



atai Life Sciences Reports First Quarter 2024 Financial Results and Corporate Updates

May 15, 2024

- *First participant dosed in Phase 1b trial of VLS-01 with data expected in 2H'24; Phase 2 study in TRD patients anticipated to initiate around YE'24*
- *Beckley Psytech's Phase 2a study of BPL-003 in TRD patients showed rapid and durable antidepressant effects; Phase 2b topline data expected in 2H'24*
- *Compass Pathways' Phase 2 study of COMP360 in PTSD patients demonstrated durable improvement in symptoms; Phase 3 data of COMP360 in TRD patients expected in 4Q'24*
- *Co-Founder Florian Brand to step down as CEO as part of a planned transition by YE'24 and to be succeeded by Co-Founder and current Chief Scientific Officer Srinivas Rao, M.D., Ph.D.*
- *Cash, marketable securities, and committed term loan funding expected to fund operations into 2026*

NEW YORK and BERLIN, May 15, 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 first quarter 2024 financial results, provided corporate updates and announced a transition in its leadership.

Florian Brand ("Mr. Brand"), Co-Founder and current CEO, will step down as CEO by the end of this year. Co-Founder Srinivas Rao, M.D., Ph.D. ("Dr. Rao"), currently the Chief Scientific Officer, will be promoted to Co-CEO effective June 1, 2024 and intends to assume the role of CEO by the end of the year subject to appointment as required by local law.

"I co-founded atai in 2018 with the bold mission to transform mental health care, and I am immensely proud of our accomplishments and continuous progress made across our R&D programs over the last six years. To that end, looking at the recent months, we have achieved many clinical milestones, with dosing in our VLS-01 Phase 1b program well underway and encouraging Phase 2 data readouts from both BPL-003 and COMP360," said Mr. Brand.

"As I prepare to turn my focus to new entrepreneurial ventures in other areas of significant unmet medical needs, I am confident in passing the torch to my Co-Founder Srini by year-end. His exceptional leadership and deep expertise in neuropsychiatric drug development have been pivotal to our success, and I am delighted that he will be leading atai into its next phase, where his experience in late stage clinical development will be especially relevant and impactful."

Dr. Rao brings over 24 years of knowledge and experience from diverse biotechnology and pharmaceutical roles, having held the titles of Chief Scientific, Medical, or Executive Officer at companies ranging from venture-backed startups to vertically integrated, publicly traded pharmaceutical companies.

"It is an honor to follow in the footsteps of my dear friend and Co-Founder, Florian. I am deeply grateful for the opportunity to continue to work with him as Co-CEOs until the end of the year and build upon our shared vision, ensuring atai's continued success in addressing challenging mental health conditions," said Dr. Rao. "In the near-term this year, I look forward to several data milestones, including the Phase 2b readout of BPL-003 in TRD, Phase 3 data of COMP360 in TRD and the VLS-01 Phase 1b readout."

Founder and Chairman Christian Angermayer commented: "Since its inception in 2018, atai has been at the forefront of mental health innovation, driven by a commitment to deliver ground-breaking therapies to those in need, with a special focus on psychedelic substances.

Florian successfully led the company from its early days through numerous R&D, business development and financing milestones, including an IPO in 2021. Florian's leadership and execution focus have been foundational to the success of atai. We look forward to seeing the new heights he will achieve.

As Florian transitions, we are deeply grateful for the enduring impact he made on our company, and while he will leave as CEO at the end of this year, he will always be part of the atai family and our success story. With his extensive experience in late stage drug development, Srini has the right profile and skillset to lead atai into its next evolutionary phase."

Corporate Updates

- Florian Brand, Co-Founder and current CEO of atai, will assume the role of Co-CEO effective June 1, 2024 and will step down as CEO by the end of this year.
- Co-Founder Srinivas Rao, currently the Chief Scientific Officer of atai, will be promoted to Co-CEO effective June 1, 2024, and intends to assume the role of CEO by the end of the year subject to appointment as required by local law.

Clinical Highlights

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

- VLS-01 is an oral transmucosal film (OTF) formulation of DMT designed to fit within the two-hour in-clinic treatment paradigm successfully established by Spravato®
- 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.
- Results of the Phase 1b study are anticipated in 2H 2024.
- The Company plans to initiate a randomized, placebo-controlled Phase 2 trial of VLS-01 in TRD patients around YE'24.

BPL-003: 5-MeO-DMT for TRD as primary indication

- Beckley Psytech's BPL-003 is an intranasal formulation of 5-methoxy- *N,N*-dimethyltryptamine (5-MeO-DMT) designed to fit within an approximately two hour in-clinic treatment paradigm.
- In March 2024, Part 1 of a Phase 2a open-label (OL) 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. Acute effects resolved on average in less than two hours, and BPL-003 was found to be well-tolerated, with no serious adverse events reported.
- In April 2024, Part 2 of the Phase 2a OL study initiated to investigate BPL-003 as an adjunctive therapy to Selective Serotonin Reuptake Inhibitors in TRD patients.
- A randomized, controlled Phase 2b study of BPL-003 in TRD patients is underway with topline data expected in 2H 2024.

COMP360: Psilocybin Therapy for TRD as primary indication

- Compass Pathways' COMP360 is an oral formulation of synthetic psilocybin that is currently being evaluated in multiple clinical studies.
- In May 2024, results from an OL Phase 2 study in 22 patients with PTSD showed that COMP360 met its primary safety endpoint and was well tolerated, with no serious adverse events. COMP360 demonstrated a rapid and durable improvement in PTSD symptoms.
 - Week 4 and 12 reductions in the CAPS-5 total score of 29.9 and 29.5, respectively, were observed.
 - The response rate, as defined by patients experiencing a ≥ 15 -point improvement on CAPS-5 score, was 81.8% at week 4 and 77.3% at week 12.
 - The remission rate, as defined by CAPS-5 total score of ≤ 20 , was 63.6% at week 4 and 54.5% at week 12.
- The Phase 3 program of COMP360 in TRD patients is composed of two pivotal trials, each with a long-term follow-up component. Pivotal Trial 1 (COMP005) topline data is expected in the fourth quarter of 2024 and Pivotal Trial 2 (COMP006) topline data is anticipated mid-2025.

Upcoming R&D Catalysts

- 1H'24
 - ELE-101 MDD Phase 1/2a initial data
- 2H'24
 - VLS-01 Phase 1b topline data
 - BPL-003 AUD Phase 2a OL data (mid'24)
 - COMP360 TRD Phase 3 Pivotal Trial 1 topline data
 - BPL-003 TRD Phase 2b data
 - IBX-210 OUD Phase 1/2a initiation
 - VLS-01 TRD Phase 2 initiation (around YE'24)

- 2025
 - RL-007 CIAS Phase 2b topline data (mid'25)
 - COMP360 TRD Phase 3 Pivotal Trial 2 topline data (mid'25)

Consolidated Financial Results

Cash, cash equivalents, and short-term investments: As of March 31, 2024, the Company had cash, cash equivalents, restricted cash and short-term investments of \$121.3 million compared to \$154.2 million as of December 31, 2023. The decrease of \$32.9 million was primarily driven by \$22.6 million net cash used in operating activities and \$10 million for the Beckley Psytech investment. The Company expects its cash, marketable securities 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 \$11.5 million for the three months ended March 31, 2024, as compared to \$19.3 million for the same prior year period. The year-over-year decrease of \$7.8 million was primarily attributable to a decrease of \$5.1 million in program-specific expenses and \$2.6 million in R&D personnel. Within program-specific expenses, the decrease was primarily driven by more clinical trials, discovery expenses and manufacturing costs in prior year. During the quarter, the Company allocated capital resources to invest in the R&D activities of its Beckley Psytech strategic investment. 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 March 31, 2024 were \$12.6 million as compared to \$14.0 million in the same prior year period. The year-over-year decrease of \$1.4 million was primarily attributable to \$2.6 million decrease in personnel related expenses, \$0.7 million net decrease of professional services and other administrative expenses, partially offset by a \$1.9 million increase related to a prior year non-income tax refund. The Company is actively controlling G&A spend. The Company expects the reduction in G&A spend over prior years to continue.

Net loss: Net loss attributable to stockholders for the three months ended March 31, 2024, was \$26.7 million as compared to \$33.1 million for the three months ended March 31, 2023.

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; transition plans for our CEO and Co-CEO; 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; 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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ATAI LIFE SCIENCES N.V.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share amounts)

Three Months Ended
March 31,

	2024	2023
	(unaudited)	
License revenue	\$ —	\$ 37
Operating expenses:		
Research and development	11,530	19,281
General and administrative	12,555	13,970
Total operating expenses	24,085	33,251
Loss from operations	(24,085)	(33,214)
Other income (expense), net	(1,596)	58
Loss before income taxes	(25,681)	(33,156)
Benefit from (provision for) income taxes	4	(165)
Losses from investments in equity method investees, net of tax	(1,701)	(1,033)
Net loss	(27,378)	(34,354)
Net loss attributable to noncontrolling interests	(665)	(1,219)
Net loss attributable to ATAI Life Sciences N.V. stockholders	\$ (26,713)	\$ (33,135)
Net loss per share attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	\$ (0.17)	\$ (0.21)
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	158,891,067	155,792,490

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

	March 31, 2024	December 31, 2023
Assets		
Cash and cash equivalents	\$ 18,867	\$ 45,034
Short term restricted cash for other investments	5,000	-
Securities carried at fair value	87,379	109,223
Committed Investment Funds	-	25,000
Prepaid expenses and other current assets	5,732	5,830
Short term notes receivable - related party, net	522	505
Long term restricted cash for other investments	10,000	-
Property and equipment, net	920	981
Operating lease right-of-use asset, net	1,115	1,223
Other investments held at fair value	90,205	89,825
Other investments	32,807	1,838
Long term notes receivable - related parties, net	98	97
Convertible notes receivable - related party	13,902	11,202
Other assets	2,574	2,720
Total assets	\$ 269,121	\$ 293,478
Liabilities and Stockholders' Equity		
Accounts payable	3,843	4,589
Accrued liabilities	10,926	15,256
Current portion of lease liability	244	275

Contingent consideration liability - related parties	607	620
Contingent consideration liability	1,406	1,637
Noncurrent portion of lease liability	907	990
Convertible promissory notes - related parties	417	164
Convertible promissory notes and derivative liability	4,099	2,666
Long term debt, net	15,140	15,047
Other liabilities	8,275	7,918
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders	222,544	242,962
Noncontrolling interests	713	1,354
Total liabilities and stockholders' equity	<u>269,121</u>	<u>293,478</u>