

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): August 6, 2026

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

Delaware
(State or other jurisdiction of
incorporation or organization)

001-16133
(Commission File Number)

06-1245881
(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 August 6, 2026, Delcath Systems, Inc. (“Delcath”) issued a press release announcing financial results and business highlights for the quarter ended June 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 August 6, 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: August 6, 2026

By: /s/ Sandra Pennell

Name: Sandra Pennell

Title: Chief Financial Officer

Delcath Systems Reports Second Quarter 2026 Results and Business Highlights

*Increases 2026 Revenue Guidance to a Range of \$104M to \$108M
Conference Call Today at 8:30 a.m. Eastern Time*

QUEENSBURY, NY – August 6, 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 second quarter ended June 30, 2026.

Second Quarter 2026 Financial Results

- Total revenue of \$29.1 million, compared with \$24.2 million in the second quarter of 2025
 - HEPZATO KIT™ revenue of \$27.1 million, compared to \$22.5 million in the second quarter of 2025
 - CHEMOSAT® revenue of \$2.0 million, compared to \$1.7 million in the second quarter of 2025
- Gross margins of 90%, compared to 86% in the second quarter of 2025
- Net income of \$2.7 million for both second quarters in 2026 and 2025
- Non-GAAP adjusted EBITDA of \$7.6 million, compared to \$9.8 million in the second quarter of 2025
- Cash provided by operations of \$5.7 million in the quarter; compared to \$7.3 million in the second quarter of 2025
- Cash and investments of \$95.9 million as of June 30, 2026

Business Highlights

- Currently 31 active treatment centers
- Approximately 30% growth in HEPZATO volume in the second quarter 2026 compared to the second quarter 2025
- Independent investigators presented retrospective data at ESMO Breast Cancer 2026 showing a 60% hepatic partial response rate with percutaneous hepatic perfusion in heavily pretreated patients with liver-dominant metastatic breast cancer
- Independent investigators presented two investigator-initiated Trials-in-Progress abstracts at ASCO 2026: one evaluating sequential HEPZATO followed by tebentafusp in metastatic uveal melanoma, and one evaluating HEPZATO in combination with nivolumab/relatlimab in metastatic cutaneous melanoma with liver metastases
- Dosed the first patient in the global Phase 2 trial of HEPZATO in combination with standard of care in patients with liver-dominant HER2-negative metastatic breast cancer

“Our strong second quarter, including total revenue of \$29.1 million and quarterly operating cash flow of \$5.7 million, reflects continued momentum in HEPZATO procedures,” said Gerard Michel, Chief Executive Officer of Delcath Systems. “As we grow our active treatment center network and drive physician adoption, we are seeing increased usage of HEPZATO in combination with systemic therapies to treat metastatic uveal melanoma. The growing clinical experience with this treatment strategy is strengthening physician confidence in HEPZATO and supporting its development as a multi-indication, liver-directed therapy platform, including colorectal and breast cancer.”

2026 Full Year Financial Guidance

The Company's financial outlook for fiscal year 2026:

- Total HEPZATO KIT and CHEMOSAT revenue to range from \$104 million to \$108 million, reflecting an increase in HEPZATO KIT volume of at least 28% over 2025
- Full year gross margins in the range of 86% to 89%
- Positive adjusted EBITDA

Second Quarter 2026 Results

Total revenue for the quarter ending June 30, 2026 was \$29.1 million compared to \$24.2 million for the same period in the prior year. Revenue in the quarter includes sales of \$27.1 million of HEPZATO in the U.S. and \$2.0 million of CHEMOSAT in Europe.

Research and development expenses for the quarter ending June 30, 2026, were \$10.4 million compared to \$6.9 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 June 30, 2026, were \$13.4 million compared to \$11.4 million for the same period in the prior year. The increase is primarily due to continued commercial expansion activities.

Net income was \$2.7 million for both the quarters ended June 30, 2026 and June 30, 2025.

Non-GAAP adjusted EBITDA for the quarter ended June 30, 2026 was \$7.6 million compared to adjusted EBITDA of \$9.8 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 June 30, 2026, the Company had \$95.9 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: Thursday, August 6, 2026

Time: 8:30 AM Eastern Time

Participant Numbers:

Toll Free: 1-800-717-1738

International: 1-646-307-1865

Webcast: https://viaid.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 filtering 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)

	June 30, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	\$ 47,521	\$ 43,454
Short-term investments	48,381	47,582
Accounts receivable	15,942	11,744
Inventories	11,713	10,252
Prepaid expenses and other current assets	6,979	6,498
Total current assets	130,536	119,530
Property, plant and equipment, net	4,019	3,166
Right-of-use assets	2,463	936
Total assets	<u>\$ 137,018</u>	<u>\$ 123,632</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 4,011	\$ 2,658
Accrued expenses	9,072	8,191
Lease liabilities, current	196	101
Total current liabilities	13,279	10,950
Lease liabilities, non-current	2,267	835
Other liabilities, non-current	327	628
Total liabilities	<u>\$ 15,873</u>	<u>\$ 12,413</u>
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 June 30, 2026 and December 31, 2025, respectively	—	—
Common stock, \$0.01 par value; 80,000,000 shares authorized; 34,636,252 shares and 34,691,671 shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively	346	347
Additional paid-in capital	647,791	639,145
Accumulated deficit	(527,250)	(528,848)
Accumulated other comprehensive income	258	575
Total stockholders' equity	121,145	111,219
Total liabilities and stockholders' equity	<u>\$ 137,018</u>	<u>\$ 123,632</u>

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

	Three months ended June 30,		Six months ended June 30,	
	2026	2025	2026	2025
Product revenue	\$ 29,133	\$ 24,156	\$ 54,127	\$ 43,940
Cost of goods sold	(2,985)	(3,318)	(6,721)	(6,163)
Gross profit	26,148	20,838	47,406	37,777
Operating expenses:				
Research and development expenses	10,380	6,882	20,204	11,889
Selling, general and administrative expenses	13,373	11,366	26,444	22,656
Total operating expenses	23,753	18,248	46,648	34,545
Operating income	2,395	2,590	758	3,232
Interest income	781	649	1,568	1,267
Other expense	(17)	(34)	(75)	\$ (30)
Income before income taxes	3,159	3,205	2,251	4,469
Income tax expense	491	508	653	703
Net income	2,668	2,697	1,598	3,766
Other comprehensive income:				
Unrealized gain on investments adjustments	(295)	57	(250)	296
Foreign currency translation adjustments	(18)	154	(67)	214
Total comprehensive income	\$ 2,355	\$ 2,908	\$ 1,281	\$ 4,276
Common share data:				
Basic income per common share	\$ 0.07	\$ 0.08	\$ 0.04	\$ 0.11
Weighted average number of basic shares outstanding	35,891,915	35,786,813	35,956,205	35,217,887
Diluted income per common share	\$ 0.07	\$ 0.07	\$ 0.04	\$ 0.09
Weighted average number of dilutive shares outstanding	39,761,480	40,262,764	39,584,329	39,890,102

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

	Three months ended June 30,		Six months ended June 30,	
	2026	2025	2026	2025
Net income	\$ 2,668	\$ 2,697	\$ 1,598	\$ 3,766
Stock-based compensation expense	5,118	7,209	10,064	14,072
Depreciation	113	51	215	94
Interest income	(781)	(649)	(1,568)	(1,267)
Income tax expense	491	508	653	703
Adjusted EBITDA (Non-GAAP)	\$ 7,609	\$ 9,816	\$ 10,962	\$ 17,368