BPL-003 Phase 3 Program Initiation on Track for Q2 2026 Following Successful FDA End-of-Phase 2 Meeting; AtaiBeckley Highlights Key Pipeline Milestones at 2026 Investor Day

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- BPL-003 holds Breakthrough Therapy Designation and is supported by positive Phase 2b results in treatment-resistant depression
- Cash runway reaffirmed through the planned early-2029 topline readouts from both parallel Phase 3 pivotal studies
- Commercial readiness advancing with scalable treatment model aligned to existing interventional psychiatry workflows
- Continued pipeline progress, including positive Phase 2a results for EMP-01 and expected Phase 2 topline for VLS-01 in H2 2026
- Replay and presentation materials available on AtaiBeckley's investor website

NEW YORK, March 10, 2026 (GLOBE NEWSWIRE) -- AtaiBeckley Inc. (NASDAQ: ATAI) ("AtaiBeckley" or "Company"), a clinical-stage biotechnology company on a mission to transform patient outcomes by developing rapid-acting, durable and convenient mental health treatments, today highlighted key clinical, regulatory, and operational milestones from its 2026 Virtual Investor Day, including the advancement of BPL-003 (mebufotenin benzoate nasal spray) toward Phase 3 initiation in Q2 2026 following a successful End-of-Phase 2 meeting with the FDA.

BPL-003, which holds Breakthrough Therapy Designation, is supported by positive Phase 2b results in treatment-resistant depression (TRD), demonstrating rapid antidepressant effects at Day 2, durable improvements through eight weeks, and higher response and remission rates following an optional second dose in the open-label extension.

The Company also reaffirmed its cash runway into early 2029, provided updates on its commercial readiness strategy, and outlined continued pipeline progress, including recently announced positive Phase 2a results for EMP-01 and its expectation that VLS-01 will deliver Phase 2 topline data in H2 2026.

Advancing BPL-003 Towards Phase 3 in Treatment-Resistant Depression
A central focus of the event was the continued advancement of BPL-003 toward Phase 3 studies in TRD. Following a successful End-of-Phase 2 meeting with the FDA, the Company remains on track to initiate two parallel Phase 3 studies – ReConnection-1 and ReConnection-2 - in Q2 2026. These pivotal trials will include a 12-week randomized, double-blind, placebo-controlled core study, followed by a 52-week open-label extension allowing individualized retreatment based on pre-specified criteria.

"BPL-003 has demonstrated rapid, durable antidepressant effects, and the FDA's supportive End-of-Phase 2 feedback enables us to advance into two parallel Phase 3 trials beginning in Q2 2026," said Srinivas Rao, Co-Founder and CEO. *"With Breakthrough Therapy Designation and a robust pivotal design, we believe BPL-003 has the potential to meaningfully reshape the treatment landscape for TRD."*

Commercial and Operational Readiness
Another key theme of the Investor Day was AtaiBeckley's continued advancement of its commercial readiness strategy for BPL-003, which is designed to integrate seamlessly into existing interventional psychiatry workflows, including those currently used for Spravato®. The Company outlined a scalable treatment model that prioritizes patient convenience and safety, without requiring in-session psychotherapy, enabling clinics to efficiently incorporate BPL-003 within established care pathways.

BPL-003 is supported by positive Phase 2b topline results, which demonstrated:

- rapid antidepressant effects at Day 2 from a single dose
- durable improvements maintained for up to eight weeks
- increased response and remission rates sustained for a further eight weeks following a second dose in the OLE

Kavita Panke, SVP of New Product Planning and Early Commercial Development, emphasized the potential operational advantages of the therapy: "*Our goal is to make BPL-003 realistic and accessible in everyday clinical practice. People need treatments that work quickly, are durable, and don't require them to reorganize their lives. BPL-003's short treatment window and intermittent dosing regimen could give clinics a practical and scalable way to reach far more patients*."

Expert Perspectives on Mental Health Treatment Needs
The event closed with a roundtable discussion featuring:

- Dr. Peter Hendricks, Clinical Psychologist and Professor at the University of Alabama at Birmingham School of Public Health
- Dr. David Feifel, Professor Emeritus of Psychiatry at the University of California, San Diego, Founder and President of the Kadima Neuropsychiatry Institute, and consultant to AtaiBeckley
- Dr. Samuel Wilkinson, Associate Professor of Psychiatry at Yale School of Medicine

The discussion explored several key themes shaping the future of TRD and interventional psychiatry, including practical barriers to care, treatment duration and dosing paradigms, clinic infrastructure readiness, and the evolving positioning of new therapies relative to current standards of care.

The external experts highlighted how shorter, streamlined in-clinic experiences and intermittent dosing regimens may meaningfully expand patient access while preserving strong clinical impact. They also noted that the current interventional psychiatry infrastructure - strengthened in recent years through broader adoption of treatments like Spravato® - is increasingly well-positioned to support next-generation therapies such as BPL-003.

Replay and Materials
Presentation slides and a replay of the Investor Day are available on the investor section of the AtaiBeckley website, under Events.

About AtaiBeckley Inc.
AtaiBeckley is a clinical-stage biotechnology company on 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 ((R)-MDMA HCl) 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 breakthroughs in mental health through 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; expectations regarding the outcome of regulatory discussions regarding the development of BPL003; expectations regarding the advancement into Phase 3 studies in adults with TRD and related milestones; expectations regarding the design of the Phase 3 program; and the potential benefits of BPL-003 for patients with TRD.

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 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.

Contact Information:
Investors:
Jason Awe, PhD
VP, Investor Relations
IR@ataibeckley.com

Media:
Charlotte Chorley
Associate Director, Communications
PR@ataibeckley.com