AEON Biopharma Reports Third Quarter 2026 Financial Results and Provides Corporate Update

November 16, 2026

- Received FDA Type 2b feedback providing greater clarity on AEON's integrated biosimilar development strategy combining comparative analytical assessment, human pharmacodynamic studies, and a substantial body of existing comparative clinical evidence -

- Submitted IND for comparative CMAP pharmacodynamic study, with initiation planned for Q1 2027 -

- Expanded analytical evidence supporting molecular similarity to BOTOX®, including approximately 98% coverage of core 150 kDa neurotoxin sequence with 100% identity across all analyzed regions -

- Approximately $6.2 million in milestone warrant proceeds provide additional capital for ongoing ABP-450 development -

ALISO VIEJO, Calif., Nov. 16, 2026 (GLOBE NEWSWIRE) -- AEON Biopharma, Inc. ("AEON" or the "Company") (NYSE American: AEON), a biopharmaceutical company advancing ABP-450 as a full-label therapeutic biosimilar to BOTOX® (onabotulinumtoxinA), today reported its financial results for the third quarter ended September 30, 2026, and provided a corporate update.

"Over the past several months, we have made important progress in advancing the scientific and regulatory foundation for ABP-450's development as a biosimilar to BOTOX ®," commented Rob Bancroft, President and Chief Executive Officer of AEON. "Our FDA Type 2b meeting provided valuable direction on integrating comparative analytical and human pharmacodynamic data with an extensive body of existing comparative clinical evidence, while our expanding analytical results continue to strengthen the foundation of our biosimilarity program. Together, these efforts are helping to advance a rigorous, scientifically informed approach to demonstrating biosimilarity to BOTOX®."

"With our CMAP IND submitted and additional capital secured through the recent milestone warrant exercises, we are positioned to advance the next phase of development, including the planned initiation of our comparative pharmacodynamic study in the first quarter of 2027. We remain focused on building the evidence necessary to bring a biosimilar to BOTOX® to the U.S. therapeutic market, representing an opportunity of approximately $3.5 billion annually."

Third Quarter 2026 Highlights and Recent Developments

- **Received official minutes from ABP-450's Biosimilar Biological Product Development ("BPD") Type 2b meeting with the U.S. Food and Drug Administration ("FDA" or the "Agency")**
  - AEON's development strategy is designed to integrate a comprehensive comparative analytical assessment with sensitive human pharmacodynamic evidence, a substantial body of previously completed comparative human clinical studies, and targeted analyses addressing indication-specific questions. Together, these complementary sources of evidence are intended to resolve residual uncertainty and establish a scientifically rigorous basis for demonstrating biosimilarity between ABP-450 and BOTOX®.
  - With respect to the proposed human pharmacodynamic component of the program, the FDA agreed in principle with AEON's two-stage design for a comparative pharmacodynamic ("PD") study using compound muscle action potential ("CMAP") measurement in the extensor digitorum brevis muscle, consisting of an initial dose-finding stage followed by a comparative PD evaluation. The Agency also provided recommendations intended to strengthen the ability to demonstrate assay sensitivity, which have been incorporated into the study protocol submitted with the Company's Investigational New Drug ("IND") application.
  - Regarding the potential use of previously completed comparative clinical studies, the FDA indicated that studies conducted by Daewoong Pharmaceutical across several indications, including studies in blepharospasm, upper limb spasticity, glabellar lines, and lateral canthal lines, can be submitted for consideration as supportive evidence, subject to appropriate scientific bridging to U.S.-licensed BOTOX® and between the ABP-450 drug product used in each study and ABP-450 as currently manufactured. Blepharospasm and upper limb spasticity are therapeutic indications included on the U.S. BOTOX® label, while glabellar lines and lateral canthal lines are included on the BOTOX Cosmetic® label.
  - With respect to indication-specific considerations, including chronic migraine, the FDA invited the Company to provide analyses supporting the rationale for the outcome of the previously conducted Phase 2 study for the prevention of migraine headache, which the Company intends to complete and provide to the FDA as part of its 351(k) Biologics License Application submission.
- **Bolstered leadership team with the addition of former Deputy Director of the FDA's Office of Neuroscience, Paul Lee, M.D., Ph.D., as acting Chief Regulatory Officer**

- Dr. Lee spent more than seven years at the FDA's Office of New Drugs, most recently serving as Deputy Director of the Office of Neuroscience from May 2024 to June 2025 and as Director of the Division of Neurology 2 from March 2023 to May 2025. Dr. Lee also co-authored a publication describing the FDA review and approval of Tyruko® (natalizumab-sztn), the first FDA-approved biosimilar to natalizumab (Tysabri®). Dr. Lee earned his M.D. and Ph.D. in Neuroscience from the University of Maryland and is board certified in neurology. Dr. Lee's regulatory and neuroscience experience will support AEON's efforts to integrate its analytical, pharmacodynamic, and existing clinical evidence into a comprehensive biosimilar development and regulatory strategy.

- **Submitted ABP-450's IND to the FDA for a comparative PD study utilizing CMAP measurements**
  - Designed to compare the pharmacodynamic activity of ABP-450 and BOTOX® using an objective, quantitative measure of neuromuscular response, with an emphasis on sensitivity to detect potential differences between the products, should they exist. By providing a sensitive assessment of the products' biological activity in humans, the study is intended to bridge the comparative analytical evidence with clinical pharmacology data, further strengthening the scientific foundation for establishing biosimilarity.
  - Following IND submission, AEON intends to advance preparations for study initiation, subject to applicable regulatory requirements, with expected study initiation in the first quarter of 2027.
- **Reported expanded structural data supporting molecular similarity of ABP-450 to BOTOX®**
  - Improved peptide-mapping methods and increased the coverage of the core botulinum neurotoxin primary sequence from approximately 93% to 98%, with 100% amino acid identity across all regions analyzed. The 98% amino acid sequence coverage represents a meaningful expansion from the approximately 93% coverage announced in November 2025. The earlier peptide-mapping work analyzed more than 3,400 amino acids across the five-protein complex and demonstrated 100% primary structure identity across all regions analyzed. The expanded work closes most of the remaining coverage gaps within the core neurotoxin and confirms sequence identity at the critical light-chain/heavy-chain activation junction.
  - Preliminary analysis demonstrated preservation of the critical disulfide bond architecture required for toxin activation in ABP-450 just as they are in BOTOX®.
  - Primary amino acid sequence and disulfide connectivity are foundational to establishing molecular similarity between ABP-450 and BOTOX® and expanded primary structure analysis was performed across six drug product samples encompassing both ABP-450 and BOTOX®. Across every region analyzed, the amino acid sequence was identical, including the critical proteolytic activation junction between the light and heavy chains. Because primary sequence is an identity attribute that is not expected to vary between lots, the 98% result reflects combined coverage generated from complementary digestion strategies and samples rather than a per-lot coverage metric.
- **Reported positive pilot forced degradation results supporting analytical comparability of ABP-450 to BOTOX®**
  - Pilot study designed to establish stability-indicating stress conditions and to confirm whether the selected conditions produced measurable degradation across time points. Under thermal stress, both ABP-450 and BOTOX® lost potency at comparable rates. Under oxidative stress, methionine sites were modified in both molecules in a similar dose-dependent pattern. Together, the results provide an additional line of analytical evidence relevant to structural comparability. The Company plans to initiate a multi-lot forced degradation comparability study in the first half of 2027.
  - Forced degradation testing is widely used in analytical comparability assessments for complex biologics and complements characterization performed on unstressed material. Rather than comparing two molecules only in their native, as-manufactured state, forced degradation deliberately stresses each molecule - through elevated temperature, oxidation, or other stress factors - and compares how each degrades over time. Because degradation pathways are highly sensitive to a protein's underlying structure, matching degradation behavior under stress can provide evidence of structural similarity beyond what standard characterization alone can detect.
- **Received approximately $6.2 million in gross proceeds from exercises of two-year milestone warrants**
  - The Company's September 30, 2026 announcement of the outcome of its BPD Type 2b meeting with the FDA satisfied the regulatory milestone under the two-year milestone warrants issued in the Company's July 2026 underwritten public offering. As a result, the expiration date of these warrants was accelerated to November 16, 2026.
  - On November 2, 2026, the Company entered into an amendment reducing the exercise price of its outstanding two-year milestone warrants from $0.3221 to $0.20 per share of common stock and from $0.3220 to $0.1999 per pre-funded warrant. The amendment applies to all outstanding two-year milestone warrants. In connection with the amendment, certain warrant holders committed to exercise a portion of the outstanding two-year milestone warrants at the reduced exercise price.
  - As of November 16, 2026, the Company had received approximately $6.2 million in gross proceeds from exercises of these warrants, providing additional capital to support the continued advancement of the ABP-450 development program. Any warrants remaining unexercised will expire on November 16, 2026.

Liquidity and Capital Resources

The Company reported cash and cash equivalents of $11.4 million as of September 30, 2026, which does not include approximately $6.2 million of proceeds from the exercise of milestone warrants received in the fourth quarter of 2026. The Company expects its cash and cash equivalents as of September 30, 2026, together with these warrant proceeds, to fund operations into the second quarter of 2027, supporting continued execution of the comparative analytical program, preparations for and planned initiation of the CMAP pharmacodynamic study, and ongoing regulatory activities.

Planned ABP-450 Development Milestones

- Continued advancement of comparative analytical studies to strengthen the evidence supporting biosimilarity between ABP-450 and BOTOX®
- Initiation of CMAP pharmacodynamic study in Q1 2027
- Initiation of multi-lot forced degradation comparability study in the first half of 2027
- Advancement of scientific bridging activities to support the use of previously completed comparative clinical studies
- Additional FDA engagement in 2027 to review the evolving integrated evidence package

About the U.S. Biosimilar Pathway

The 351(k) biosimilar pathway is grounded in a totality-of-the-evidence approach. The FDA evaluates a proposed biosimilar using the most sensitive and scientifically informative methods available to identify potential differences from its reference product, with comparative analytical assessment providing the scientific foundation. The nature and extent of any additional studies the FDA may require prior to approval are informed by the residual uncertainty remaining after that assessment. Once biosimilarity is established, the FDA has the authority to approve a biosimilar for additional indications of the reference product through scientifically justified extrapolation, without requiring separate clinical studies in each indication.

In October 2025, the FDA issued draft guidance proposing that a comparative efficacy study — a comparative clinical study with efficacy endpoints — may not be necessary where, among other things, a comparative analytical assessment demonstrates that a proposed product is highly similar to its reference product. The draft guidance reflects the FDA's view that comparative analytical methods are generally more sensitive than comparative efficacy studies for detecting differences between products.

About AEON Biopharma

AEON Biopharma is a biopharmaceutical company pursuing full-label access to the U.S. therapeutic neurotoxin market via biosimilarity to BOTOX®. The U.S. therapeutic neurotoxin market is estimated to be approximately $3.5 billion annually, representing a major opportunity for biosimilar entry. ABP-450 is the same botulinum toxin complex currently approved and marketed for cosmetic indications by Evolus, Inc. under the name Jeuveau®. ABP-450 is manufactured by Daewoong Pharmaceutical in a facility that has been authorized by the U.S. Food and Drug Administration, Health Canada, and the European Medicines Agency for the manufacture of third-party botulinum toxin products. AEON has exclusive development and commercialization rights for therapeutic indications of ABP-450 in the United States, Canada, the European Union, the United Kingdom, and certain other international territories. To learn more about AEON, visit www.aeonbiopharma.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Forward-looking statements include all statements that do not relate solely to historical or current facts, including without limitation statements regarding the Company's product development and business prospects, and can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue" or the negative versions of those words or other comparable words. Forward-looking statements are not guarantees of future actions or performance. Forward-looking statements in this press release include statements regarding the Company's anticipated cash runway and future capital requirements; the expected proceeds from warrant exercises; the timing, design, initiation and execution of the Company's planned clinical and analytical studies; the sensitivity and potential evidentiary value of the CMAP pharmacodynamic study; the Company's ability to complete the comparative analytical assessment and scientific bridging activities; the potential for the Company's integrated evidence package to support a determination of biosimilarity without a standalone comparative clinical efficacy study; the scope and timing of any future FDA review, approval or indication extrapolation; the Company's regulatory strategy and development plans for ABP-450; the potential market opportunity for ABP-450; and the anticipated contributions of its management team. These forward-looking statements are based on information currently available to the Company and its current plans or expectations and are subject to a number of risks and uncertainties that could significantly affect current plans. Should one or more of these risks or uncertainties materialize, or the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended, or planned. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, performance, or achievements. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results.

Factors that may cause actual results to differ materially from current expectations include, but are not limited to: (i) the Company's ability to meet continued stock exchange listing standards; (ii) the Company's ability to obtain additional and sufficient financing; (iii) the Company's anticipated financial performance, including cash and cash equivalents; (iv) the Company's plans regarding any interactions with the FDA; (v) the outcome of any regulatory interactions; (vi) the possibility that the FDA may require additional analytical, pharmacodynamic, clinical or other studies; (vii) the Company's ability to obtain necessary regulatory and institutional approvals, activate clinical sites and initiate its planned studies within anticipated timelines; and (viii) other risks and uncertainties set forth in the sections entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in the Company's filings with the Securities and Exchange Commission (the "SEC"), which are available on the SEC's website at www.sec.gov.

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AEON BIOPHARMA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share data and par value amounts)

	September 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,417	$ 3,006
Prepaid expenses and other current assets	1,146	392
Total current assets	12,563	3,398
Property and equipment, net	58	162
Operating lease right-of-use asset	798	1,052
Other assets	710	948
Total assets	$ 14,129	$ 5,560
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 981	$ 942
Accrued clinical trials expenses	929	1,426
Accrued compensation	981	2,872
Other accrued expenses	1,681	1,657
Total current liabilities	4,572	6,897
Convertible notes at fair value, including related party amount of $1,969 and $34,600 at September 30, 2026 and December 31, 2025, respectively	1,969	34,600
Operating lease liability	821	893
Derivative liability	—	14,879
Warrant liabilities	4,353	3,276
Contingent consideration liability	6	42
Other liabilities	22	—
Total liabilities	11,743	60,587
Commitments and contingencies		
Stockholders' equity (deficit):		
Class A common stock, $0.0001 par value; 1,040,000,000 shares authorized at September 30, 2026 and December 31, 2025, and 59,084,675 and 12,105,902 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	14	9
Additional paid-in capital	483,674	415,783
Accumulated deficit	(481,302)	(470,819)
Total stockholders' equity (deficit)	2,386	(55,027)
Total liabilities and stockholders' equity (deficit)	$ 14,129	$ 5,560

AEON BIOPHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(in thousands, except share and per share data)

	Three Months Ended September 30,	Nine Months Ended September 30,

	2026	2025	2026	2025
Operating expenses:				
Selling, general and administrative	$ 2,990	$ 1,933	$ 9,884	$ 8,316
Research and development	1,515	597	6,488	2,485
Change in fair value of contingent consideration	(22)	(37)	(36)	(3,509)
Total operating costs and expenses	4,483	2,493	16,336	7,292
Loss from operations	(4,483)	(2,493)	(16,336)	(7,292)
Other (loss) income:				
Change in fair value of convertible notes	(214)	(1,877)	(9,154)	(5,362)
Change in fair value of warrants	7,014	(236)	16,611	85,950
Loss on issuance of warrants	—	—	—	(75,644)
Loss on extinguishment of debt	—	—	(76)	—
Loss on derivative liability	—	—	(1,743)	—
Other income, net	148	68	215	263
Total other income (loss), net	6,948	(2,045)	5,853	5,207
Income (loss) before taxes	2,465	(4,538)	(10,483)	(2,085)
Income taxes	—	—	—	—
Net income (loss)	$ 2,465	$ (4,538)	$ (10,483)	$ (2,085)
Basic and diluted net income (loss) per share attributable to common stockholders	$ 0.01	$ (0.39)	$ (0.17)	$ (0.23)
Weighted average shares of common stock outstanding used to compute basic and diluted net income (loss) per share	89,957,587	11,634,946	60,548,285	8,931,566