UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 04, 2026

ODYSSEY THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-43270**	**86-3384382**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
51 Sleeper Street, Suite 800 Boston, Massachusetts		**02210**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 865-9628

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	ODTX	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 4, 2026, Odyssey Therapeutics, Inc. (the "Company") announced its financial results for the three months ended September 30, 2026. A copy of the press release issued in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release, dated November 4, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Odyssey Therapeutics, Inc.

Date: November 4, 2026

By: /s/ Jason Haas
Jason Haas
Chief Financial Officer

Odyssey Therapeutics Reports Third Quarter 2026 Financial Results and Provides Corporate Update

Additional analyses from the Phase 2a induction period for OD-001 further strengthen clinical proof of concept in ulcerative colitis

Completed IND-enabling studies for OD-002, a first-in-class oral SLC15A4 inhibitor

$387 million in cash, cash equivalents and marketable securities as of September 30, 2026, expected to fund operations into the second half of 2028

BOSTON, November 4, 2026 (GLOBE NEWSWIRE) - Odyssey Therapeutics, Inc. (Nasdaq: ODTX) ("Odyssey" or the "Company"), a clinical-stage biopharmaceutical company seeking to transform the standard of care for patients suffering from autoimmune and inflammatory diseases by developing medicines that precisely target disease pathology, today reported financial results for the third quarter ended September 30, 2026, and provided an update on recent progress and anticipated milestones.

"Over the past several months, we have made meaningful progress across our entire pipeline, highlighted by additional analyses from the Phase 2a induction period for OD-001 demonstrating that clinical efficacy is supported by concordant biomarker and transcriptomic findings, further reinforcing previously established clinical proof of concept in patients with ulcerative colitis," said Gary D. Glick, Ph.D., founder and chief executive officer of Odyssey Therapeutics. "We have also continued to advance the clinical development of OD-001 while completing IND-enabling studies for OD-002, our SLC15A4 inhibitor. Together with an enhanced executive leadership team and strong financial foundation, these achievements position us to execute on our clinical development strategy and drive continued progress throughout our portfolio."

Recent Business Highlights and Developments

Pipeline developments

- **OD-001: RIPK2 scaffolding inhibitor**
    - **Presented additional Phase 2a induction results that strengthen clinical proof of concept.** In October, Odyssey presented additional findings from the Phase 2a induction period involving 56 efficacy-evaluable patients with moderate-to-severe ulcerative colitis at United European Gastroenterology (UEG) Week and shared new clinical and translational analyses during a

company webcast. Clinical efficacy results are supported by concordant findings across clinical outcomes and inflammatory biomarkers, mucosal transcriptomics, and histologic improvement, further reinforcing the clinical proof of concept and providing additional biological evidence consistent with RIPK2 scaffolding inhibition.

- **OD-002: SLC15A4 inhibitor**
    - **Completed IND-enabling studies for OD-002, a first-in-class oral SLC15A4 inhibitor.** OD-002 targets SLC15A4, a convergence point that integrates upstream TLR7, TLR8 and TLR9 signaling to activate IRF5. By targeting this convergence point, OD-002 is designed to broadly modulate disease-driving innate immune pathways, including TLR7/8/9-mediated responses implicated in pathogenic B-cell activity, autoantibody production, and pro-inflammatory cytokine signaling, while preserving normal host defense functions of IRF5.
- **OD-003: TNFR2 agonist**
    - **Upcoming presentation of preclinical data at ACR Convergence 2026.** Odyssey will present preclinical data demonstrating expansion of regulatory T cells (Tregs) with enhanced stability, suppressive function and tissue-homing potential at the American College of Rheumatology (ACR) Convergence 2026 meeting, taking place November 6-11. The findings support the therapeutic potential of OD-003 across autoimmune and inflammatory diseases as the program advances through IND-enabling studies.
- **OD-004: TSLP/IL-33 bispecific antagonist**
    - **Nominated development candidate for OD-004.** Odyssey selected a development candidate for OD-004, its potentially best-in-class TSLP/IL-33 bispecific antagonist, with potency for both targets comparable or superior to approved and investigational monospecific agents. The program is advancing into IND-enabling studies.

Corporate highlights

- **Ensured continuity of clinical leadership with appointment of chief medical officer.** Odyssey appointed Anthony Opipari, M.D., Ph.D., as chief medical officer.

Dr. Opipari joined Odyssey at its formation and played a central role in the design and execution of the Phase 2a OD-001 monotherapy trial in ulcerative colitis, overseeing its rapid advancement from initiation through completion while maintaining rigorous standards of clinical quality, data integrity, and operational execution. The trial established clinical proof of concept for OD-001 and demonstrated Odyssey's ability to execute efficiently in a competitive therapeutic area. His appointment ensures continuity of proven clinical leadership as Odyssey advances OD-001 into its next phase of development and progresses its broader pipeline.

- **Strengthened organizational leadership and operational capabilities with appointment of chief people officer.** Odyssey appointed Laura Hare as chief people officer, bringing more than 20 years of experience in organizational strategy, transformation and operations across biotechnology and technology-driven companies. Ms. Hare previously served as chief operating officer and chief people officer at CHARM Therapeutics, where she led initiatives to integrate AI-enabled drug discovery with scientific operations, improve organizational alignment and drive operational efficiency. Earlier in her career, she held senior leadership roles at F-star Therapeutics, supporting the company's transition to clinical-stage development, international expansion and public-company operations. At Odyssey, Ms. Hare will lead people strategy and organizational development, with a focus on fostering cross-functional collaboration, enhancing operational discipline and implementing scalable infrastructure to support continued growth and pipeline advancement.

Anticipated key clinical milestones

- **OD-001 (RIPK2 scaffolding inhibitor):** Topline induction results from the Phase 2b monotherapy trial and Phase 2a combination trial with vedolizumab are expected in the second half of 2027.
- **OD-002 (SLC15A4 inhibitor):** Following completion of IND-enabling studies, Odyssey expects to initiate a Phase 1/2a clinical trial in the first half of 2027, initially enrolling healthy participants, followed by patient cohorts across multiple indications, including cutaneous lupus erythematosus and other autoimmune diseases. The Company expects to report healthy participant data in the second half of 2027, including results from an *ex vivo* stimulation assay that has demonstrated translational relevance to clinical efficacy in lupus trials of other agents targeting TLR7/8.

Third Quarter 2026 Financial Results

As of September 30, 2026, Odyssey had cash, cash equivalents and marketable securities of $387 million, which are expected to fund Odyssey's operations into the second half of 2028.

Research and development expenses were $42.1 million for the quarter ended September 30, 2026, compared to $26.3 million for the same period in 2025. The increase primarily reflected higher external research and development costs associated with advancing the Company's clinical and preclinical programs. General and administrative expenses were $11.2 million for the quarter ended September 30, 2026, compared to $10.2 million for the same period in 2025. The increase primarily reflected higher personnel-related expenses, including stock-based compensation.

Net loss was $53.1 million for the quarter ended September 30, 2026, compared to a net loss of $35.5 million for the same period in 2025. Adjusted net loss (non-GAAP) was $41.9 million for the quarter ended September 30, 2026. See "Non-GAAP Financial Measures" below for additional information and a reconciliation to the most directly comparable GAAP financial measure.

Additional financial information will be available in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2026, which will be filed with the U.S. Securities and Exchange Commission and made available at www.sec.gov and through the "Investors" section of the Company's website at investors.odysseytx.com.

Non-GAAP Financial Measures

This press release includes adjusted net loss, a financial measure that is not prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). Adjusted net loss is defined as GAAP net loss excluding non-cash changes in the fair value of contingent consideration and stock-based compensation expense.

Management believes adjusted net loss provides investors with useful supplemental information regarding the Company's operating performance. Management uses adjusted net loss, together with GAAP financial measures, to evaluate the Company's operating performance and facilitate comparisons across reporting periods.

Adjusted net loss should not be considered in isolation or as a substitute for GAAP net loss. Because other companies may calculate similarly titled non-GAAP financial

measures differently, adjusted net loss may not be comparable to similarly titled measures reported by other companies.

The following table reconciles GAAP net loss to adjusted net loss:

	Three Months Ended September 30,	
	2026	2025
	(in millions)	
GAAP Net Loss	$ (53.1)	$ (35.5)
Change in fair value of contingent consideration	3.3	1.9
Stock-based compensation expense	7.9	4.9
Adjusted Net Loss (Non-GAAP)	$ (41.9)	$ (28.7)

About Odyssey Therapeutics

Odyssey Therapeutics is a clinical-stage biopharmaceutical company seeking to transform the standard of care for patients suffering from autoimmune and inflammatory diseases by developing medicines that are designed to precisely target disease pathology. Since its founding in 2021, Odyssey has built a portfolio of internally discovered and developed medicines with its first program advancing through multiple clinical milestones. Odyssey's portfolio leverages the scientific expertise of its team of experienced drug hunters and a comprehensive suite of tools to efficiently advance product candidates that the Company believes have the potential to induce deep and durable remission for patients across several inflammatory diseases with unmet need.

For more information, please visit www.odysseytx.com and follow Odyssey on LinkedIn or X.

Forward-looking statements

This press release includes certain disclosures that contain "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements regarding the interpretation and potential implications of Phase 2a clinical, safety and exploratory transcriptomic results for OD-001; evidence of treatment activity and RIPK2 inhibition; the potential efficacy, safety and therapeutic applications of OD-001 as a monotherapy and in combination with vedolizumab; the conduct, enrollment, timing and anticipated results of ongoing and planned clinical trials; the advancement and anticipated regulatory and clinical milestones

of OD-002 and other pipeline programs; and the Company's expected cash runway, financial position and ability to fund future operations.

Forward-looking statements may be identified by words such as “anticipate,” “believe,” “could,” “expect,” “intend,” “goal,” “may,” “plan,” “potential,” “will,” “would” and variations of these words or similar expressions, although not all forward-looking statements contain these identifying words. Forward-looking statements reflect Odyssey’s current expectations and involve risks and uncertainties that could cause actual results to differ materially. These include the inherent limitations of an open-label trial without a concurrent placebo control; uncertainties associated with exploratory transcriptomic findings; the possibility of different outcomes in future trials; clinical, regulatory, competitive and third-party risks; and other factors described under “Risk Factors” in Odyssey’s most recent Form 10-Q and other SEC filings. Odyssey undertakes no obligation to update these statements except as required by law.

Contact

Benjamin Navon
Senior Director, Communications
(857) 431-8785

For investors
investors@odysseytx.com

For media
media@odysseytx.com