



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

August 13, 2024

- Reported positive Phase 1b results of VLS-01 (buccal film DMT); expect to initiate a Phase 2 study in treatment-resistant depression patients around YE'24
- Announced clinical development plans for EMP-01 (oral R-MDMA); expect to initiate a Phase 2 study of EMP-01 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, Aug. 13, 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 second quarter 2024 financial results and provided corporate updates.

"Over the past quarter, we've made significant strides to advance our pipeline, with key updates from our VLS-01 and EMP-01 programs," stated Dr. Srinivas Rao, Co-Chief Executive Officer and Co-founder of atai. "Our positive Phase 1b results for VLS-01 underscore its potential as a best-in-class oral treatment for patients suffering from treatment-resistant depression, and we look forward to initiating the Phase 2 study around year-end.

Clinical development plans for EMP-01 are advancing with a Phase 2 study in Social Anxiety Disorder (SAD) set to begin around year-end. This follows encouraging Phase 1 results, where EMP-01 demonstrated a unique subjective profile compared to racemic MDMA and classical psychedelics. With no novel molecules approved for SAD in over 20 years, it remains an area of critical unmet need.

Looking ahead, our team is focused on several important readouts and study initiations in the second half of the year. As such, we continue to establish our position as a leader in mental health innovation, with a robust set of high potential programs aimed at addressing the areas of most significant unmet need."

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.
- Recently, atai announced positive topline data from the Phase 1b trial of VLS-01 buccal film in 17 healthy participants. Peak plasma concentration of VLS-01 occurred within 30-45 minutes. VLS-01 was shown to induce a short psychedelic experience, with subjective effects generally resolving within 90-120 minutes.
- VLS-01 demonstrated a favorable safety profile and was well tolerated, with all adverse events classified as either mild or moderate, most resolving on the day of dosing, and none related to blood pressure, heart rate, or suicidality.
- The Company expects 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 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.

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)
 - IBX-210 opioid use disorder (OUD): Phase 1b/2a initiation
 - BPL-003 TRD: Phase 2b complete patient enrollment
 - BPL-003 alcohol use disorder (AUD): Phase 2a topline open-label data
 - ELE-101 major depressive disorder (MDD): Phase 2a topline open-label data
 - COMP360 TRD: Phase 3 Pivotal Trial 1 topline data

- 2025

- o RL-007 cognitive impairment associated with schizophrenia (CIAS): Phase 2b topline data (mid'25)
- o COMP360 TRD: Phase 3 Pivotal Trial 2 topline data (mid'25)

Consolidated Financial Results

Cash, cash equivalents, and short-term securities (primarily US treasuries and government agency securities): As of June 30, 2024, the Company had cash, cash equivalents, restricted cash and short-term securities of \$103.3 million compared to \$154.2 million as of December 31, 2023. The decrease of \$50.9 million was primarily driven by \$38.8 million net cash used in operating activities, \$10 million for the Beckley Psytech investment, and \$3.9 million funding of strategic investments. The Company expects its cash, short-term securities, public equity holdings, and committed term loan facility with Hercules Capital, Inc. to be sufficient to fund operations into 2026.

Research and development (R&D) expenses: R&D expenses were \$12.6 million for the three months ended June 30, 2024, as compared to \$15.5 million for the same prior year period. The year-over-year decrease of \$2.9 million was primarily attributable to a decrease of \$1.0 million in program-specific expenses and \$1.9 million in R&D personnel. Within program-specific expenses, the decrease was primarily driven by more clinical trial and discovery expenses in prior 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 June 30, 2024, were \$13.4 million as compared to \$16.6 million in the same prior year period. The year-over-year decrease of \$3.2 million was primarily attributable to a \$1.9 million decrease in personnel related expenses, \$1.8 million net decrease of professional services and other administrative expenses, partially offset by a \$0.5 million increase in public company and investor relations expense. The Company expects the reduction in G&A spend over prior years to continue.

Other income (expense), net. Other expense for the three months ended June 30, 2024, was \$31.3 million as compared to \$0.2 million income in the same prior year period. Other expense for the 2024 second quarter includes a \$30.6 million reduction in the fair value of our assets and liabilities, net. This primarily consists of a \$29.1 million reduction in investments held at fair value, \$7.5 million reduction in the fair value of related party notes receivable, and \$4.8 million decrease in fair value of convertible note liability.

Net loss: Net loss attributable to stockholders for the three months ended June 30, 2024, was \$57.3 million as compared to \$33.0 million for the three months ended June 30, 2023.

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," "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.

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-- 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		Six Months Ended	
June 30,		June 30,	
2024	2023	2024	2023

	(unaudited)		(unaudited)	
	\$	\$	\$	\$
License revenue	273	172	273	209
Operating expenses:				
Research and development	12,605	15,476	24,136	34,757
General and administrative	13,397	16,558	25,952	30,529
Total operating expenses	<u>26,002</u>	<u>32,034</u>	<u>50,088</u>	<u>65,286</u>
Loss from operations	<u>(25,729)</u>	<u>(31,862)</u>	<u>(49,815)</u>	<u>(65,077)</u>
Other income (expense), net	<u>(31,348)</u>	<u>204</u>	<u>(32,943)</u>	<u>263</u>
Loss before income taxes	<u>(57,077)</u>	<u>(31,658)</u>	<u>(82,758)</u>	<u>(64,814)</u>
Provision for income taxes	<u>(19)</u>	<u>(185)</u>	<u>(15)</u>	<u>(351)</u>
Losses from investments in equity method investees, net of tax	<u>(273)</u>	<u>(1,928)</u>	<u>(1,974)</u>	<u>(2,961)</u>
Net loss	<u>(57,369)</u>	<u>(33,771)</u>	<u>(84,747)</u>	<u>(68,126)</u>
Net loss attributable to noncontrolling interests	<u>(57)</u>	<u>(729)</u>	<u>(722)</u>	<u>(1,948)</u>
Net loss attributable to ATAI Life Sciences N.V. stockholders	<u><u>\$ (57,312)</u></u>	<u><u>\$ (33,042)</u></u>	<u><u>\$ (84,025)</u></u>	<u><u>\$ (66,178)</u></u>
Net loss per share attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	<u><u>\$ (0.36)</u></u>	<u><u>\$ (0.21)</u></u>	<u><u>\$ (0.53)</u></u>	<u><u>\$ (0.42)</u></u>
Weighted average common shares outstanding attributable to				
ATAI Life Sciences N.V. stockholders — basic and diluted	<u><u>160,387,701</u></u>	<u><u>155,792,490</u></u>	<u><u>159,643,518</u></u>	<u><u>155,793,323</u></u>

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

	June 30, 2024	December 31, 2023
	(unaudited)	(1)
Assets		
Cash and cash equivalents	\$ 19,333	\$ 45,034
Securities carried at fair value	69,013	109,223
Short term restricted cash for other investments	15,000	-
Committed investment funds	-	25,000
Prepaid expenses and other current assets	4,690	5,830
Short term convertible notes receivable - related party	7,976	-
Short term notes receivable - related party, net	1,896	505
Property and equipment, net	873	981
Operating lease right-of-use asset, net	1,043	1,223
Other investments held at fair value	61,141	89,825
Other investments	32,381	1,838
Long term notes receivable - related party, net	-	97
Convertible notes receivable - related party	-	11,202
Other assets	2,432	2,720
Total assets	<u><u>\$ 215,778</u></u>	<u><u>\$ 293,478</u></u>
Liabilities and Stockholders' Equity		
Accounts payable	3,814	4,589
Accrued liabilities	12,911	15,256
Current portion of lease liability	239	275
Other current liability	680	—
Contingent consideration liability - related parties	580	620
Contingent consideration liability	1,373	1,637
Noncurrent portion of lease liability	838	990
Convertible promissory notes and derivative liability - related party	1,270	164
Convertible promissory notes and derivative liability	2,049	2,666
Long term debt, net	15,236	15,047
Other liabilities	8,255	7,918
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders	167,890	242,962
Noncontrolling interests	643	1,354
Total liabilities and stockholders' equity	<u><u>\$ 215,778</u></u>	<u><u>\$ 293,478</u></u>

(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.