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 12, 2026

Parabilis Medicines, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-43331**	**47-4505725**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
30 Acorn Park Drive Cambridge, Massachusetts		**02140**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 945-9510

Not Applicable
(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 $0.0001 per share	PBLS	The Nasdaq Stock Market LLC

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 12, 2026, Parabilis Medicines, Inc. (the "Company") announced its financial results and business highlights for the quarter ended September 30, 2026. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information included under Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is being 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, and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release issued by Parabilis Medicines, Inc. on November 12, 2026, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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.

Parabilis Medicines, Inc.

Date: November 12, 2026

By: /s/ Thomas Kotarakos
Thomas Kotarakos
Chief Financial Officer

Exhibit 99.1

Parabilis Medicines Reports Third Quarter 2026 Financial Results and Provides Business Updates

Presented updated Phase 1/2 data at ESMO Congress 2026 demonstrating a 72.2% objective response rate at the 32-week landmark and a favorable safety and tolerability profile for zolucatetide in desmoid tumors

Reached alignment with the U.S. FDA on dose, regimen and trial design for upcoming PEDESTAL Phase 3 registrational trial in desmoid tumors

Initiated a dose-ranging clinical study of zolucatetide in familial adenomatous polyposis (FAP)

Entered into a clinical collaboration with Revolution Medicines to evaluate zolucatetide in combination with zoldonrasib and cetuximab in patients with previously treated RAS G12D mutant microsatellite stable metastatic colorectal cancer (MSS CRC)

Ended the third quarter with $1.1 billion in cash, cash equivalents and marketable securities, expected to fund operations into 2030

CAMBRIDGE, Mass., November 12, 2026 — Parabilis Medicines (Nasdaq: PBLS), a clinical-stage biopharmaceutical company dedicated to creating extraordinary medicines for patients with serious diseases by unlocking historically undruggable targets, today reported financial results and business updates for the third quarter ended September 30, 2026.

“With each successive clinical update, we are building a stronger foundation for zolucatetide as a unique medicine with the potential to make a meaningful difference for patients across multiple diseases,” said Mathai Mammen, M.D., Ph.D., Chairman, Chief Executive Officer and President of Parabilis Medicines. “The updated results presented at ESMO further reinforce our confidence in the depth and consistency of desmoid tumor responses, alongside a favorable safety and tolerability profile. With our Phase 3 dosing, regimen and trial design aligned with the FDA, we are well positioned to initiate PEDESTAL in the first half of 2027, bringing us closer to delivering a potentially transformative treatment for patients with desmoid tumors.”

Dr. Mammen continued, “We are also continuing to deliver on zolucatetide’s potential to become a pipeline in a product, advancing development in FAP, adamantinomatous craniopharyngioma (ACP), hepatocellular carcinoma (HCC) and other Wnt-driven diseases, while pursuing a scientifically grounded combination approach in MSS CRC through our collaboration with Revolution Medicines. In parallel, we are selectively

advancing a broader pipeline of programs against other historically undruggable targets. The progress across our portfolio continues to strengthen our conviction in the ability of our Helicon™ platform to repeatedly translate breakthrough science into medicines that can meaningfully improve patients' lives."

Recent Business Highlights and Anticipated Milestones

Continued Advancement of Zolucatetide

Desmoid tumors

- Presented compelling clinical data from a June 22, 2026, data cut of the ongoing Phase 1/2 trial of zolucatetide at the European Society for Medical Oncology (ESMO) Congress 2026, demonstrating:
    - An objective response rate (ORR) of 72.2% (13/18) among patients evaluable at the 32-week landmark who received a starting dose of ≥450 mg
    - A disease control rate (DCR) of 100%, with no disease progression, across all 46 response-evaluable patients receiving a starting dose of ≥450 mg
    - A favorable safety and tolerability profile now shown in 76 patients, with no treatment discontinuations due to treatment-related adverse events (TRAEs)
- Reached alignment with the U.S. Food and Drug Administration (FDA) on a global Phase 3 trial design; plan to initiate the randomized, double-blind PEDESTAL Phase 3 registrational trial in the first half of 2027 with topline results anticipated in 2029
- Selected for an oral presentation at the Connective Tissue Oncology Society (CTOS) Annual Meeting in November 2026, featuring data from the June 22, 2026, data cut
- Initiated a Phase 1/2 clinical trial of zolucatetide in patients with desmoid tumors in China to support the planned inclusion of patients in China in the global PEDESTAL Phase 3 registrational trial

Familial adenomatous polyposis

- Initiated a dose-ranging clinical cohort as part of the ongoing Phase 1/2 trial to evaluate zolucatetide in patients with FAP and identify the optimal dose and regimen
- Anticipate disclosing translational data demonstrating on-target activity at a medical meeting in the first quarter of 2027

- Anticipate disclosing clinical data from additional patients with FAP in the first quarter of 2027, building on compelling early observations of duodenal polyp reductions in two patients

Adamantinomatous craniopharyngioma

- Anticipate disclosing updated clinical data from additional patients with ACP in the first half of 2027, building on encouraging early antitumor activity in three patients

Hepatocellular carcinoma and additional Wnt/β-catenin-driven tumors

- Anticipate disclosing additional clinical data in HCC at a medical meeting in the first quarter of 2027, building on evidence of early activity in a heavily pretreated patient

- Continue evaluating zolucatetide across additional Wnt/β-catenin-driven tumor types as part of the ongoing Phase 1/2 clinical trial

Clinical collaboration with Revolution Medicines in RAS G12D mutant MSS CRC

- Entered into a clinical collaboration with Revolution Medicines (RevMed) to evaluate zolucatetide in combination with RevMed's zoldonrasib, an investigational, oral RAS(ON) G12D-selective covalent tri-complex inhibitor, and cetuximab, an EGFR inhibitor, in patients with previously treated RAS G12D mutant MSS CRC; Parabilis will sponsor and conduct the study, with RevMed supplying zoldonrasib and equally sharing the costs of the trial

- Supported by clinical translational data from the Phase 1/2 trial showing reciprocal upregulation of mitogen-activated protein kinase (MAPK) and downregulation of the Wnt pathway in patients with MSS CRC treated with zolucatetide, alongside a manageable safety and tolerability profile

- Also supported by preclinical data showing enhanced tumor growth inhibition when zolucatetide was combined with zoldonrasib in a CRC patient-derived xenograft model

Advancement of the Helicon Platform and Discovery Pipeline

- Continued advancing wholly owned preclinical programs, including ERG and allosteric AR^{ON} degraders in prostate cancer and a β-catenin degrader program, alongside ongoing research under the strategic collaboration with Regeneron to develop Antibody-Helicon Conjugates (AHCs) targeting intracellular proteins

Corporate Updates

- Appointed Craig L. Tendler, M.D., to the Board of Directors in August 2026, bringing extensive oncology drug development and regulatory experience

Upcoming Investor Conferences

- Announced that Mathai Mammen, M.D., Ph.D., Chairman, CEO and President, will deliver a company presentation at the Jefferies Global Healthcare Conference in London, UK, on Monday, November 16, 2026, at 12:30 p.m. GMT / 7:30 a.m. EST, and participate in a fireside chat at the Evercore ISI 9th Annual Healthcare Conference on Monday, November 30, 2026, at 3:50 p.m. EST; webcasts will be available at https://investors.parabilismed.com/

Third Quarter 2026 Financial Results

Cash position and runway: Cash, cash equivalents and marketable securities were $1.1 billion as of September 30, 2026, compared to $27.7 million as of December 31, 2025. The Company's cash, cash equivalents and marketable securities as of September 30, 2026, are expected to fund operations into 2030.

Revenue: Revenues for the quarter ended September 30, 2026, were $2.1 million from collaboration agreements, compared to no revenue for the comparable prior-year period.

R&D expenses: Research and development expenses were $45.6 million for the quarter ended September 30, 2026, compared to $28.2 million for the comparable prior-year period. The increase of $17.4 million was primarily driven by ongoing investment in the clinical development of zolucatetide across a number of indications and increased employee-related costs (including stock-based compensation) associated with increased hiring to support the advancing clinical pipeline.

G&A expenses: General and administrative expenses were $11.3 million for the quarter ended September 30, 2026, compared to $6.6 million for the comparable prior-year period. The increase of $4.7 million was primarily attributable to higher employee-related costs (including stock-based compensation) related to increased hiring to support the Company's growth as it advances its clinical programs and expenses associated with operating as a public company.

Net loss: Net loss was $44.5 million for the quarter ended September 30, 2026, compared to $33.5 million for the comparable prior-year period. The increase in net loss of $11.0 million was primarily driven by increased operating costs.

About Parabilis Medicines

Parabilis Medicines (Nasdaq: PBLS) is a clinical-stage biopharmaceutical company dedicated to creating extraordinary medicines for patients with serious diseases by unlocking biologically important targets long considered undruggable. The Company has pioneered a new class of alpha-helical peptides – Helicons™ – capable of modulating intracellular proteins that have historically been beyond the reach of conventional medicines. The Company's lead investigational medicine, zolucatetide, is the first and only direct inhibitor of the β-catenin:TCF interaction, a central node in the Wnt/β-catenin pathway that has eluded drug developers for decades. Zolucatetide is being evaluated in the clinic across multiple Wnt/β-catenin-driven diseases, including desmoid tumors, familial adenomatous polyposis (FAP), adamantinomatous craniopharyngioma (ACP), hepatocellular carcinoma (HCC) and a range of other rare and common solid tumor indications. Beyond zolucatetide, Parabilis is pursuing a follow-on β-catenin degrader program and advancing additional Helicon-based programs focused on other challenging targets, including ERG and allosteric AR^{ON} in prostate cancer, where we believe our medicines could have life-altering impact. For more information, visit www.parabilismed.com or follow us on LinkedIn.

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. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, express or implied statements regarding: the clinical development of zolucatetide for the treatment of desmoid tumors, FAP, ACP, HCC, CRC and other rare, Wnt-driven tumors, including the initiation, timing, progress, results and future data releases of our ongoing and planned clinical trials; the expected initiation and timing of the Company’s planned Phase 3 registrational trial in desmoid tumors; the expected timing and results of the ongoing Phase 1/2 study in desmoid tumors; the expected enrollment and timing of certain clinical studies and patient cohorts in FAP, CRC and other Wnt-driven tumors; the expected timing and results of the Company’s preclinical development of its ERG degrader, AR^{ON} degrader and β-catenin degrader development candidates; the potential of the Company’s Helicon™ technology platform; expectations regarding the development of any future product candidates using the Company’s Helicon™ technology platform; expectations regarding the efficacy, tolerability and commercial potential of zolucatetide; and expectations for the Company’s uses of capital, expenses and financial results, including its cash runway into 2030.

Any forward-looking statements in this press release are based on management’s current expectations and beliefs and are subject to a number of risks and uncertainties that could negatively affect the Company’s business, operating results, financial condition and stock

value. Factors that could cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release include, without limitation: risks relating to the Company's research and development activities; the Company's ability to execute on its strategy including obtaining the requisite regulatory approvals on the expected timeline, if at all; uncertainties relating to preclinical and clinical development activities; the Company's dependence on third parties to conduct clinical trials, manufacture its product candidates and develop and commercialize its product candidates, if approved; the Company's ability to attract, integrate and retain key personnel; risks related to the Company's financial condition and need for substantial additional funds in order to complete development activities and commercialize a product candidate, if approved; risks related to regulatory developments and approval processes of the U.S. Food and Drug Administration and comparable foreign regulatory authorities; risks related to establishing and maintaining the Company's intellectual property protections; and risks related to the competitive landscape for the Company's product candidates; as well as other risks and uncertainties described in greater detail in "Risk Factors," in the Company's most recent Quarterly Report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in the Company's subsequent filings with the Securities and Exchange Commission. Any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law, and claims the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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Parabilis Medicines, Inc.
Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 521,198	$ 27,711
Accounts receivable - related party	443	—
Marketable securities	350,425	—
Prepaid expenses and other current assets	6,953	1,647
Total current assets	879,019	29,358
Property and equipment, net	9,506	6,715
Restricted cash	2,855	2,855
Operating lease right-of-use assets	34,291	39,360
Marketable securities, non-current	201,309	—
Other assets	4,262	2,532
Total assets	$ 1,131,242	$ 80,820
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 20,209	$ 17,272
Accrued expenses and other current liabilities	24,012	18,630
Operating lease liabilities, current portion	7,810	7,174
Deferred revenue, current portion	13,544	—
Finance lease liabilities, current portion	684	638
Term loan, net of discount	2,000	13,077
Total current liabilities	68,259	56,791
Operating lease liabilities, net of current portion	30,381	36,341
Finance lease liabilities, net of current portion	951	1,470
Deferred revenue, net of current portion	27,304	—
Other liabilities	—	2,742
Total liabilities	126,895	97,344
Commitments and contingencies		
Convertible preferred stock	—	509,971
Stockholders' equity (deficit):		
Preferred stock	—	—
Common stock	12	—
Non-voting common stock	—	—
Additional paid-in capital	1,690,022	15,009
Accumulated other comprehensive loss	(1,913)	—
Accumulated deficit	(683,774)	(541,504)
Total stockholders' equity (deficit)	1,004,347	(526,495)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 1,131,242	$ 80,820

Parabilis Medicines, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Collaboration revenue	$ 671	$ —	$ 819	$ —
Collaboration revenue - related party	1,443	—	1,443	—
Total revenue	2,114	—	2,262	—
Operating expenses:				
Research and development	45,597	28,199	122,727	92,230
General and administrative	11,253	6,646	32,610	19,376
Total operating expenses	56,850	34,845	155,337	111,606
Loss from operations	(54,736)	(34,845)	(153,075)	(111,606)
Other income (expense):				
Interest income	10,369	711	16,987	3,017
Interest expense	(124)	(398)	(626)	(1,193)
Sublease income - related party	—	1,057	—	3,171
Change in fair value of simple agreement for future equity	—	—	(5,556)	—
Total other income, net	10,245	1,370	10,805	4,995
Net loss	$ (44,491)	$ (33,475)	$ (142,270)	$ (106,611)
Cumulative dividends on convertible preferred stock	—	(10,395)	(32,181)	(30,360)
Deemed dividend upon down-round of convertible preferred stock	—	—	(7,875)	—
Net loss allocable to common stockholders	$ (44,491)	$ (43,870)	$ (182,326)	$ (136,971)
Net loss per share allocable to common stockholders, basic and diluted	$ (0.36)	$ (21.66)	$ (3.51)	$ (67.78)
Weighted average common shares outstanding, basic and diluted	123,593,149	2,025,284	51,962,288	2,020,689
Comprehensive loss:				
Net loss	$ (44,491)	$ (33,475)	$ (142,270)	$ (106,611)
Unrealized gains (losses) on marketable securities	(1,895)	—	(1,913)	(21)
Comprehensive loss	$ (46,386)	$ (33,475)	$ (144,183)	$ (106,632)