oral Neuromodulator, Enhances Synaptic Plasticity and Cognition in Non-Clinical Models*". The poster will be presented at the American College of Neuropsychopharmacology (ACNP) annual meeting on Dec 5, 2023, 5:00 – 7:00 PM ET.

VLS-01: N,N-dimethyltryptamine (DMT) for Treatment Resistant Depression (TRD)

- VLS-01 is an oral transmucosal formulation (OTF) of DMT, a partial agonist of the 5-HT-1A/2A/2C receptors, developed to induce a short duration of psychedelic effect of approximately 30 to 45 minutes.
- In October 2023, the company announced the completion of a Phase 1 study in healthy participants, in which VLS-01 was found to be well-tolerated with a favorable safety profile.
- Pharmacokinetic and pharmacodynamic data confirmed systemic delivery of VLS-01 via atai's proprietary oral, transmucosal route at levels comparable to those achieved with 30 mg IV DMT.
- In preparation of initiating a Phase 2 trial in TRD, atai plans to further optimize VLS-01 by incorporating taste masking, an intrinsic backing layer, and enhancements to increase permeability.
- The company has received regulatory approval to initiate a Phase 1b healthy volunteer study and expects to enroll the first participant in 1H 2024.

DMX-1002: Ibogaine for Opioid Use Disorder (OUD)

- DMX-1002 is an oral formulation of ibogaine, an oneirogenic indole alkaloid with cholinergic, glutamatergic and monoaminergic receptor modulatory activity.
- In August 2023, the company reported data from a Phase 1 study in which 9 mg/kg of DMX-1002 achieved plasma concentrations and psychedelic experiences consistent with previous studies of Ibogaine.

- The treatment-related adverse events (AEs) and side effects, such as QT prolongation, were similar to those observed in prior trials of ibogaine, and nearly all AEs (>94%) were rated mild-to-moderate in severity. There were no serious adverse events reported.
- These Phase 1 results enable discussions with regulatory authorities to assess progressing DMX-1002 into a proof-of-concept study in OUD.
- In November 2023, atai acquired all remaining outstanding shares of its subsidiary, DemeRx IB, Inc. The acquisition brings DMX-1002 into atai as a wholly-owned asset, and streamlines clinical and general and administrative operations.

EMP-01: 3,4-methylenedioxy-methamphetamine (MDMA) derivative for Post-Traumatic Stress Disorder (PTSD)

- EMP-01 is an oral formulation of an MDMA derivative, designed to be a better tolerated alternative to racemic MDMA.
- The Phase 1 study is designed to evaluate the safety and tolerability of single-ascending doses of EMP-01 in healthy adult participants.
- The company expects to report initial results of the Phase 1 study later this year in line with previous guidance.

EGX-A and EGX-B: Novel 5-HT2A Receptor Agonists

- EGX-A and EGX-B are lead candidates from atai's internal drug discovery engine, which were discovered using an artificial intelligence/machine learning-driven approach. They are psychedelic-like with novel, non-tryptamine structures with differentiated 5-HT receptor pharmacology compared to traditional psychedelics.
- The company announced the acceptance of two non-clinical poster presentations highlighting the discovery of two novel 5-HT2A receptor agonists that exhibit psychedelic activity.
    - *"Novel 5-HT2A receptor agonist exhibit translational antidepressant and psychedelic drug-like profiles in a model of treatment-resistant depression"* will be presented at the Neuroscience 2023 Annual Meeting on Nov 14, 2023, 1:00 – 5:00 PM ET.
    - *"Discovery of novel 5-HT2A receptor agonists with psychedelic drug-like in vitro and in vivo pharmacological activity and therapeutic potential for treatment-resistant depression"* will be presented at the upcoming ACNP annual meeting on Dec 5, 2023, 5:00 – 7:00 PM ET.

COMP360: Psilocybin Therapy for TRD, PTSD and Anorexia Nervosa

- COMPASS Pathways is currently conducting a phase 3 program in TRD patients composed of two pivotal trials, each of which will have a long-term follow-up component.
- Both, Pivotal Trial 1 (COMP005) and Pivotal Trial 2 (COMP006), are ongoing and on track with top line data expected in summer 2024 and mid 2025 respectively.
- The top-line data of the Phase 2 study in PTSD is expected by the end of 2023, and a Phase 2 study in Anorexia Nervosa is ongoing.
- The publication of a paper in Psychopharmacology showed the potential of AI technologies to support investigational COMP360 psilocybin treatment in TRD.

Following the respective sessions at the upcoming medical meetings, the posters / presentations will be posted at https://ir.atai.life/news-events/events.

Consolidated Financial Results

Cash, Cash Equivalents, and Short-term investments: Cash, cash equivalents and short-term investments totaled $209.0 million as of September 30, 2023, compared to $273.1 million as of December 31, 2022. The decrease of $64.1 million was primarily driven by net cash used in operating activities of $62.2 million, and $5.2 million of funding in strategic investments, offset by $0.7 million proceeds from sale of investment and exercise of stock options. 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 were $13.3 million for the three months ended September 30, 2023, compared to $19.0 million for the three months ended September 30, 2022. The decrease of $5.7 million was primarily attributable to a $3.2 million decrease of costs in our clinical programs, $1.6 million decrease of costs related to our non-clinical activities and $0.9 million decrease in personnel expenses (inclusive of a $0.6 million decrease in non-cash share-based compensation).

General and Administrative (G&A) Expenses: General and administrative expenses were $13.6 million for the three months ended September 30, 2023, compared to $19.4 million for the three months ended September 30, 2022. The decrease of $5.8 million was largely attributable to a decrease of $2.8 million in personnel related costs (inclusive of $1.6 million decrease in non-cash share-based compensation), $1.8 million decrease in public company related administrative costs and a $1.2 million decrease in non-income taxes.

Net Income (Loss): Net income attributable to shareholders for the three months ended September 30, 2023 was $44.2 million, which included a $69.0

million non-cash change in fair value of other investments related to an accounting method change of our COMPASS Pathways plc investment and $8.3 million of non-cash share-based compensation expense. Net loss attributable to shareholders for the three months ended September 30, 2022, was $33.9 million (including non-cash share-based compensation expense of $10.5 million).

About atai Life Sciences

atai is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders. Founded as a response to the significant unmet need and lack of innovation in the mental health treatment landscape, atai is dedicated to acquiring and 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: 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 commercialization of our current product candidates and any other product candidates we may identify and pursue, if approved, including our ability to successfully build a specialty sales force and commercial infrastructure to market our current product candidates and any other product candidates we may identify and pursue, 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 our communications with regulatory authorities to discuss future studies and trials; 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 position to fund our operations and the length of time it may do so; 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.

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 our Form 10-Qs, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
License revenue	$ 87	$ 24	$ 296	$ 195
Operating expenses:				
Research and development	13,290	19,028	48,047	52,437

Acquisition of in-process research and development	—	—	—	357
General and administrative	13,631	19,419	44,159	54,623
Total operating expenses	26,921	38,447	92,206	107,417
Loss from operations	(26,834)	(38,423)	(91,910)	(107,222)
Other income (expense), net	70,681	5,289	70,944	11,361
Net income (loss) before income taxes	43,847	(33,134)	(20,966)	(95,861)
Provision for income taxes	(238)	(135)	(588)	(227)
Losses from investments in equity method investees, net of tax	(238)	(2,432)	(3,199)	(14,680)
Net income (loss)	43,371	(35,701)	(24,753)	(110,768)
Net loss attributable to noncontrolling interests	(873)	(1,814)	(2,821)	(3,394)
Net income (loss) attributable to ATAI Life Sciences N.V. stockholders	$ 44,244	$ (33,887)	$ (21,932)	$ (107,374)
Net income (loss) per share attributable to ATAI Life Sciences N.V. stockholders — basic	$ 0.28	$ (0.22)	$ (0.14)	$ (0.69)
Net income (loss) per share attributable to ATAI Life Sciences N.V. stockholders — diluted	$ 0.25	$ (0.22)	$ (0.14)	$ (0.69)
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — basic	155,792,490	156,607,468	155,793,601	154,713,922
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — diluted	177,565,973	156,607,468	155,793,601	154,713,922

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

	September 30, 2023 (unaudited)	December 31, 2022 (1)
Assets		
Cash and cash equivalents	$ 76,492	$ 190,613
Securities carried at fair value	132,502	82,496
Prepaid expenses and other current assets	6,831	14,036
Property and equipment, net	992	928
Operating lease right-of-use asset, net	1,258	226
Other Investments held at fair value	71,511	—
Other investments	3,659	6,755
Convertible notes receivable - related party	1,519	—
Long term notes receivable - related parties, net	10,349	7,262
Other assets	3,107	3,125
Total assets	$ 308,220	$ 305,441
Liabilities and Stockholders' Equity		
Accounts payable	5,506	2,399
Accrued liabilities	13,008	17,306
Current portion of lease liability	292	180
Other current liabilities	889	12
Contingent consideration liability - related parties	900	953
Non-current portion of lease liability	1,011	44
Convertible promissory notes - related parties, net of discounts and deferred issuance costs	410	415
Long-term debt, net	14,956	14,702
Other liabilities	2,736	3,664
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders	266,276	260,740
Noncontrolling interests	2,236	5,026
Total liabilities and stockholders' equity	$ 308,220	$ 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.