# 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): March 31, 2021**

# 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.)** |

**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 March 31, 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 and fiscal year ended December 31, 2020.

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 8.01 Other Events.**

On March 31, 2021, the Company issued a press release announcing positive preliminary results from its Phase 3 FOCUS Trial of HEPZATO in patients with metastatic ocular melanoma. On the same date, the Company issued an additional press release announcing additional information regarding the power calculation for the Phase 3 FOCUS Trial. The full text of these press releases are attached as Exhibits 99.2 and 99.3, respectively, and incorporated in this Item 8.01 by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of the Company, dated March 31, 2021, announcing financial results for the fiscal quarter and fiscal year ended December 31, 2020 |
| 99.2 | Press Release of the Company, dated March 31, 2021, announcing positive preliminary results from its Phase 3 FOCUS Trial |
| 99.3 | Press Release of the Company, dated March 31, 2021, announcing additional information regarding FOCUS Trial power calculation |
| 104 | Cover Page Interactive File (the cover page tags are 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: April 1, 2021

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

**Delcath Systems, Inc. Announces Fourth Quarter 2020 Results, Highlights Preliminary Positive FOCUS Trial Results; Conference Call Today at 8:00am Eastern Time**

March 31, 2021

NEW YORK, March 31, 2021 (GLOBE NEWSWIRE) — Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today reported business highlights and financial results for the fourth quarter ended December 31, 2020, and earlier today reported preliminary topline data. The company will host its quarterly call at 8:00am ET today, with a primary focus on discussing the preliminary top line data.

**Recent Business Highlights**

*During and since the fourth quarter of 2020, the company:*

- Reported positive preliminary results from the FOCUS Clinical Trial (NCT02678572) for Patients with Hepatic Dominant Ocular Melanoma treated with HEPZATO based on an analysis of currently evaluable patients. The preliminary analysis included 87% of treated patients and final results are expected later in the year. The primary endpoint, overall response rate (ORR), as determined by an independent review committee, exceeded the prespecified threshold for success. Additionally, both prespecified ORR and Progression Free Survival comparative analyses against the best alternative care arm demonstrated a statistically significant improvement. The safety profile was consistent with the safety profile of CHEMOSAT treatment described in previous European single-center and multi-center publications with no new safety signals observed in this patient population.
- Initiated a consulting engagement to select a portfolio of follow-on indications which will maximize the value of the HEPZATO Kit and CHEMOSAT platform.
- Completed an underwritten public offering of common stock at a price of $13.25 per share yielding $22.2 million in gross proceeds.
- Strengthened the executive team with the appointment of Gerard Michel as Chief Executive Officer and Kevin Muir as Vice President of Commercial Operations.

“The fourth quarter marked the start of a critical transformation for Delcath,” said Gerard Michel, CEO of Delcath. “Since October, we have attracted new investors, strengthened the management team and, most importantly, released preliminary results from the FOCUS trial which, as of this compilation, suggests a significant improvement in the benefit risk ratio versus an earlier generation of Delcath’s proprietary percutaneous hepatic perfusion system. We look forward to continued progress in 2021, as we prepare both to file an NDA in early 2022 and expand the development of HEPZATO into additional areas of high unmet need.”

**Fourth Quarter 2020 Financial Results:**

*Income Statement Highlights.*

Product revenue for the three months ended December 31, 2020 was approximately $379 thousand, compared to $398 thousand for the prior year period from our sales of CHEMOSAT procedures in Europe. Selling, general and administrative expenses were approximately $4.5 million compared to $2.1 million in the prior year quarter. Research and development expenses for the quarter were $2.7 million compared to $2.7 million in the prior year quarter. Total operating expenses for the quarter were $7.3 million compared with $4.8 million in the prior year quarter.

We recorded a net loss for the three months ended December 31, 2020, of $7.0 million, compared to a net income of $12.5 million for the same period in 2019.

*Balance Sheet Highlights.*

At December 31, 2020, we had cash, cash equivalents and restricted cash totaling $28.8 million, as compared to cash, cash equivalents and restricted cash totaling $10.2 million at December 31, 2019. During the three months ended December 31, 2020 and December 31, 2019, we used $4.6 million and $5.4 million, respectively, of cash in our operating activities.

*Conference Call Information*

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

Date: March 31, 2021
Time: 8:00 AM Eastern Time
Toll Free: 877-407-8035
International: 201-689-8035

The call will also be available over the Internet and accessible at: **https://www.webcaster4.com/Webcast/Page/2475/40544**

**About Delcath Systems, Inc.**

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our investigational product – HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system) – is designed to administer high-dose chemotherapy to the liver while minimizing systemic exposure and associated side effects. In addition to the FOCUS Trial which is investigating the treatment of mOM, we have initiated a global Phase 3 clinical trial for intrahepatic cholangiocarcinoma (ICC) called the ALIGN Trial. We have paused our work on the ALIGN Trial while we reevaluate the trial design. HEPZATO KIT has not been approved by the U.S. Food & Drug Administration (FDA) for sale in the U.S. In Europe, our system is marketed under the trade name Delcath CHEMOSAT® Hepatic Delivery System for Melphalan (CHEMOSAT) and has been CE Marked and used at major medical centers to treat a wide range of cancers of the liver. CHEMOSAT is being marketed under an exclusive licensing agreement with medac GmbH, a privately held multi-national pharmaceutical company headquartered in Germany that specializes in the treatment and diagnosis of oncological, urological and autoimmune diseases.

**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.

**Contact:**

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*Hayden IR*

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**DELCATH SYSTEMS, INC.**

**Consolidated Balance Sheet**

*(in thousands, except share and per share data)*

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 28,575 | $ 10,002 |
| Restricted cash | 181 | 181 |
| Accounts receivables, net | 57 | 21 |
| Inventories | 855 | 654 |
| Prepaid expenses and other current assets | 2,670 | 1,759 |
| Total current assets | 32,338 | 12,617 |
| Property, plant and equipment, net | 1,351 | 735 |
| Right-of-use assets | 946 | 860 |
| Total assets | $ 34,635 | $ 14,212 |
| **Liabilities and Stockholders' Equity (Deficit)** | | |
| Current liabilities | | |
| Accounts payable | $ 1,774 | $ 4,533 |
| Accrued expenses | 5,241 | 6,947 |
| Deferred revenue, current | 525 | 482 |
| Lease liabilities, current | 495 | 664 |
| Convertible notes payable, current | 2,000 | — |
| Warrant liability | — | 3,368 |
| Total current liabilities | 10,035 | 15,994 |
| Deferred revenue, non-current | 2,072 | 2,378 |
| Lease liabilities, non-current | 450 | 197 |
| Convertible notes payable, non-current | — | 2,000 |
| Total liabilities | 12,557 | 20,569 |
| Commitments and contingencies (Note 13) | | |
| Stockholders' Equity (Deficit) | | |
| Preferred stock, $.01 par value; 10,000,000 shares authorized; 20,631 and 41,517 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively | — | — |
| Common stock, $.01 par value; 40,000,000 and 1,000,000,000 shares authorized; 5,996,101 and 67,091 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively* | 60 | 1 |
| Additional paid-in capital | 417,449 | 364,785 |
| Accumulated deficit | (395,327) | (371,171) |
| Accumulated other comprehensive (loss) income | (104) | 28 |
| Total stockholders' equity (deficit) | 22,078 | (6,357) |
| Total liabilities and stockholders' equity (deficit) | $ 34,635 | $ 14,212 |

* reflects, a one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

**DELCATH SYSTEMS, INC.**

**Consolidated Statements of Operations and Comprehensive Loss**

*(in thousands, except share and per share data)*

| | Year ended December 31, 2020 | 2019 |
|---|---|---|
| Product revenue | $ 1,156 | $ 1,101 |
| Other revenue | 490 | 479 |
| Cost of goods sold | (640) | (719) |
| Gross profit | 1,006 | 861 |
| Operating expenses: | | |
| Research and development expenses | 11,201 | 9,490 |
| Selling, general and administrative expenses | 11,108 | 11,279 |
| Total operating expenses | 22,309 | 20,769 |
| Operating loss | (21,303) | (19,908) |
| Change in fair value of the warrant liability, net | (2,832) | 17,493 |
| Loss on issuance of financial instrument | — | (1,720) |
| Interest expense | (175) | (4,746) |
| Other income | 154 | 2 |
| Net loss | (24,156) | (8,879) |
| Deemed dividend for triggering of warrant down round feature | (55) | — |
| Net loss attributable to common stockholders | $ (24,211) | $ (8,879) |
| Net loss | $ (24,156) | $ (8,879) |
| Other comprehensive (loss) income: | | |
| Foreign currency translation adjustments | (132) | $ (22) |
| Total other comprehensive loss | $ (24,288) | $ (8,901) |
| Common share data: | | |
| Basic loss per common share* | $ (8.35) | $(342.83) |
| Diluted loss per common share* | $ (8.35) | $(342.83) |
| Weighted average number of basic shares outstanding* | 2,897,827 | 25,900 |
| Weighted average number of diluted shares outstanding* | 2,897,827 | 25,900 |

* reflects, one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

Source: Delcath Systems, Inc.

**Delcath Systems, Inc. Announces Positive Preliminary Results from Phase 3 FOCUS Trial of HEPZATO in Patients with Metastatic Ocular Melanoma**

March 31, 2021

Based on Preliminary Data, FOCUS Trial Achieves Prespecified Success Threshold

*Conference Call Today at 8:00am Eastern Time*

NEW YORK, March 31, 2021 (GLOBE NEWSWIRE) — Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today announced positive top-line preliminary results from the company's Phase 3 FOCUS trial of HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system) in patients with liver dominant metastatic ocular melanoma (mOM).

- Based on the preliminary analysis of 87% of enrolled patients using prespecified analyses the Independent Review Committee (IRC) assessed Overall Response Rate (ORR) of 29.2% [95% Confidence Interval (CI): 20.1, 39.8] in the Intent to Treat (ITT) population which exceeded the predefined success criteria (21.0%) for the primary ORR endpoint.
- Based on predefined exploratory analyses, evaluable patients in the HEPZATO arm had a statistically significant improvement over Best Alternative Care (BAC) in the following prespecified endpoints:
- ORR of 32.9% [95% CI: 22.8, 44.4] versus 13.8% [95% CI: 3.9, 31.7] for the BAC arm (Chi-square P<0.05).
- Median Progression Free Survival of 9.0 months [95% CI: 6.2,11.8] versus 3.1 months [95% CI: 2.7, 5.7] for the BAC arm (HR=0.41; p<0.001).

Disease Control Rate of 70.9% [95% CI: 59.6, 80.6] versus 37.9% [95% CI: 20.7, 57.7] for patients in the BAC arm (p<0.002).

Duration of Response and Overall Survival are not yet evaluable. Since not all patients were evaluable for all time points, these preliminary analyses may change as data matures.

The safety profile in this trial was consistent with the safety profile of PHP treatment described in European single-center and multi-center publications with no new safety signals observed in this patient population. In the HEPZATO safety population of 94 patients, 38 patients (40.4%) experienced a treatment-emergent serious adverse event. The most commonly reported treatment-emergent serious adverse events were thrombocytopenia (14.9% of patients), neutropenia (10.6% of patients), and leukopenia (4.2% of patients), which were well-manageable. 5% of patients experienced treatment-emergent serious cardiac adverse events. In all cases the events resolved with no ongoing complications. There were no treatment-related deaths in the trial.

"Metastatic ocular melanoma is a disease with a dismal prognosis and new therapies are urgently needed," noted Dr. Jonathan Zager MD FACS, lead investigator of the FOCUS study, senior member and Director of Regional Therapies at Moffitt Cancer Center. "The strength of these preliminary efficacy data, including progression free survival and overall response rates, coupled with an improved safety profile versus the first-generation product, suggests that HEPZATO would offer a compelling clinical benefit were it approved by FDA."

"While the analysis is preliminary and the trial is still ongoing, these results strongly suggest that the final FOCUS dataset will demonstrate a significantly improved benefit-risk profile compared with BAC that could form the basis of our NDA resubmission to the FDA," said Gerard Michel, CEO of Delcath. "We look forward to reporting additional results later in the year as the data matures."

**About the FOCUS Trial and the Preliminary Analysis**

These preliminary results are based on a data cut on March 12, 2021 and include 79 treated HEPZATO patients for whom there are at least 2 imaging timepoints from which to evaluate response or were censored after the first scan due to progression or death. 11 additional patients were treated but are not yet evaluable in the HEPZATO arm. Another 11 patients were enrolled in the HEPZATO arm and not treated. 29 of 32 treated BAC patients were available for analysis. 10 patients were enrolled in the BAC arm and not treated. Data are expected to continue to evolve as additional patients and time points become evaluable.

The FOCUS trial is intended to evaluate the efficacy of HEPZATO treatment for patients with mOM with the primary endpoint of ORR as assessed by an IRC per RECIST v1.1. Per protocol, patients were to be treated every 6 weeks to 8 weeks until the earlier of 6 cycles or progression. Tumor responses were to be assessed every 12 weeks (+/- 2 weeks) until progression.

The single arm trial was powered to demonstrate a superior ORR versus checkpoint inhibitors, one of the few mOM treatment categories with a significant amount of peer reviewed publications. The checkpoint inhibitor ORR was calculated based on a meta-analysis covering 16 different publications and 476 patients. Based on those assumptions a 21.0% ORR was required to demonstrate superiority over the checkpoint inhibitors at a 95% confidence interval.

The single arm trial was initially designed and conducted as a randomized controlled study with a BAC comparator arm before being amended to a single arm trial. While the modified trial was not powered to test superiority versus BAC, comparative analyses against the BAC arm were included in the revised statistical analysis plan

**Conference Call Information**

Dr. Jonathan Zager MD FACS, lead investigator of the FOCUS study, senior member and Director of Regional Therapies at Moffitt Cancer Center will join the Delcath management team during today's conference call.

Date: March 31, 2021
Time: 8:00 AM Eastern Time
Toll Free: 877-407-8035
International: 201-689-8035

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

**https://www.webcaster4.com/Webcast/Page/2475/40544 About HEPZATOTM KIT and CHEMOSAT®**

The HEPZATOTM KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZAT O TM , is a drug/device combination product HEPZATO is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, our commercial product is a stand-alone 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. In the United States, HEPZATO is considered a combination drug and device product regulated by the United States Food and Drug Administration, or the FDA. Primary jurisdiction for regulation of HEPZATO has been assigned to the FDA's Center for Drug Evaluation and Research. The FDA has granted Delcath six orphan drug designations (five for melphalan in ocular melanoma, cutaneous melanoma, cholangiocarcinoma, hepatocellular carcinoma, and neuroendocrine tumor indications and one for doxorubicin in the hepatocellular carcinoma indication). HEPZATO has not been approved for sale in the United States.

In Europe, CHEMOSAT is regulated as a Class IIb medical device and received its CE Mark in 2012. We are commercializing CHEMOSAT in select markets in the United Kingdom and the European Union, or EU, where we believe the prospect of securing reimbursement coverage for the use of CHEMOSAT is strongest.

**About Metastatic Ocular Melanoma**

Approximately 5,000-6,200 cases of ocular melanoma are diagnosed in the United States and Europe annually, and approximately 50% of these patients will develop metastatic disease. Of metastatic cases of ocular melanoma, approximately 90% of patients develop liver involvement. According to Lane et al., *JAMA Ophthalmol*. 2018 Sep 1;136(9):981-98, once ocular melanoma has spread to the liver, median overall survival for these patients is generally 3.9 months (untreated) to 6.3 months (treated). There is no one standard of care for patients with ocular melanoma liver metastases. Based on 2018 research, an estimated 2,500-3,100 patients with ocular melanoma liver metastases in the United States, the United Kingdom and the EU may be eligible for treatment with HEPZATO annually.

**About Delcath Systems, Inc.**

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**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.

**Contact:**

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*Hayden IR*

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Source: Delcath Systems, Inc.

**Delcath Systems, Inc. Shares Additional Information Regarding FOCUS Trial Power Calculation**

March 31, 2021

**20.1% Lower Bound of Preliminary ORR Analysis Exceeds Required 8.3% Threshold**

NEW YORK, March 31, 2021 (GLOBE NEWSWIRE) — Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today provided additional information regarding the power calculation for the Phase 3 FOCUS trial of HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system) in patients with liver dominant metastatic ocular melanoma (mOM).

In the summer of 2018, the Company amended the protocol for the FOCUS trial to a single arm design. In consultation with FDA, the FOCUS single arm trial was powered to demonstrate a superior Overall Response Rate (ORR) versus checkpoint inhibitors, one of the few mOM treatment categories with a significant amount of peer reviewed publications.

A point estimate of 21.0% ORR was calculated as the requirement to demonstrate superiority over the checkpoint inhibitors given the planned trial size and this threshold was shared with investors. The checkpoint inhibitor ORR was calculated based on a meta-analysis covering 16 different publications and 476 patients. The pooled overall response rate was 5.5% with a 95% Confidence Interval of 3.6%—8.3%. To achieve statistical significance at a 95% Confidence Interval the lower bound of the ORR for HEPZATO needs to exceed the 8.3% upper bound of the meta-analysis. A preliminary analysis of 87% of enrolled patients analyses by the Independent Review Committee yielded an ORR of 29.2% [95% CI: 20.1, 39.8] in the Intent to Treat population, which substantially exceeds the 21.0%-point-estimate requirement. For further clarity, since the 20.1% lower bound exceeds the 8.3% upper bound of the meta-analysis the predefined success threshold was met. Further detail is available on the events and presentations section of the company website.

**About Delcath Systems, Inc.**

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our investigational product – HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system) – is designed to administer high-dose chemotherapy to the liver while minimizing systemic exposure and associated side effects. In addition to the FOCUS Trial which is investigating the treatment of mOM, we have initiated a global Phase 3 clinical trial for intrahepatic cholangiocarcinoma (ICC) called the ALIGN Trial. We have paused our work on the ALIGN Trial while we reevaluate the trial design. HEPZATO KIT has not been approved by the U.S. Food & Drug Administration (FDA) for sale in the U.S. In Europe, our system is marketed under the trade name Delcath CHEMOSAT® Hepatic Delivery System for Melphalan (CHEMOSAT) and has been CE Marked and used at major medical centers to treat a wide range of cancers of the liver. CHEMOSAT is being marketed under an exclusive licensing agreement with medac GmbH, a privately held multi-national pharmaceutical company headquartered in Germany that specializes in the treatment and diagnosis of oncological, urological and autoimmune diseases.

**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.

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Source: Delcath Systems, Inc.