UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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 9, 2026

DELCATH SYSTEMS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	001-16133	06-1245881
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(IRS Employer Identification No.)

566 Queensbury Avenue
Queensbury, NY 12804
(Address of principal executive offices) (Zip Code)
(518) 743-8892
(Registrant's telephone number, including area code)
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, $.01 par value	**DCTH**	**The Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 9, 2026, Delcath Systems, Inc. ("Delcath") issued a press release announcing financial results and business highlights for the quarter ended September 30, 2026 (the "Press Release"). A copy of the press release is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto and is incorporated herein by reference.

The information contained in this Current Report on Form 8-K, including the Press Release, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the Press Release shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission by Delcath whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01
Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated November 9, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

DELCATH SYSTEMS, INC.

Date: November 9, 2026

By: /s/ Sandra Pennell

Name: Sandra Pennell

Title: Chief Financial Officer

Delcath Systems Reports Third Quarter 2026 Results and Business Highlights

Increases 2026 Revenue Guidance to a Range of $115 million to $117 million
Conference Call Today at 8:30 a.m. Eastern Time

QUEENSBURY, NY – November 9, 2026, Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, today announced financial results and business highlights for the third quarter ended September 30, 2026.

Third Quarter 2026 Financial Results

- Total revenue of $35.1 million, compared with $20.6 million in the third quarter of 2025
  - HEPZATO KIT™ revenue of $32.7 million, compared to $19.3 million in the third quarter of 2025
  - CHEMOSAT® revenue of $2.4 million, compared to $1.3 million in the third quarter of 2025
- Gross margins of 89%, compared to 87% in the third quarter of 2025
- Net income of $7.0 million, compared to $0.8 million in the third quarter of 2025
- Non-GAAP adjusted EBITDA of $11.5 million, compared to $5.3 million in the third quarter of 2025
- Cash provided by operations of $8.2 million in the quarter; compared to $4.8 million in the third quarter of 2025
- Cash and investments of $104.3 million as of September 30, 2026; and no debt

Business Highlights

- Currently 33 active treatment centers
- Approximately 72% growth in HEPZATO volume in the third quarter 2026 compared to the third quarter 2025
- Advanced the global Phase 2 DELUMA trial (NCT06875128), evaluating HEPZATO in combination with standard-of-care therapy versus standard of care alone in liver-dominant HER2-negative metastatic breast cancer; first patient dosed July 9, 2026, at the European Institute of Oncology in Milan, Italy. The randomized trial is designed to enroll approximately 90 patients at more than 20 U.S. and European sites.

“We are pleased with the continued momentum in our business, with meaningful progress across both commercial operations and clinical development,” said Gerard Michel, Chief Executive Officer of Delcath Systems. “Growing physician experience with HEPZATO, strong engagement across our treatment center network, and increasing interest in its use alongside systemic therapies reinforce our confidence in the long-term opportunity. We are also expanding our pipeline, with a planned IND submission for cholangiocarcinoma in early 2027 and, pending FDA agreement, completion of ongoing preclinical development of an oxaliplatin-based PHP product by mid-2027.”

2026 Full Year Financial Guidance

The Company’s financial outlook for fiscal year 2026:

- Total HEPZATO KIT and CHEMOSAT revenue to range from $115 million to $117 million, reflecting an increase in HEPZATO KIT volume of at least 41% over 2025
- Full year gross margins in the range of 87% to 89%
- Positive adjusted EBITDA

Third Quarter 2026 Results

Total revenue for the quarter ending September 30, 2026 was $35.1 million compared to $20.6 million for the same period in the prior year. Revenue in the quarter includes sales of $32.7 million of HEPZATO in the U.S. and $2.4 million of CHEMOSAT in Europe.

Research and development expenses for the quarter ending September 30, 2026, were $11.0 million compared to $8.0 million for the same period in the prior year. The increase is primarily due to increased clinical headcount and increased clinical trial activity.

Selling, general and administrative expenses for the quarter ended September 30, 2026, were $13.1 million compared to $10.3 million for the same period in the prior year. The increase is primarily due to continued commercial expansion activities.

Net income was $7.0 million for the quarter ended September 30, 2026, compared to $0.8 million for the same period in the prior year.

Non-GAAP adjusted EBITDA for the quarter ended September 30, 2026 was $11.5 million compared to adjusted EBITDA of $5.3 million for the same period in the prior year. A table reconciling non-GAAP measures is included in this press release for reference.

As of September 30, 2026, the Company had $104.3 million in cash and investments, and no debt.

Conference Call Information

To participate in this event, dial in approximately 5 to 10 minutes before the beginning of the call.

Event Date: Monday, November 9, 2026
Time: 8:30 AM Eastern Time

Participant Numbers:
Toll Free: 1-800-717-1738
International: 1-646-307-1865
Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1767384&tp_key=cbc23b55c8

A replay of the webinar will be available shortly after the conclusion of the call and will be archived on the company's website https://investors.delcath.com/news-events/events-and-presentations.

GAAP v. Non-GAAP Measures

Delcath’s reported earnings are prepared in accordance with generally accepted accounting principles in the United States, or GAAP, and represent earnings as reported to the Securities and Exchange Commission. Delcath has provided in this release certain financial information that has not been prepared in accordance with GAAP. Delcath’s management believes that the non-GAAP adjusted EBITDA described in this release, which includes adjustments for specific items that are generally not indicative of our core operations, provides additional information that is useful to investors in understanding Delcath’s underlying performance, business and performance trends, and helps facilitate period-to-period comparisons and comparisons of its financial measures with other companies in Delcath’s industry. However, the non-GAAP financial measures that Delcath uses may differ from measures that other companies may use. Non-GAAP financial measures are not required to be uniformly applied, are not audited and should not be considered in isolation or as substitutes for results prepared in accordance with GAAP.

About Delcath Systems, Inc., HEPZATO KIT and CHEMOSAT

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. The company's proprietary products, HEPZATO KIT™ (HEPZATO (melphalan) for Injection/Hepatic Delivery System) and CHEMOSAT® Hepatic Delivery System (HDS) for Melphalan percutaneous hepatic perfusion (PHP), are designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects during a PHP procedure.

In the United States, HEPZATO KIT is considered a combination drug and device product and is regulated and approved for sale as a drug by the FDA. HEPZATO KIT is comprised of the chemotherapeutic drug melphalan and Delcath's proprietary HDS. The HDS is used to isolate the hepatic venous blood from the systemic circulation while simultaneously filtrating hepatic venous blood during melphalan infusion and washout. The use of the HDS results in loco-regional delivery of a relatively high melphalan dose, which can potentially induce a clinically meaningful tumor response with minimal hepatotoxicity and reduce systemic exposure. HEPZATO KIT is approved in the United States as a liver-directed treatment for adult patients with metastatic uveal melanoma (mUM) with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation. Please see the full Prescribing Information, including BOXED WARNING for the HEPZATO KIT.

In Europe, the device-only configuration of the HDS is regulated as a Class III medical device and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used in the conduct of percutaneous hepatic perfusion procedures at major medical centers to treat a wide range of cancers of the liver.

Safe Harbor / Forward-Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf. This press release contains forward-looking statements, including the Company's statements regarding the possible synergy seen in the successful Phase 2 CHOPIN Trial being transferable to clinical practice; Company's 2026 financial outlook, which are subject to certain risks and uncertainties, that can cause actual results to differ materially from those described. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Factors that may cause such differences include, but are not limited to, uncertainties relating to: the Company's commercialization plans and its ability to successfully commercialize the HEPZATO KIT; contributions to adjusted EBITDA; the Company's successful management of the HEPZATO KIT supply chain, including securing adequate supply of critical components necessary to manufacture and assemble the HEPZATO KIT; successful FDA inspections of the facilities of the Company and those of its third-party suppliers/manufacturers; the Company's successful implementation and management of the HEPZATO KIT Risk Evaluation and Mitigation Strategy; the potential benefits of the HEPZATO KIT as a treatment for patients with primary and metastatic disease in the liver; the Company's ability to obtain reimbursement for the HEPZATO KIT; and the Company's ability to successfully enter into any necessary purchase and sale agreements with users of the HEPZATO KIT. For additional information about these factors, and others that may impact the Company, please see the Company's filings with the Securities and Exchange Commission, including those on Forms 10-K, 10-Q, and 8-K. However, new risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. Accordingly, you should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. We undertake no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.

Investor Relations Contact:
ICR Healthcare
investorrelations@delcath.com

DELCATH SYSTEMS, INC.

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands, except share and per share data)

	September 30, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 55,538	$ 43,454
Short-term investments	48,777	47,582
Accounts receivable	20,214	11,744
Inventories	10,501	10,252
Prepaid expenses and other current assets	6,525	6,498
Total current assets	141,555	119,530
Property, plant and equipment, net	5,127	3,166
Right-of-use assets	2,408	936
Total assets	$ 149,090	$ 123,632
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 3,475	$ 2,658
Accrued expenses	9,351	8,191
Lease liabilities, current	196	101
Total current liabilities	13,022	10,950
Lease liabilities, non-current	2,212	835
Other liabilities, non-current	319	628
Total liabilities	$ 15,553	$ 12,413
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; 14,192 and 14,192 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	—	—
Common stock, $0.01 par value; 80,000,000 shares authorized; 34,771,239 shares and 34,691,671 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	348	347
Additional paid-in capital	653,118	639,145
Accumulated deficit	(520,298)	(528,848)
Accumulated other comprehensive income	369	575
Total stockholders' equity	133,537	111,219
Total liabilities and stockholders' equity	$ 149,090	$ 123,632

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Income
(Unaudited)
(in thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Product revenue	$ 35,102	$ 20,563	$ 89,229	$ 64,503
Cost of goods sold	(3,918)	(2,624)	(10,639)	(8,787)
Gross profit	31,184	17,939	78,590	55,716
Operating expenses:				
Research and development expenses	11,011	7,986	31,215	19,875
Selling, general and administrative expenses	13,057	10,341	39,501	32,997
Total operating expenses	24,068	18,327	70,716	52,872
Operating income	7,116	(388)	7,874	2,844
Interest income	852	796	2,420	2,063
Other expense	(1)	(33)	(76)	$ (63)
Income before income taxes	7,967	375	10,218	4,844
Income tax expense (benefit)	1,015	(455)	1,668	248
Net income	6,952	830	8,550	4,596
Other comprehensive income (loss):				
Unrealized gain on investments adjustments	115	296	(135)	592
Foreign currency translation adjustments	(4)	(13)	(71)	201
Total comprehensive income	$ 7,063	$ 1,113	$ 8,344	$ 5,389
Common share data:				
Basic income per common share	$ 0.19	$ 0.02	$ 0.24	$ 0.13
Weighted average number of basic shares outstanding	36,074,348	36,383,277	35,996,019	35,610,619
Diluted income per common share	$ 0.17	$ 0.02	$ 0.21	$ 0.12
Weighted average number of dilutive shares outstanding	41,019,553	40,056,814	40,059,103	39,949,941

DELCATH SYSTEMS, INC.
Reconciliation of Reported Net Income (GAAP) to Adjusted EBITDA (NON-GAAP Measure)
(Unaudited)
(in thousands)

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Net income	$ 6,952	$ 830	$ 8,550	$ 4,596
Stock-based compensation expense	4,233	5,648	14,297	19,720
Depreciation	153	64	368	158
Interest income	(852)	(796)	(2,420)	(2,063)
Income tax expense	1,015	(455)	1,668	248
Adjusted EBITDA (Non-GAAP)	$ 11,501	$ 5,291	$ 22,463	$ 22,659