Obsidian Therapeutics Reports Third Quarter 2026 Financial Results and Business Updates

November 12, 2026

- *Presented positive updated efficacy and pooled safety data on amsoki-cel in advanced melanoma at the 41st Annual SITC Meeting, including a 67% ORR (n=10/15), median PFS of 8.3 months and median DOR not yet reached at 14.3 months median study follow-up*
- *Enrollment is ongoing in registration-enabling cohort of the Phase 1/2 Agni-01 multicenter study, with topline data expected by year-end 2027*
- *Strengthened Board of Directors with appointment of Mark Reisenauer*
- *Cash, cash equivalents, and marketable securities of $324.4 million as of September 30, 2026, with expected cash runway into 2H 2028*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 12, 2026-- Obsidian Therapeutics, Inc. (“Obsidian”) (Nasdaq: OBX), a clinical-stage biopharmaceutical company harnessing novel protein-regulation technology to develop engineered tumor-infiltrating lymphocyte (TIL) cell therapies, today reported financial results for the third quarter ended September 30, 2026, highlighting recent progress and business updates.

“2026 has been a transformative year so far for Obsidian. In the third quarter, we closed an oversubscribed $350 million financing, completed our transaction with Galera Therapeutics, and debuted on Nasdaq as a publicly traded company,” said Madan Jagasia, M.D., Chief Executive Officer of Obsidian. “We have made substantial progress advancing amsoki-cel, with enrollment ongoing in the registration-enabling immune checkpoint inhibitor-resistant advanced melanoma cohort of our Agni-01 study. The updated data we presented at SITC further strengthen our belief in the program, highlighting amsoki-cel’s consistent, favorable safety profile and encouraging clinical activity in patients with advanced melanoma, including an objective response rate of 67%, median progression-free survival of 8.3 months, and median duration of response not yet reached at median study follow-up of 14.3 months. We remain on track to complete enrollment in the registration-enabling cohort by the end of the first quarter of 2027 and report topline data by year-end 2027.”

Third Quarter 2026 and Recent Updates

Amsokigene autoleucel (amsoki-cel, formerly OBX-115)

- Enrollment in the registration-enabling cohort of the Phase 1/2 Agni-01 multicenter study of amsoki-cel in patients with immune checkpoint inhibitor (ICI)-resistant advanced or metastatic melanoma is expected to be completed by the end of the first quarter of 2027, with topline data expected by the end of 2027.
    - The Company announced initiation of enrollment in August 2026. The single-arm registration-enabling cohort is part of the ongoing Agni-01 study (NCT06060613), which is a multicenter Phase 1/2 study, designed to further evaluate the safety and efficacy of amsoki-cel at the recommended phase 2 dose (RP2D) in patients with ICI-resistant advanced melanoma. The primary endpoint is objective response rate (ORR) as measured per Response Evaluation Criteria in Solid Tumors (RECIST v1.1) by a blinded independent central review (BICR).
- Updated amsoki-cel results presented at the Society for Immunotherapy of Cancer (SITC) 2026 Annual Meeting continued to suggest encouraging efficacy, durable clinical benefit and a consistent, favorable safety profile in patients with ICI-resistant advanced melanoma. The presentation included updated efficacy data from the single-arm, open-label Phase 1/2 Agni-01 multicenter study as of a September 25, 2026, data cutoff in 15 patients treated at the RP2D. Additional data included pooled safety data across 37 patients from the Phase 1 first-in-human (FIH) single-center study and the Phase 1/2 Agni-01 multicenter study as of a May 5, 2026, data cutoff.
    - In the efficacy set (n=15), a 67% ORR, per RECIST v1.1, was observed, including 2 confirmed complete responses (CR) and 8 confirmed partial responses (PR). 2 of the 8 patients who achieved a PR demonstrated a 100% reduction in the sum of diameters (SOD) of target lesions. Data demonstrated a durable clinical benefit, including 5 of 10 responses ongoing as of the median 14.3-month study follow-up, median progression-free survival (PFS) of 8.3 months, and 33% of all treated patients (5/15) remained in deep, ongoing response at the 12-month post-infusion landmark. The median duration of response (mDOR) was not reached.
    - In the pooled safety set (n=37), there were no dose-limiting toxicities (DLT), treatment-related mortality (TRM), immune effector cell-associated neurotoxicity syndrome (ICANS) or ICU transfers, and the majority of non-hematologic treatment-emergent adverse events (TEAEs) occurring in ≥30% of patients were Grade 2 or less, with one reported Grade 3 cytokine release syndrome (CRS).
- The Company also announced a publication in *Nature Medicine* summarizing safety and efficacy data as of a May 5, 2026, data cutoff from the FIH and ongoing Agni-01 studies. The publication, “Regulatable Membrane-Bound IL-15 Engineered TIL Cell Therapy for Immune Checkpoint Inhibitor-Resistant Advanced Melanoma: Pooled Analysis of Phase 1 and 1/2 Trials,” is available online here.

- Obsidian is also investigating amsoki-cel in patients with non-small cell lung cancer (NSCLC) in the Agni-01 trial. NSCLC Phase 1 data are expected in the first half of 2027.

Corporate Updates

- Obsidian completed its transaction with Galera Therapeutics and began trading on Nasdaq on August 4, 2026, under the ticker symbol “OBX.” The Company also closed a previously announced oversubscribed private placement of $350 million in gross proceeds.
- In November 2026, Obsidian appointed Mark Reisenauer to the Board of Directors. Mr. Reisenauer brings more than 30 years of experience successfully commercializing and launching products in the oncology space. Most recently, he served as Chief Executive Officer and a director of Assertio, which was acquired by Zydus Lifesciences. Previously, he served as President of U.S. Commercial at Astellas Pharmaceuticals Inc., where he grew sales to nearly $5 billion while overseeing Marketing, Sales, Policy and Government Affairs and Market Access teams. Earlier in his career, he served as Senior Vice President and Chief Commercial Officer at Micromet, Inc., which was acquired by Amgen, where he led commercial launch activities and pipeline development. He also held senior roles at Abbott Laboratories, where he led global commercialization, licensing, and R&D strategy for oncology products and co-chaired the Oncology Therapeutic Executive Committee.

Third Quarter 2026 Financial Results

- Cash, cash equivalents, and marketable securities were $324.4 million as of September 30, 2026. Obsidian expects that its current cash, cash equivalents, and marketable securities will support planned operations into the second half of 2028.
- Research and development expenses were $27.5 million for the three months ended September 30, 2026.
- General and administrative expenses were $10.3 million for the three months ended September 30, 2026.
- Acquired in-process research and development expense associated with the Galera transaction was $15.1 million for the three months ended September 30, 2026.
- Net loss was $50.7 million, or $1.23 per basic and diluted share, for the three months ended September 30, 2026.

About Obsidian Therapeutics

Obsidian Therapeutics, Inc. is a clinical-stage biopharmaceutical company harnessing novel protein-regulation technology to develop engineered TIL cell therapies for the treatment of patients with solid tumors. Obsidian’s proprietary cytoDRiVE® technology is designed to precisely regulate the timing and level of protein function by using FDA-approved small-molecule drugs. Obsidian has offices in Cambridge and Bedford, MA. For more information, please visit www.obsidiantx.com.

About Amsokigene Autoleucel (amsoki-cel, formerly OBX-115)

Obsidian leverages its cytoDRiVE® platform to develop engineered TIL cell therapies. Obsidian’s lead investigational TIL program, amsoki-cel, is a novel engineered tumor-derived autologous T cell immunotherapy (tumor-infiltrating lymphocyte [TIL] cell therapy) armored with pharmacologically regulatable membrane-bound IL15 (mbIL15). Amsoki-cel has the potential, if approved, to become a meaningful therapeutic option for patients with advanced (unresectable or metastatic) melanoma and other solid tumors by leveraging the expected benefits of mbIL15 and Obsidian’s proprietary, differentiated manufacturing process designed to enhance persistence, antitumor activity, and clinical safety of TIL cell therapy. Obsidian is investigating amsoki-cel in the Phase 1/2 Agni-01 multicenter trial in patients with advanced solid tumors (NCT06060613).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by the following words: “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “aim,” “may,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Such statements include, but are not limited to, implied and express statements concerning beliefs and expectations regarding: future clinical development activities, therapeutic potential, clinical benefits and safety of Obsidian’s product candidates; potential indications and patient populations for amsoki-cel, if approved; the expected benefits of mbIL15, Obsidian's manufacturing process and its cytoDRiVE® platform; the anticipated timing of completion of enrollment in the registration-enabling cohort of the Agni-01 study by the end of the first quarter of 2027 and availability of topline data by year-end 2027 as well as availability of NSCLC Phase 1 data in the first half of 2027; Obsidian's expected cash runway and the sufficiency of its cash, cash equivalents and marketable securities to fund planned operations; anticipated contributions by members of Obsidian’s Board and management team; and expectations regarding timing, progress, objectives or plans for Obsidian’s development of its clinical pipeline and interactions with regulatory agencies.

These forward-looking statements relate to Obsidian, its business, prospects and results of operations, and are subject to certain risks and uncertainties posed by many factors and events that could cause Obsidian’s actual business, prospects and results of operations to differ materially from those anticipated by such forward-looking statements. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: Obsidian’s ability to advance amsoki-cel through clinical development, and to obtain regulatory approval of amsoki-cel; the results of preclinical studies, or clinical studies not being predictive of future results in connection with future studies; the possibility that updated or additional data from the Agni-01 study may differ from results reported to date; the

initiation, timing, progress and results of clinical trials, including the timing of completion of enrollment and data readouts; Obsidian's ability to fund its development activities and achieve development goals; the accuracy of Obsidian's estimates of its expenses, capital requirements and the period over which its cash resources will be sufficient to fund operations; Obsidian's dependence on third parties to conduct clinical trials and manufacture amsoki-cel; Obsidian's ability to attract, hire and retain key personnel, and protect its intellectual property; Obsidian's financial condition and need for substantial additional funds in order to complete development activities and commercialize amsoki-cel, if approved; regulatory developments and approval processes of the U.S. Food and Drug Administration and comparable foreign regulatory authorities; Obsidian's competitors and industry; and other risks and uncertainties described under the heading "Risk Factors" included in the Quarterly Report on Form 10-Q for the quarter ended September 30, 2026. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. These forward-looking statements are based upon Obsidian's current expectations and involve assumptions that may never materialize or may prove to be incorrect. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise, except as required by applicable law.

Obsidian intends to use its Investor Relations website as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor Obsidian's Investor Relations website, in addition to following Obsidian's press releases, SEC filings, public conference calls, presentations, and webcasts.

OBSIDIAN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS)
(UNAUDITED)

	Three months ended September 30,		Nine months ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	27,547	25,046	64,828	69,123
General and administrative	10,316	4,588	19,455	15,372
Acquired in-process research and development	15,052	—	15,052	—
Total operating expenses	52,915	29,634	99,335	84,495
Loss from operations	(52,915)	(29,634)	(99,335)	(84,495)
Other income, net:				
Interest and other income	2,259	1,166	3,182	4,145
Total other income	2,259	1,166	3,182	4,145
Loss before income tax expense	(50,656)	(28,468)	(96,153)	(80,350)
Income tax benefit (expense)	—	—	—	—
Net Loss	$ (50,656)	$ (28,468)	$ (96,153)	$ (80,350)

OBSIDIAN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)
(UNAUDITED)

	September 30, 2026	**December 31, 2025**
Cash, cash equivalents, and marketable securities	$ 324,354	$ 80,486
Total assets	340,744	88,580
Total liabilities	20,163	16,589
Convertible preferred stock	—	338,028
Total stockholders' equity (deficit)	$ 320,581	$ (266,037)

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