



atai Life Sciences Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate and Clinical Highlights

March 28, 2024

- *Strategic investment in Beckley Psytech to accelerate the development of psychedelic-based therapies that fit within the two hour in-clinic treatment paradigm established by Spravato®*
- *Initial BPL-003 (intranasal 5-MeO-DMT) Phase 2a open-label results demonstrated a rapid and durable antidepressant effect through three months in TRD patients; top-line results from a controlled Phase 2b TRD study anticipated in 2H 2024*
- *Dosing commenced in VLS-01 (oral transmucosal DMT) Phase 1b study, with optimized formulation designed to improve pharmacokinetics and patient experience ahead of anticipated Phase 2 trial in TRD*
- *Cash, marketable securities, and committed term loan funding expected to fund operations into 2026*

NEW YORK and BERLIN, March 28, 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 fourth quarter and full year 2023 financial results and provided corporate and clinical highlights.

"In 2023, we demonstrated our continued commitment to transforming mental health care for those most in need. Much of our recent focus has centred on psychedelic-based therapies for depression - such as BPL-003, an intranasal formulation of 5-MeO-DMT - that require two hours or less in a clinic. We believe that the combination of a short treatment time and durable efficacy has the potential to enable accessible and convenient interventional treatments at scale. The recent BPL-003 Phase 2a data from Beckley Psytech are encouraging in anticipation of the larger Phase 2b results in the second half of this year. The data showed that acute effects resolved on average in less than two hours, the antidepressant effect was rapid, and was sustained for three months," said Florian Brand, atai Chief Executive Officer and Co-founder.

Mr. Brand continued, "Another asset designed as a two hour in-clinic treatment is VLS-01, an oral transmucosal formulation of N,N-DMT, which recently started dosing in a Phase 1b trial. Looking ahead, we anticipate several important milestones throughout the next year, including the Phase 2b readout from BPL-003."

Corporate Highlights

- In January 2024, atai made a strategic investment in Beckley Psytech, a private clinical-stage biotechnology company. The transaction added two clinical-stage assets, BPL-003 and ELE-101 to atai's programs. Atai owns 35.5% of Beckley Psytech and holds a time-limited right of first refusal on a future sale of the company, asset sales or other transfer of commercial rights, as well as an indefinite right of first negotiation for BPL-003 and ELE-101.
- In November 2023, atai acquired all remaining outstanding shares of its subsidiary, DemeRx IB, Inc., streamlining clinical, general and administrative operations.
- atai realized operational efficiencies by simplifying and optimizing its organizational structure in line with its revised business and pipeline priorities.

Clinical Highlights

BPL-003: 5-MeO-DMT for Treatment-Resistant Depression (TRD)

- BPL-003 is an intranasal formulation of 5-methoxy-*N,N*-dimethyltryptamine (5-MeO-DMT) designed to fit within a two hour in-clinic treatment paradigm.
- In March 2024, a Phase 2a open-label study showed that a single administration of BPL-003 resulted in rapid and durable antidepressant effects, with 45% of patients in remission three months after dosing. The acute effects of BPL-003 resolved on average in less than two hours, and it was found to be safe and well-tolerated in this trial population, with no serious adverse events (SAEs) reported.
- A controlled Phase 2b study of BPL-003 in 225 TRD patients is underway across multiple sites, including the United States, Australia and Europe, with topline data expected in 2H 2024.
- Data from a Phase 2a open-label study in Alcohol Use Disorder patients is expected mid-2024.

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

- VLS-01 is an oral transmucosal film (OTF) formulation of DMT designed to fit within a two-hour treatment paradigm.
- In March 2024, we announced the initiation of dosing in a Phase 1b study that is designed to evaluate the relative safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of an optimized OTF formulation of VLS-01, compared to intravenous (IV) DMT.
- The optimized formulation is designed to improve the PK and the patient and provider experience ahead of moving into an anticipated Phase 2 trial in TRD.
- Results of the Phase 1b trial are anticipated in 2H 2024.

ELE-101: Psilocin for Major Depressive Disorder (MDD)

- ELE-101 is an IV formulation of psilocin, the active moiety of psilocybin.
- ELE-101 has the potential to offer the therapeutic benefits of psilocybin in a more consistent, controllable, and shorter treatment paradigm of approx. 2 hours.
- Initial results from the ELE-01 Phase 1/2a study are anticipated in H1 2024.

COMP360: Psilocybin Therapy for TRD

- COMP360 is a formulation of synthetic psilocybin.
- COMP360 is currently being evaluated in a Phase 3 program in TRD patients composed of two pivotal trials, each of which will have a long-term follow-up component.
- Pivotal Trial 1 (COMP005) top-line data is expected in the fourth quarter of 2024 and Pivotal Trial 2 (COMP006) top-line data is anticipated mid-2025.
- Phase 2 open-label efficacy data in PTSD is expected in Spring 2024.

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

- IBX-210 is an IV formulation of semi-synthetic ibogaine.
- In August 2023, the Phase 1 study results demonstrated that 9 mg/kg of oral ibogaine leads to robust psychedelic experiences. However, a high degree of inter-individual PK variability and significant QT prolongation were noted across all doses. While deemed to be clinically manageable, both factors have the potential to increase site burden and limit scalability.
- atai has developed a novel IV formulation of ibogaine. The objective is to improve safety, reduce PK variability and achieve a shorter and more predictable in-clinic time.
- A Phase 1/2a study of IBX-210 for the treatment of OUD is anticipated to initiate in the second half of this year.

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 will evaluate 20mg and 40mg of RL-007 vs. placebo in patients living with CIAS. Topline results are expected mid-2025.
- The Company will deliver a presentation at the 2024 Congress of the Schizophrenia International Research Society in Florence (Italy) on April 4, 2024 from 10:00 AM – 12:00 PM CET.

Consolidated Financial Results

Cash, cash equivalents, and short-term investments: Cash and cash equivalents and short-term investments were \$154.2 million as of December 31, 2023, as compared to \$273.1 million as of December 31, 2022. The decrease of \$118.9 million was primarily driven by \$84.1 million net cash used in

operating activities, \$25.0 million designated for the Beckley Psytech investment and \$15.0 million of additional investments to advance our programs. The Company expects its cash, marketable securities and committed term loan facility with Hercules Capital, Inc. will be sufficient to fund operations into 2026.

Research and development (R&D) expenses: R&D expenses were \$14.2 million and \$62.2 million for the three and twelve months ended December 31, 2023, respectively, as compared to \$21.9 million and \$74.3 million for the same prior year periods. The year-over-year full-year decrease of \$12.1 million was primarily attributable to a decrease of \$10.1 million of contract research organization expenses and \$2.1 million in R&D personnel costs as a result of the deprioritization of certain programs.

General and administrative (G&A) expenses: G&A expenses for the three and twelve months ended December 31, 2023 were \$19.4 million and \$63.6 million, respectively, as compared to \$15.7 million and \$70.4 million in the same prior year periods. The year-over-year decrease of \$6.8 million was primarily attributable to a \$8.1 million decrease in personnel expenses, \$2.0 million net decrease of professional services and other administrative expenses, partially offset by a \$3.3 million increase related to a prior year non-income tax refund.

Net loss: Net loss attributable to shareholders for the three and twelve months ended December 31, 2023 was \$18.3 million and \$40.2 million, respectively, as compared to \$45.0 million and \$152.4 million for the comparable prior year periods.

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 the plans and objectives of management for future operations 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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ATAI LIFE SCIENCES N.V.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2023	2022	2023	2022
	(unaudited)			
License revenue	\$ 18	\$ 38	\$ 314	\$ 233
Operating expenses:				
Research and development	14,156	21,876	62,203	74,313
Acquisition of in-process research and development	—	—	—	357
General and administrative	19,423	15,727	63,582	70,350
Total operating expenses	33,579	37,603	125,785	145,020
Loss from operations	(33,561)	(37,565)	(125,471)	(144,787)
Other income (expense), net	15,241	(1,756)	86,185	9,605

Loss before income taxes	(18,320)	(39,321)	(39,286)	(135,182)
Provision for income taxes	(428)	(6,002)	(1,016)	(6,229)
Losses from investments in equity method investees, net of tax	(394)	(1,326)	(3,593)	(16,006)
Net loss	(19,142)	(46,649)	(43,895)	(157,417)
Net loss attributable to noncontrolling interests	(850)	(1,638)	(3,671)	(5,032)
Net loss attributable to ATAI Life Sciences N.V. stockholders	<u>\$ (18,292)</u>	<u>\$ (45,011)</u>	<u>\$ (40,224)</u>	<u>\$ (152,385)</u>
Net loss per share attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.28)</u>	<u>\$ (0.25)</u>	<u>\$ (0.98)</u>
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	<u>158,842,995</u>	<u>158,703,781</u>	<u>158,833,785</u>	<u>155,719,585</u>

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

	<u>December 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Assets		
Cash and cash equivalents	\$ 45,034	\$ 190,613
Securities carried at fair value	109,223	82,496
Committed Investment Funds	25,000	—
Prepaid expenses and other current assets	5,830	14,036
Short term notes receivable	505	—
Property and equipment, net	981	928
Operating lease right-of-use asset, net	1,223	226
Other investments held at fair value	89,825	—
Other investments	1,838	6,755
Long term notes receivable - related parties, net	97	7,262
Convertible notes receivable - related party	11,202	—
Other assets	2,720	3,125
Total assets	<u>\$ 293,478</u>	<u>\$ 305,441</u>
Liabilities and Stockholders' Equity		
Accounts payable	4,589	2,399
Accrued liabilities	15,256	17,306
Current portion of contingent consideration liability - related parties	275	180
Other current liabilities	—	12
Contingent consideration liability - related parties	620	953
Contingent consideration liability	1,637	—
Noncurrent portion of lease liability	990	44
Convertible promissory notes - related parties	164	415
Convertible promissory notes	2,666	—
Long term debt, net	15,047	14,702
Other liabilities	7,918	3,664
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders	242,962	260,740
Noncontrolling interests	1,354	5,026
Total liabilities and stockholders' equity	<u>\$ 293,478</u>	<u>\$ 305,441</u>