



AtaiBeckley Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Business and Clinical Update

March 6, 2026

- Phase 3 pivotal program initiation for BPL-003 in treatment-resistant depression remains on track for Q2 2026 following successful End-of-Phase 2 meeting with the U.S. Food and Drug Administration
- On-track for VLS-01 Phase 2 Elumina trial topline data readout anticipated in H2 2026
- Exploratory Phase 2a trial of EMP-01 in Social Anxiety Disorder met its primary safety and tolerability objective and demonstrated clinically meaningful improvements across key efficacy measures
- Cash runway through the planned early-2029 topline readouts from both Phase 3 pivotal studies
- Virtual Investor Day scheduled for March 6, 2026

NEW YORK, March 06, 2026 (GLOBE NEWSWIRE) -- AtaiBeckley Inc. (NASDAQ: ATAI) ("AtaiBeckley" or the "Company"), a clinical-stage biotechnology company on a mission to transform patient outcomes by developing rapid-acting, durable and convenient mental health treatments, today announced fourth quarter and full year 2025 financial results and provided key regulatory, clinical and business updates.

"Following our strategic combination of atai Life Sciences and Beckley Psytech, and U.S. redomiciliation, we have entered a pivotal execution phase," said Srinivas Rao, M.D., Ph.D., Chief Executive Officer and Co-Founder of AtaiBeckley. "We received constructive feedback from the FDA on the Phase 3 development plan for BPL-003 in treatment-resistant depression, positioning us to initiate our pivotal program in the second quarter of 2026. We also reported positive topline results from our exploratory Phase 2a study of EMP-01 in Social Anxiety Disorder, which met its primary safety objective and demonstrated clinically meaningful improvements across key efficacy measures after just two administrations and without adjunct psychotherapy. With multiple clinical catalysts ahead and capital expected to fund operations into 2029, we believe AtaiBeckley is well positioned to advance a differentiated portfolio of rapid-acting mental health therapies."

Program Updates and Anticipated Milestones

BPL-003: mebufotenin benzoate nasal spray for TRD

- In March 2026, the Company announced a successful End-of-Phase 2 meeting with the FDA regarding the development of BPL-003 for treatment-resistant depression (TRD), a debilitating and chronic condition affecting millions of people around the world but with limited rapid-acting treatment options.
- The FDA indicated support for advancement into Phase 3 studies in adults with TRD and provided constructive feedback on the overall design and requirements for a potential NDA package for this indication.
- The Phase 3 program is designed to include two pivotal studies, ReConnection-1 and ReConnection-2, each consisting of a 12-week, randomized, double-blind, placebo-controlled core study followed by a 52-week open-label extension (OLE):
 - **ReConnection-1:**
 - Approximately 350 participants
 - Single-dose of BPL-003 across three treatment arms - 8 mg, 4 mg, and placebo (randomized 2:1:2)
 - Designed to replicate and extend Phase 2b treatment response and further characterize dose-response relationship for BPL-003
 - **ReConnection-2:**
 - Approximately 300 participants
 - Two-dose design (Day 1 and Day 15) across two arms - 8 mg BPL-003 and placebo (randomized 1:1)
 - Designed to evaluate if a two-dose induction model increases magnitude and durability of initial response
- The primary endpoint in both pivotal trials will be the change from baseline in the MADRS total score at Week 4.
- Both trials include a 52-week OLE allowing individualized 8 mg BPL-003 retreatment at 8- or 12-week intervals with the aim of maintaining remission.
- Phase 3 program initiation remains on track for Q2 2026.
- Topline data from the core studies of both ReConnection-1 and -2 anticipated by early 2029.
- First patient dosed in the Part 4 cohort of the open-label Phase 2a study, evaluating a two-dose induction regimen (8 mg + 8 mg) of BPL-003 in TRD patients receiving defined antidepressants. Initial data expected in Q4 2026.

VLS-01: dimethyltryptamine (DMT) buccal film for TRD

- VLS-01 is an investigational proprietary oral transmucosal film formulation of DMT applied to the buccal surface, designed to fit within the established two-hour interventional psychiatry treatment paradigm.
- Phase 2 Elumina study topline data readout is anticipated in H2 2026.

EMP-01: Oral R-enantiomer of 3,4-methylenedioxy-methamphetamine (R-MDMA) for social anxiety disorder (SAD)

- In February 2026, the Company reported topline results from the exploratory, randomized, double-blind, placebo-controlled Phase 2a trial of EMP-01 in SAD:
 - Key findings:
 - Met primary safety and tolerability objective with a generally favorable and manageable profile
 - Clinically meaningful placebo-adjusted least squares mean reduction of 11.85 points on the Liebowitz Social Anxiety Scale (LSAS) at Day 43 (Hedges' $g = 0.45$; $p\text{-value} = 0.036$, one-tailed)
 - 49% responder rate on Clinician Global Impression–Improvement (CGI-I) vs. 15% for placebo, corresponding to a Number Needed to Treat (NNT) of 2.95
 - Demonstrated improvements across Fear and Avoidance sub-domains of LSAS
- In December 2025, the Company was granted a new U.S. patent covering the EMP-01 drug substance, extending expected exclusivity through 2043.
- More detailed analyses of the data will be described in upcoming scientific venues and are expected to inform next development steps.

Business Highlights

- Completed the strategic combination in November 2025 between Atai Life Sciences N.V. and Beckley Psytech Limited, creating AtaiBeckley, a global leader in transformative mental health therapies.
- Completed the redomiciliation to the United States in December 2025 as a Delaware-incorporated company with headquarters in New York, NY.
- AtaiBeckley Inc. was added to the NASDAQ Biotechnology Index (NBI) in December 2025.
- The Company will host a Virtual Investor Day on March 6, 2026, centered on BPL-003 and the Phase 3 development strategy.
- The Virtual Investor Day will feature:
 - Detailed overview of the BPL-003 Phase 3 program
 - Discussion of the commercial opportunity in treatment-resistant depression
 - Key opinion leader roundtable discussing the evolving psychedelic therapeutic landscape and operational considerations in interventional psychiatry

Upcoming Anticipated Milestones and Events

- March 6, 2026: Virtual Investor Day
- Q2 2026: Initiation of BPL-003 Phase 3 ReConnection-1 and ReConnection-2 trials
- H2 2026: Topline data from VLS-01 Elumina Phase 2 study
- Q4 2026: Initial data from Phase 2a BPL-003 Part 4 cohort

Consolidated Financial Results

Cash, cash equivalents, and short-term securities (primarily US treasuries): As of December 31, 2025, the Company had cash, cash equivalents and short-term securities of \$220.7 million compared to \$72.3 million of cash, cash equivalents, restricted cash and short-term securities as of December 31, 2024. The \$148.4 million increase is primarily attributable to \$291.1 million in net proceeds from equity-related issuances and \$9.1 million in proceeds from sale of equity holdings, partially offset by \$102.7 million used in operations, \$21.8 million payoff of Hercules debt facility, \$20.0 million in payments relating to the Beckley Psytech investment prior to the strategic combination, and \$10.0 million investment in digital assets. The Company expects its cash, cash equivalents, short-term investments and other liquid assets to fund operations into 2029.

Research and development (R&D) expenses: R&D expenses were \$19.0 million and \$53.1 million for the three and twelve months ended December 31, 2025, respectively, as compared to \$18.9 million and \$55.5 million for the same prior year periods. The year-over-year full-year decrease of \$2.4 million was primarily attributable to decreased personnel-related expenses and consulting services, partially offset by higher clinical program contract research organizations and manufacturing costs.

We recorded non-cash acquisition of in-process R&D expenses of \$527.0 million and \$530.0 million for the three and twelve months ended December 31, 2025, respectively, primarily relating to the strategic combination with Beckley Psytech.

General and administrative (G&A) expenses: G&A expenses for the three and twelve months ended December 31, 2025, were \$25.1 million and \$65.1 million, respectively, as compared to \$11.3 million and \$47.5 million in the same prior year periods. The year-over-year increase of \$17.6 million was primarily attributable to increased legal and professional service expenses in connection with the Beckley Psytech strategic combination and the Company's redomiciliation to the United States, partially offset by decreases in personnel-related expenses.

Net income (loss): Net loss attributable to stockholders for the three and twelve months ended December 31, 2025, was \$544.8 million and \$660.0 million, respectively, as compared to \$39.0 million and \$149.3 million for the comparable prior year periods. Net loss attributable to stockholders for the twelve months ended December 31, 2025, includes \$24.4 million non-cash reduction in the fair value of assets and liabilities, net, \$14.2 million of non-cash stock-based compensation, and \$10.7 million non-cash gain related to the investment in Beckley Psytech. Net loss attributable to stockholders for the twelve months ended December 31, 2024, includes \$48.9 million non-cash reduction in the fair value of assets and liabilities, net and \$25.5 million of non-cash stock-based compensation.

About AtaiBeckley Inc.

AtaiBeckley is a clinical-stage biotechnology company with a mission to transform patient outcomes by developing rapid-acting, durable and convenient mental health treatments. AtaiBeckley's pipeline of novel therapies includes BPL-003 (mebufotenin benzoate nasal spray) for treatment-resistant depression (TRD), VLS-01 (DMT buccal film) for TRD and EMP-01 (oral R-MDMA) for social anxiety disorder. BPL-003 is in Phase 3 planning, VLS-01 and EMP-01 are in Phase 2 clinical development. The Company is also advancing a drug discovery program to identify novel, non-hallucinogenic 5-HT2AR agonists for opioid use disorder and TRD. These programs aim to create new breakthroughs in mental health by providing transformative interventional psychiatry therapies that can integrate seamlessly into healthcare systems.

For the latest updates and to learn more about the AtaiBeckley mission, visit www.ataibeckley.com or follow the Company on [LinkedIn](#) and on [X](#).

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, and Section 21E of the Securities Exchange Act of 1934, as amended. 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 and the outcome of related regulatory discussions; expectations regarding our intellectual property portfolio; 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") or Quarterly Reports on Form 10-Q filed with the SEC, as such factors may be updated from time to time in our other filings with the SEC. AtaiBeckley disclaims any obligation 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 --

ATAIBECKLEY INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Amounts in thousands, except share and per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2025	2024	2025	2024
	(unaudited)			
Revenue	\$ 1,066	\$ (5)	\$ 4,089	\$ 308
Operating expenses:				
Research and development	18,962	18,942	53,062	55,455
Acquisition of in-process research and development	527,000	—	530,000	—

General and administrative	25,086	11,318	65,088	47,544
Total operating expenses	571,048	30,260	648,150	102,999
Loss from operations	(569,982)	(30,265)	(644,061)	(102,691)
Other income (expense), net	25,062	(8,919)	(15,788)	(45,714)
Net loss before income taxes	(544,920)	(39,184)	(659,849)	(148,405)
Benefit from (provision for) income taxes	82	193	(298)	356
Losses from investments in equity method investees, net of tax	—	—	—	(2,000)
Net loss	(544,838)	(38,991)	(660,147)	(150,049)
Net loss attributable to noncontrolling interests	(25)	(33)	(100)	(780)
Net loss attributable to AtaiBeckley Inc. stockholders	<u>\$ (544,813)</u>	<u>\$ (38,958)</u>	<u>\$ (660,047)</u>	<u>\$ (149,269)</u>
Net loss per share attributable to AtaiBeckley Inc. stockholders — basic and diluted	<u>\$ (1.73)</u>	<u>\$ (0.24)</u>	<u>\$ (2.91)</u>	<u>\$ (0.93)</u>
Weighted average common shares outstanding attributable to AtaiBeckley Inc. stockholders — basic and diluted	<u>314,276,378</u>	<u>160,711,543</u>	<u>226,532,786</u>	<u>160,159,983</u>

ATAIBECKLEY INC.
CONDENSED CONSOLIDATED BALANCE SHEET
(Amounts in thousands)

	December 31, 2025	December 31, 2024
Assets		
Cash and cash equivalents	\$ 85,300	\$ 17,505
Securities carried at fair value	135,351	44,825
Short-term restricted cash for other investments	—	10,000
Other current investments held at fair value	35,389	—
Prepaid expenses and other current assets	19,644	7,795
Property and equipment, net	2,166	2,535
Operating lease right-of-use assets, net	1,846	1,334
Other investments held at fair value	—	28,887
Other investments	—	42,079
Intangible assets, net	2,851	3,246
Goodwill	331	331
Digital assets	8,735	—
Other assets	1,110	850
Total assets	<u>\$ 292,723</u>	<u>\$ 159,387</u>
Liabilities and Stockholders' Equity		
Accounts payable	\$ 4,906	\$ 2,616
Accrued liabilities	14,168	9,847
Current portion of lease liabilities	271	477
Short-term convertible promissory notes and derivative liability - related party	—	1,150
Short-term convertible promissory notes and derivative liability	—	1,840
Current portion of long-term debt	—	6,374
Deferred revenue	1,524	721
Other current liabilities	2,610	1,926
Contingent consideration liability - related party	104	110
Contingent consideration liabilities	205	212
Noncurrent portion of lease liabilities	1,801	732
Pre-funded warrant liabilities	44,379	—
Long-term debt, net	—	14,133
Other liabilities	754	2,695
Total stockholders' equity attributable to AtaiBeckley Inc. stockholders	221,874	116,297
Noncontrolling interests	<u>127</u>	<u>257</u>

Total liabilities and stockholders' equity

\$	292,723	\$	159,387
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