atai Life Sciences Reports Third Quarter 2024 Financial Results and Provides Corporate Updates

November 13, 2024

- The United States Food and Drug Administration cleared the investigational new drug application for VLS-01 (buccal film DMT); atai expects to initiate a Phase 2 study in treatment-resistant depression patients around YE'24

- Remain on track to initiate a Phase 2 study of EMP-01 (oral R-MDMA) in social anxiety disorder patients around YE'24

- Cash, marketable securities, and committed term loan funding expected to fund operations into 2026

NEW YORK and BERLIN, Nov. 13, 2024 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) ("atai" or "Company"), (NASDAQ: ATAI) ("atai" or "Company"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, today announced third quarter 2024 financial results and provided corporate updates.

"As we approach the end of 2024, we continue to see progress and momentum across our pipeline, both with our wholly owned programs and strategic investments," stated Dr. Srinivas Rao, Co-Chief Executive Officer and Co-founder of atai. "We are on track to initiate Phase 2 trials for VLS-01 and EMP-01 around year-end and we look forward to topline Phase 2b data from Beckley Psytech's BPL-003 in the second quarter of 2025. Our team is focused on executing these trials with the utmost scientific rigor and is driven by our goal of being the leader in developing new psychedelic treatment options to mental health patients in need of innovative, safe and effective solutions."

Recent Clinical Highlights

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

- VLS-01 is a proprietary oral transmucosal film formulation of DMT applied to the buccal surface designed to fit within a two-hour in-clinic treatment paradigm.
- The United States Food and Drug Administration (FDA) cleared the investigational new drug (IND) application for VLS-01, allowing the Company to proceed with its plans to initiate a randomized, double-blind, placebo-controlled Phase 2 study to assess the safety, efficacy and durability of response of repeated doses of VLS-01 buccal film in patients with TRD.
- The Phase 2 study is expected to initiate the study in U.S. around year-end 2024.

EMP-01: R-enantiomer of 3,4-methylenedioxy-methamphetamine (R-MDMA) for Social Anxiety Disorder (SAD)

- EMP-01 is an oral formulation of R-MDMA that demonstrated a unique, dose-dependent subjective effect profile in a Phase 1 trial that was generally found to be more similar to classical psychedelics than to racemic MDMA.
- atai expects to initiate an exploratory, randomized, double-blind, placebo-controlled Phase 2 study to assess the safety, tolerability and efficacy of EMP-01 in adults with SAD around year-end 2024.
- SAD is an area of high unmet medical need with approximately 18 million people in the U.S. diagnosed in the past year and no novel molecules approved in over two decades.

IBX-210: Intravenous (IV)-Ibogaine for Opioid Use Disorder (OUD)

- IBX-210 is a novel IV formulation of ibogaine, which is an indole alkaloid with potential for clinical benefit for substance use disorder
- Completed productive FDA pre-IND meeting to initiate discussions and alignment on a modern ibogaine IND.
- atai plans to run additional non-clinical studies prior to launching a Phase 1b study.

Novel 5-HT2A Receptor Agonists

- Discovery program to identify novel, non-hallucinogenic 5-HT2AR agonists for TRD using artificial intelligence (AI)/machine learning (ML)-informed drug design and medicinal chemistry.
- Presented data at the Society for Neuroscience (SfN) annual meeting aimed to show that these compounds are promising chemical starting points for new analogs with further improved 5-HT2AR vs. 5-HT2BR agonist selectivity that maintain translational antidepressant-like activity with potential for non-hallucinogenic effects.

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

- RL-007 is an orally bioavailable compound that has demonstrated pro-cognitive effects in multiple pre-clinical and clinical studies, including two Phase 1 and two Phase 2 trials.
- The ongoing Phase 2b study is evaluating 20mg and 40mg of RL-007 vs. placebo in patients living with CIAS. Topline results are expected mid-2025.

Recent Corporate Updates
Completed the acquisition of IntelGenx Corp.

- IntelGenx is a drug delivery company focused on the development and manufacturing of novel oral thin film products for the pharmaceutical market and manufactures VLS-01 (buccal film DMT).
- Neither equity nor cash from the Company was used to acquire IntelGenx.

Anticipated Upcoming R&D Catalysts

- H2'24
  - VLS-01 TRD: Phase 2 initiation (around YE'24)
  - EMP-01 SAD: Phase 2 initiation (around YE'24)
  - BPL-003 alcohol use disorder (AUD): Phase 2a topline open-label data
  - ELE-101 major depressive disorder (MDD): Phase 2a topline open-label data
- 2025
  - BPL-003 TRD: Phase 2b topline data (Q2'25)
  - RL-007 cognitive impairment associated with schizophrenia (CIAS): Phase 2b topline data (mid'25)
  - VLS-01 TRD: Phase 2 topline data (around YE'25)
  - EMP-01 SAD: Phase 2 topline data (around YE'25)

Consolidated Financial Results
Cash, cash equivalents, and short-term securities (primarily US treasuries and government agency securities): As of September 30, 2024, the Company had cash, cash equivalents, restricted cash and short-term securities of $101.0 million compared to $154.2 million as of December 31, 2023. The decrease of $53.2 million was primarily driven by $58.1 million net cash used in operating activities, $10.0 million for the Beckley Psytech investment, and $7.7 million investment to advance our programs; partially offset by $16.1 million in proceeds from the partial sale of our ADSs holdings in Compass Pathway, and $5.0 million in proceeds from our committed term loan with Hercules Capital, Inc. The Company expects its cash, short-term securities, public equity holdings, and committed term loan facility to be sufficient to fund operations into 2026.

Research and development (R&D) expenses: R&D expenses were $12.4 million for the three months ended September 30, 2024, as compared to $13.3 million for the same prior year period. The year-over-year decrease of $0.9 million was primarily attributable to a decrease of $2.7 million in R&D personnel-related expenses, partially offset by an increase of $1.7 million in program-specific expenses. Within program-specific expenses, the increase was primarily driven by additional clinical trial expenses in the current year. The Company is anticipating R&D spend to increase as its R&D programs progress into later stage clinical trials.

General and administrative (G&A) expenses: G&A expenses for the three months ended September 30, 2024, were $10.3 million as compared to $13.6 million in the same prior year period. The year-over-year decrease of $3.3 million was primarily attributable to a $3.5 million decrease in personnel-related expenses and administrative costs. The Company expects the reduction in G&A spend over prior years to continue.

Net income (loss): Net loss attributable to stockholders for the three months ended September 30, 2024, was $26.3 million, which included $2.0 million of non-cash change in fair value of notes receivables and other investments and $5.0 million of non-cash share-based compensation. Net income attributable to stockholders 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 change of our Compass Pathways plc investment and $8.3 million of non-cash share-based compensation.

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, as amended. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "anticipate," "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: our business strategy and plans; the potential, success, cost and timing of development of our product candidates, including the progress of preclinical and clinical trials and related milestones; expectations regarding our strategic investment in Beckley Psytech and other investments; expectations regarding our cash runway; and the plans and objectives of management for future operations, research and development and capital expenditures.

Forward-looking statements are neither promises nor guarantees, but involve known and unknown risks and uncertainties that could cause actual results to differ materially from those projected, including, without limitation, the important factors described in the section titled "Risk Factors" in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC"), as such factors may be updated from time to time in atai's other filings with the SEC. atai disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release, other than to the extent required by applicable law.

Contact Information
Investor Contact:

IR@atai.life

Media Contact:
PR@atai.life

-- Financial Statements Attached --

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(unaudited)		(unaudited)	
License revenue	$ 40	$ 87	$ 313	$ 296
Operating expenses:				
Research and development	12,377	13,290	36,513	48,047
General and administrative	10,265	13,631	36,226	44,159
Total operating expenses	22,642	26,921	72,739	92,206
Loss from operations	(22,602)	(26,834)	(72,426)	(91,910)
Other income (expense), net	(3,861)	70,681	(36,795)	70,944
Net income (loss) before income taxes	(26,463)	43,847	(109,221)	(20,966)
Benefit from (provision for) income taxes	178	(238)	163	(588)
Losses from investments in equity method investees, net of tax	(26)	(238)	(2,000)	(3,199)
Net income (loss)	(26,311)	43,371	(111,058)	(24,753)
Net loss attributable to noncontrolling interests	(25)	(873)	(747)	(2,821)
Net income (loss) attributable to ATAI Life Sciences N.V. stockholders	$ (26,286)	$ 44,244	$ (110,311)	$ (21,932)
Net income (loss) per share attributable to ATAI Life Sciences N.V. stockholders — basic	$ (0.16)	$ 0.28	$ (0.69)	$ (0.14)
Net income (loss) per share attributable to ATAI Life Sciences N.V. stockholders — diluted	$ (0.16)	$ 0.25	$ (0.69)	$ (0.14)
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — basic	160,621,817	155,792,490	159,973,201	155,793,601
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — diluted	160,621,817	177,565,973	159,973,201	155,793,601

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

	September 30, 2024	December 31, 2023
	(unaudited)	(1)
Assets		
Cash and cash equivalents	$ 29,963	$ 45,034
Securities carried at fair value	55,957	109,223
Short-term restricted cash for other investments	15,000	-
Committed investment funds	-	25,000
Prepaid expenses and other current assets	7,454	5,830
Short-term notes receivable - related party, net	5,700	505
Property and equipment, net	865	981
Operating lease right-of-use asset, net	1,032	1,223
Other investments held at fair value	45,227	89,825
Other investments	33,893	1,838
Long-term notes receivable - related party, net	-	97
Convertible notes receivable - related party	-	11,202
Other assets	2,428	2,720
Total assets	$ 197,519	$ 293,478
Liabilities and Stockholders' Equity		

Accounts payable	4,880	4,589
Accrued liabilities	11,953	15,256
Current portion of lease liability	257	275
Short-term convertible promissory notes and derivative liability - related party	925	—
Short-term convertible promissory notes and derivative liability	1,481	—
Other current liability	147	—
Contingent consideration liability - related parties	650	620
Contingent consideration liability	1,388	1,637
Noncurrent portion of lease liability	808	990
Convertible promissory notes and derivative liability - related party	—	164
Convertible promissory notes and derivative liability	—	2,666
Long-term debt, net	20,336	15,047
Other liabilities	8,378	7,918
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders	145,720	242,962
Noncontrolling interests	596	1,354
Total liabilities and stockholders' equity	$ 197,519	$ 293,478

(1) The condensed consolidated financial statements as of and for the year ended December 31, 2023 are derived from the audited consolidated financial statements as of that date.