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, 2021

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

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

1633 Broadway, Suite 22C, New York, New York 10019
(Address of principal executive offices) (Zip Code)

(212) 489-2100
(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, 2021, Delcath Systems, Inc. (the "Company") issued a press release, furnished as Exhibit 99.1 and incorporated in this Item 2.02 by reference, announcing its financial results for the fiscal quarter ended September 30, 2021.

The information contained in this Item 2.02, 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, or otherwise subject to the liabilities of Section 18. Furthermore, the information contained in this Item 2.02, including Exhibit 99.1, shall not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1	Press Release of the Company, dated November 9, 2021, announcing financial results for the fiscal quarter ended September 30, 2021.
104	Cover Page Interactive File (the cover page tags 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 thereunto duly authorized.

DELCATH SYSTEMS, INC.

Date: November 10, 2021

By: /s/ Gerard Michel
Name: Gerard Michel
Title: Chief Executive Officer

Delcath Systems Announces Third Quarter 2021 Results

November 9, 2021

NEW YORK, Nov. 09, 2021 (GLOBE NEWSWIRE) — Delcath Systems, Inc. (Nasdaq: **DCTH**), an interventional oncology company focused on the treatment of rare primary and metastatic cancers of the liver, today reported business highlights and financial results for the third quarter ended September 30, 2021.

Recent Business Highlights

During and since the third quarter Delcath:

- Entered a debt facility with Avenue Venture Opportunities Fund, L.P. providing up to $20 million with an initial $15 million funded at closing,
- Submitted to and received approval from the FDA for an expanded access protocol for the use of HEPZATOTM Kit (melphalan hydrochloride for injection/hepatic delivery system) in the treatment of patients with liver dominant metastatic ocular melanoma,
- Updated guidance of the Class 2 resubmission of the NDA to mid-year from the end of the first quarter,
- Hired 3 senior executives in clinical operations, regulatory and medical affairs to support the resubmission of the NDA and further clinical development of HEPZATO, and

Announced it will host a comprehensive Investor Update event on Thursday, December 2nd, from 10:00am ET – 1:00pm ET covering FOCUS trial results as well as development plans for the use of HEPZATO in the treatment of patients with intrahepatic cholangiocarcinoma and colorectal cancer.

In addition, during the third quarter independent investigators:

- Presented three abstracts on the use of Chemosat® Hepatic Delivery System with Melphalan in the treatment of metastatic ocular melanoma (mOM) at the 2021 Cardiovascular and Interventional Radiological Society of Europe conference (CIRSE) including,
  - *Safety and toxicity of combining hepatic percutaneous perfusion with ipilimumab plus nivolumab in advanced uveal melanoma: phase 1b of the CHOPIN Trial*[1]
  - *Long-term results of percutaneous hepatic perfusion with melphalan in patients with unresectable liver metastases from uveal melanoma: a multicenter retrospective study*[2]
  - *Safety and efficacy of chemosaturation with percutaneous hepatic perfusion of melphalan for metastatic uveal melanoma: an 8-year retrospective study of 250 interventions in 81 patients*[3]
- Published *Repeated percutaneous hepatic perfusion with melphalan can maintain long-term response in patients with liver cancers*[4] in the journal Cardiovascular and Interventional Radiology.

“It’s very exciting to see the initial results of the CHOPIN Trial. These early results in the first trial to combine percutaneous hepatic perfusion with combination immunotherapy show promise with no dose limiting toxicities observed to date. The significant disease control and repeatability of the procedure with limited cumulative toxicity observed in these recent publications is consistent with what we have seen documented from other institutions,” said Dr. Johnny John, SVP Clinical Operations and Medical Affairs.

“During the quarter we strengthened our balance sheet and added senior personnel to the Delcath team,” said Gerard Michel, CEO of Delcath. “With the additional capital and senior leadership, Delcath has the required resources to accomplish its strategic priorities – the filing of the HEPZATO NDA in mid-2022, preparing for the subsequent US launch when approved, and expanding the development of HEPZATO into additional areas of high unmet need.”

Financial Results:

Income Statement Highlights.

Product revenue for the three months ended September 30, 2021 was approximately $522 thousand, compared to $466 thousand for the prior year period from our sales of CHEMOSAT procedures in Europe. Selling, general and administrative expenses were approximately $4.0 million compared to $2.0 million in the prior year quarter. Research and development expenses for the quarter were $3.0 million compared to $3.3 million in the prior year quarter. Total operating expenses for the quarter were $7.0 million compared with $5.3 million in the prior year quarter. Expenses for the quarter included approximately $2.5 million of stock option expense compared to no stock option expense in the prior year quarter.

The Company recorded a net loss for the three months ended September 30, 2021, of $7.1 million, compared to a net loss of $5.0 million for the same period in 2020.

Balance Sheet Highlights.

On September 30, 2021, we had cash, cash equivalents and restricted cash totaling $29 million, as compared to cash, cash equivalents and restricted cash totaling $11.1 million at September 30, 2020. During the three months ended September 30, 2021 and September 30, 2020, we used $16.2 million and $17.8 million, respectively, of cash in our operating activities.

On August 6, 2021 we closed a $20 million venture debt financing transaction with Avenue Venture Opportunities Fund, L.P. (“Avenue Venture Fund”), at which time an initial $15 million tranche of the loan was funded, including $4 million funded into a restricted account to be released upon achievement of certain milestones. The Company may request an additional $5 million tranche of the loan between October 1, 2022 and December 31, 2022, the funding of which will be at Avenue Venture Fund’s discretion.

Also, on August 6, 2021, we amended two existing convertible notes through an extension of the term of the notes until 2024 and lowered the conversion factor in consideration for the notes becoming subordinate to the Avenue Venture Fund debt.

Additional details concerning the Avenue Venture Fund facility and modification of the existing convertible notes are contained in the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 11, 2021.

Conference Call Information

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

Date: November 9, 2021
Time: 8:30 AM Eastern Time
Toll Free: 888-506-0062; Entry Code: 676028
International: 973-528-0011; Entry Code: 676028

The call will also be available over the Internet and accessible at:

https://www.webcaster4.com/Webcast/Page/2475/43392

About Delcath Systems, Inc.

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. The Company’s proprietary percutaneous hepatic perfusion (PHP) system is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In the United States, the PHP system is being developed under the tradename HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO, and is considered a combination drug and device product regulated by the United States Food and Drug Administration (FDA).

In Europe, the PHP system is regulated as a Class IIb medical device and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used 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 news release contains forward-looking statements, which are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to, uncertainties relating to: the timing and results of the Company’s clinical trials, including without limitation the mOM and ICC clinical trial programs, as well as the receipt of additional data and the performance of additional analyses with respect to the mOM clinical trial, our determination whether to continue the ICC clinical trial program or to focus on other alternative indications, and timely monitoring and treatment of patients in the global Phase 3 mOM clinical trial and the impact of the COVID-19 pandemic on the completion of our clinical trials; the impact of the presentations at major medical conferences and future clinical results consistent with the data presented; approval of Individual Funding Requests for reimbursement of the CHEMOSAT procedure; the impact, if any, of ZE reimbursement on potential CHEMOSAT product use and sales in Germany; clinical adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in Europe including the key markets of Germany and the UK; the Company’s ability to successfully commercialize the HEPZATO KIT/CHEMOSAT system and the potential of the HEPZATO KIT/CHEMOSAT system as a treatment for patients with primary and metastatic disease in the liver; our ability to obtain reimbursement for the CHEMOSAT system in various markets; approval of the current or future HEPZATO KIT/CHEMOSAT system for delivery and filtration of melphalan or other chemotherapeutic agents for various indications in the U.S. and/or in foreign markets; actions by the FDA or foreign regulatory agencies; the Company’s ability to successfully enter into strategic partnership and distribution arrangements in foreign markets and the timing and revenue, if any, of the same; uncertainties relating to the timing and results of research and development projects; and uncertainties regarding the Company’s ability to obtain financial and other resources for any research, development, clinical trials and commercialization activities. These factors, and others, are discussed from time to time in our filings with the Securities and Exchange Commission. 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.

1. Tong T, Burgmans M, van der Kooij M, Speetjens F, van Erkel A, Van der Meer R, van Rijswijk C, van den Bosch S, Jonker M, Roozen I, Lutjeboer J, Rijksen F, van Persijn van Meerten E, Martini C, Zoethout R, Tijl F, Blank C, Kapiteijn E.

Safety and Toxicity of Combining Hepatic Percutaneous Perfusion with Ipilimumab plus Nivolumab in advanced Uveal Melanoma: phase 1b of the CHOPIN Trial. In: Cardiovascular and Interventional Radiological Society of Europe (CIRSE) Summit 2021 Abstract Book; 25-27 September 2021; Online. FP-96:s95.

2. Samim M, Tong T, Kapiteijn E, Meijer TS, Speetjens F, Brüning R, Schroeder H, El-Sanosy S, Maschke H, Wacker F, Vogel A, Dewald C, Goeman J, Burgmans M. Long-term results of percutaneous hepatic perfusion with melphalan in patients with unresectable liver metastases from uveal melanoma: a multicenter retrospective study. In: Cardiovascular and Interventional Radiological Society of Europe (CIRSE) Summit 2021 Abstract Book; 25-27 September 2021; Online. FP-97:s96.

3. Gibson T, Vigneswaran G, Patel S, Gupta S, Karydis I, Wheater M, Stedman B, Modi S. Safety and efficacy of chemosaturation with percutaneous hepatic perfusion of melphalan for metastatic uveal melanoma: an 8-year retrospective study of 250 interventions in 81 patients. In: Cardiovascular and Interventional Radiological Society of Europe (CIRSE) Summit 2021 Abstract Book; 25-27 September 2021; Online. FP-132:s106-s107.

4. Veelken R, Maiwald B, Strocka S, Petersen TO, Moche M, Ebel S, Denecke T, Rehak M, Struck MF, Forstmeyer D, Rademacher S, Seehofer D, Berg T, van Bömmel F. Repeated percutaneous hepatic perfusion with melphalan can maintain long-term response in patients with liver cancers. Cardiovasc Intervent Radiol. 2021 Oct 29. doi: 10.1007/s00270-021-02983-2. Epub ahead of print.

Contact:

Delcath Investor Relations

Email: **investorrelations@delcath.com**

Hayden IR

James Carbonara
(646)-755-7412
james@haydenir.com

DELCATH SYSTEMS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share data)

	September 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 24,865	$ 28,575
Restricted cash	4,151	181
Accounts receivable, net	69	57
Inventories	1,238	855
Prepaid expenses and other current assets	1,995	2,670
Total current assets	32,318	32,338
Property, plant and equipment, net	1,380	1,351
Right-of-use assets	727	946
Total assets	$ 34,425	$ 34,635
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,187	$ 1,774
Accrued expenses	3,269	4,859
Deferred revenue, current	496	525
Lease liabilities, current	409	495
Loan payable, current	—	382
Convertible notes payable, current	—	2,000
Total current liabilities	5,361	10,035
Deferred revenue, non-current	1,584	2,072
Lease liabilities, non-current	318	450
Loan payable, non-current	10,834	—
Convertible notes payable, non-current	4,602	—
Total liabilities	22,699	12,557
Commitments and contingencies (Note 11)	—	—
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 11,707 and 20,631 shares issued and outstanding at September 30, 2021, and December 31, 2020, respectively	—	—
Common stock, $.01 par value; 40,000,000 shares authorized; 7,356,289 and 5,996,101 shares issued and outstanding at September 30, 2021, and December 31, 2020, respectively	74	60
Additional paid-in capital	427,301	417,449
Accumulated deficit	(415,629)	(395,327)
Accumulated other comprehensive loss	(20)	(104)
Total stockholders' equity	11,726	22,078
Total liabilities and stockholders' equity	$ 34,425	$ 34,635

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Product revenue	$ 395	$ 340	$ 1,054	$ 778
Other revenue	127	126	393	361
Cost of goods sold	(227)	(188)	(541)	(434)
Gross profit	295	278	906	705
Operating expenses:				
Research and development expenses	2,955	3,260	10,159	8,457
Selling, general and administrative expenses	4,036	1,998	10,621	6,571
Total operating expenses	6,991	5,258	20,780	15,028
Operating loss	(6,696)	(4,980)	(19,874)	(14,323)
Change in fair value of the warrant liability, net	—	—	—	(2,832)
Interest expense, net	(420)	(44)	(501)	(132)
Other income (loss)	(9)	33	73	160
Net loss	(7,125)	(4,991)	(20,302)	(17,127)
Deemed dividend for triggering of warrant down round feature	—	—	—	(55)
Net loss attributable to common stockholders	$ (7,125)	$ (4,991)	$ (20,302)	$ (17,182)
Net loss	$ (7,125)	$ (4,991)	$ (20,302)	$ (17,127)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	51	(103)	84	(39)
Total other comprehensive loss	$ (7,074)	$ (5,094)	$ (20,218)	$ (17,166)
Common share data:				
Basic loss per common share	$ (0.94)	$ (1.16)	$ (2.93)	$ (7.75)
Diluted loss per common share	$ (0.94)	$ (1.16)	$ (2.93)	$ (7.75)
Weighted average number of basic shares outstanding	7,587,643	4,288,593	6,923,541	2,217,611
Weighted average number of diluted shares outstanding	7,587,643	4,288,593	6,923,541	2,217,611

Source: Delcath Systems, Inc.