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): January 13, 2025

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)

(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 January 13, 2025, Delcath Systems, Inc. ("Delcath") issued a press release announcing preliminary financial results for the quarter ended and full year ended December 31, 2024 (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 Item 2.02, including Exhibit 99.1, 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 nor shall it be incorporated by reference into any other filing by Delcath with the U.S. Securities and Exchange Commission whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

On January 13, 2025, Delcath made available an updated corporate presentation that may be used in connection with presentations at conferences and investor meetings, which can be found on the Company's website (the "Corporate Presentation"). The Corporate Presentation is furnished as Exhibit 99.2 and incorporated by reference in this Item 7.01.

The information contained in this Item 7.01, including Exhibit 99.2, 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 nor shall it be incorporated by reference into any other filing by Delcath with the U.S. Securities and Exchange Commission whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On January 13, 2025, Delcath disclosed in the Corporate Presentation that as of December 31, 2024, (i) it had a total of 14 active sites utilizing HEPZATO KIT and (ii) there were approximately 36.2 million shares of its common stock issued and outstanding.

On January 13, 2025, Delcath also announced the following preliminary unaudited fourth quarter and full year 2024 financial and operational results:

- Total fourth quarter and full year revenue expected to be approximately $15.1 million and $37.2 million, respectively
- HEPZATO KIT™ fourth quarter and full year revenue expected to be approximately $13.7 million and $32.3 million, respectively
- CHEMOSAT® fourth quarter and full year revenue expected to be approximately $1.4 million and $4.9 million, respectively
- Gross margins expected to be in the 80%-85% range
- $53.2 million of cash, cash equivalents and short term investments and no debt as of December 31, 2024

Delcath has not yet completed its financial close process for the fourth quarter and full year 2024 and, as a result, actual results may vary from the estimated preliminary results set forth in this Current Report on Form 8-K due to a number of factors, including audit adjustments and other developments that may arise between now and the time the financial results for the fourth quarter and fiscal year ended December 31, 2024, are finalized. The estimated preliminary financial results have not been audited or reviewed by the Delcath's independent registered public accounting firm. These estimates should not be viewed as a substitute for Delcath's full interim or annual audited financial statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated January 13, 2025.
99.2	Corporate Presentation, dated January 13, 2025.
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: January 13, 2025

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

Delcath Systems Announces Preliminary Fourth Quarter and Full Year 2024 Financial Results

Fourth Quarter Revenue Approximately $15.1 Million and

Full Year Total Revenue Approximately $37.2 Million

QUEENSBURY, NY – January 13, 2025, Delcath Systems, Inc. (Nasdaq: DCTH) ("Delcath" or the "Company"), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today announced preliminary financial results for the fourth quarter and year-ended December 31, 2024.

Preliminary Fourth Quarter and Full-Year 2024 Financial Results (unaudited)

- Total fourth quarter and full year revenue expected to be approximately $15.1 million and $37.2 million, respectively
- HEPZATO KIT™ fourth quarter and full year revenue expected to be approximately $13.7 million and $32.3 million, respectively
- CHEMOSAT® fourth quarter and full year revenue expected to be approximately $1.4 million and $4.9 million, respectively
- Gross margins expected to be in the 80%-85% range
- As of December 31, 2024, the Company had approximately $53.2 million of cash, cash equivalents and short-term investments and no debt

Final financial results for the fourth quarter and full year 2024 and a detailed business update will be provided during Delcath's annual financial results release and investor call scheduled for March 6, 2025.

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 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 Hepatic Delivery System (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.

Preliminary and Unaudited Nature of Reported Results

The Company has not yet completed its financial close process for the fourth quarter and full year 2024 and, as a result, actual results may vary from the estimated preliminary results set forth in this press release due to a number of factors, including audit adjustments and other developments that may arise between now and the time the financial results for the fourth quarter and fiscal year ended December 31, 2024, are finalized. The estimated preliminary financial results have not been audited or reviewed by the Company's independent registered public accounting firm. These estimates should not be viewed as a substitute for the Company's full interim or annual audited financial statements.

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, 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: changes to the estimated preliminary results set forth in this press release as a result of audit adjustments and other developments that may arise between now and the time the financial results for the fourth quarter and fiscal year ended December 31, 2024, are finalized; the Company's commercialization plans and its ability to successfully commercialize the HEPZATO KIT; 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

Exhibit 99.2

Delcath

Corporate Presentation

NASDAQ: DCTH

January 2025

Forward-Looking Statement

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 presentation contains forward-looking statements, 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: changes to the estimated preliminary results set forth herein as a result of audit adjustments and other developments that may arise between now the time the financial results for the fourth quarter and fiscal year ended December 31, 2024, are finalized; the Company's ability to successfully commercialize the HEPZATO KIT; 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 Delcath and third-party suppliers/manufacturers; the Company's successful implementation and management of the HEPZATO KIT Risk Evaluation and Mitigation Strategy; the potential of the HEPZATO KIT as a treatment for patients with primary and metastatic disease in the liver; our ability to obtain reimbursement for commercialized product; the Company's ability to successfully enter into any necessary purchase and sale agreements with users of the HEPZATO KIT; the timing and results of the Company's clinical trials; our determination whether to continue a clinical trial program or to focus on other alternative indications; the impact of the COVID-19 pandemic or other pandemics 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; 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.

The Company has not yet completed its financial close process for the fourth quarter and full year 2024 and, as a result, actual results may vary from the estimated preliminary results set forth in this presentation due to a number of factors, including audit adjustments and other developments that may arise between now and the time the financial results for the fourth quarter and fiscal year ended December 31, 2024, are finalized. The estimated preliminary financial results have not been audited or reviewed by the Company's independent registered public accounting firm. These estimates should not be viewed as a substitute for the Company's full interim or annual audited financial statements.

Delcath Corporate Summary

HEPZATO/CHEMOSAT

- 1Q 2024 HEPZATO (drug/device) US launch for mUM*, CHEMOSAT (device only) in EU
- Included in NCCN Guidelines
- First and only FDA approved whole-liver directed therapy
- Preliminary Q4 Results; Expected to be $15.1M of Revenue and Gross Margins 80%-85%

Commercial Opportunity

- Ultra orphan pricing with J-Code
- Focused call points
- US mUM TAM ~$600M

Strong Financial Position

- Cash and investments as of 12/31/2024 = $53.2M
- At $11.2M of Revenue, Q3 2024 Operating Cash Burn of $3.6M
- Expected Q2 2025 receipt of ~$17M from warrant exercise ($10 strike price)
- No outstanding debt obligations

Experienced Management Team

- Expertise in commercializing high value, specialty products
- TheraSphere (BSX) veterans

Significant upside beyond mUM

- HDS platform technology with utility across a broad set of cancer types
- Strong efficacy signals in multiple other tumor types
- Unique interventional oncology asset

Anticipated 2025 Catalysts

- Further site activation and revenue build
- Cash flow positive
- CHOPIN data readout
- Initiate CRC and BCC trials

* metastatic Uveal Melanoma (mUM)

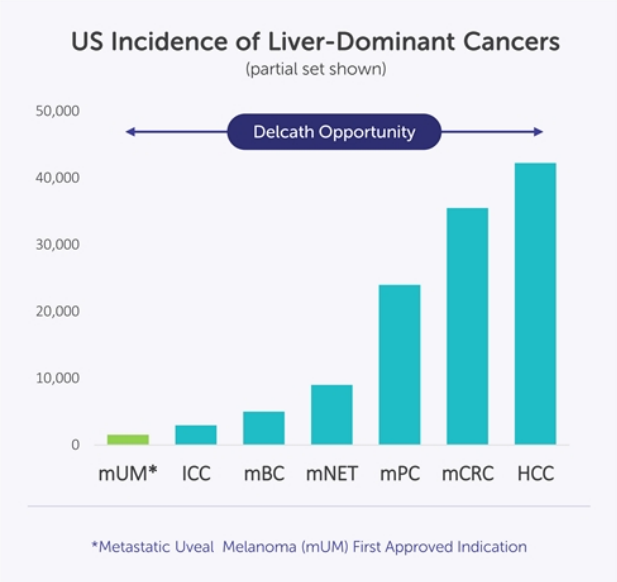
HIGH UNMET NEED:

Liver-Dominant Cancers

Liver-Dominant Cancers: High Incidence with High Unmet Medical Need

Up to **80%** **of patients with liver metastases are not amenable to surgical resection**
largely due to extensive tumor burden[1]

- Limited Overall Survival - Unresectable Liver Cancer
- Liver: Common Site of Metastases
  - Often the life-limiting organ
- Limited Effective Systemic Treatments
  - Systemic Therapies: low efficacy
  - Immuno-oncology agents become less effective in the presence of metastases

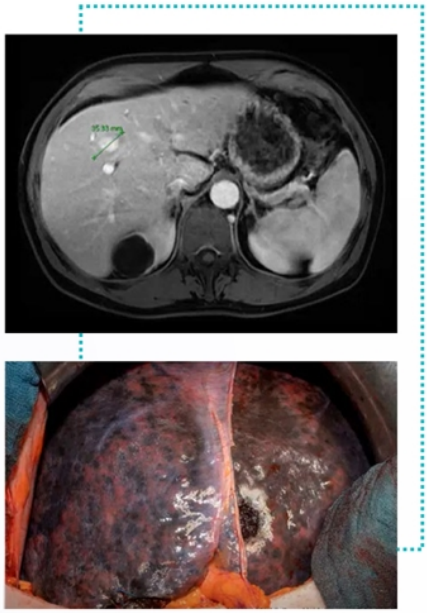


[1] Reddy S, et al. Isolated hepatic perfusion for patients with liver metastases, Ther Adv Med Oncol. 2014 Jul; 6(4): 180-194.

Diffuse Disease and Whole Liver Treatment

Liver metastases in mUM and other Cancers are Often Multi-focal

- Solitary **liver lesions** are often treated with **surgery or ablation**.
- Radiographically, metastatic disease can **initially present** only as **focal lesions**.
- **Micrometastases** are difficult to detect – recurrence is common
- Traditional **liver-directed therapy** mechanism of action is **not optimal** if a whole liver treatment is needed.
- Whole organ therapy delivers **medication to a specific organ** then filters out the medication to **minimize systemic exposure**.



Actual mUM patient sent for a liver resection based upon radiographic diagnosis*

* Data on File

Major Liver-Directed Therapies

MAJORITY OF TREATMENT

Trans Arterial Chemo Embolization (TACE)[2]

- Beads obstruct blood flow to tumor and elute chemo
- 50-60k treatments and rising per year in US

SIRT (Y90)[3]

- Radioactive beads delivered into a portion of the liver
- 10-15k treatments and rising per year in US

Limitations

- Tumors recur and retreatment options limited due to damage to vasculature (TACE) and hepatotoxicity (Y90)
- Diffuse disease cannot be treated with a tumor-by-tumor modality (TACE) and bilobar treatment is hepatotoxic (Y90)
- Many tumors not imageable and micro-metastases are common, neither TACE or Y90 can treat the entire liver
- Neither approved for the treatment of mUM and lacking substantial high quality data set to support usage

[2] Xu L, T, Funchain P, F, Bena J, F, Li M, Tarhini A, Berber E, Singh A, D: Uveal Melanoma Metastatic to the Liver: Treatment Trends and Outcomes. Ocul Oncol Pathol 2019;5:323-332. doi: 10.1159/000495113.
[3] Lane AM, Kim IK, Gragoudas ES. Survival Rates in Patients After Treatment for Metastasis From Uveal Melanoma. JAMA Ophthalmol. 2018 Sep 1;136(9):981- 986.

HEPZATO KIT™

(melphalan) for Injection/
Hepatic Delivery System (HDS)

HEPZATO KIT™
(melphalan) for Injection/
Hepatic Delivery System (HDS)

Percutaneous Hepatic Perfusion (PHP)

Effective, Safe & Repeatable Liver-focused Disease Control

1. Isolation

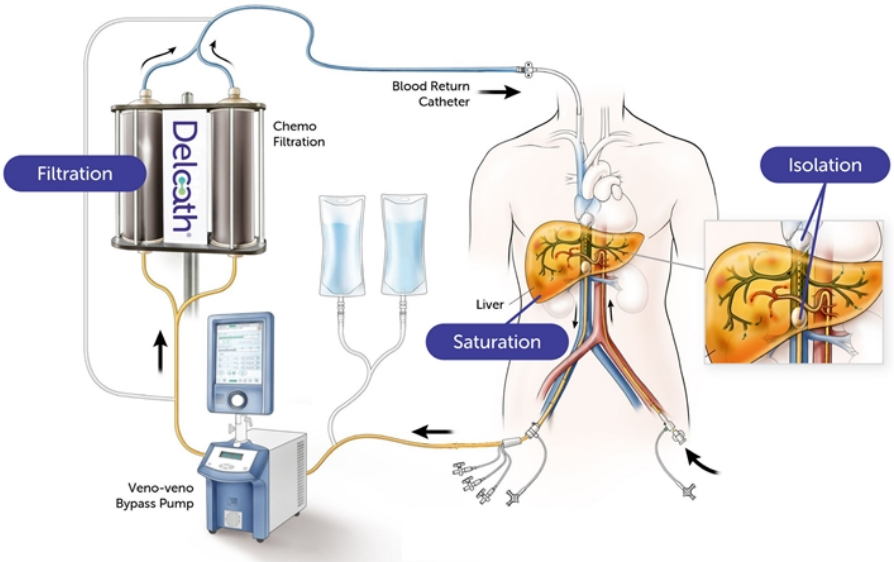
Hepatic venous flow is isolated, enabling >6X greater local concentration of chemo

2. Saturation

Melphalan (chemo) treats micro and macro lesions simultaneously regardless of location in the liver

3. Filtration

Proprietary filters remove greater than 85% of chemo from the body[4]



[4] Heppt, M, et al. Combined immune checkpoint blockade for metastatic uveal melanoma: a retrospective, multi-center study. J Immunotherap Cancer. 2019 Nov 13;7(1):299.

Indication Statement

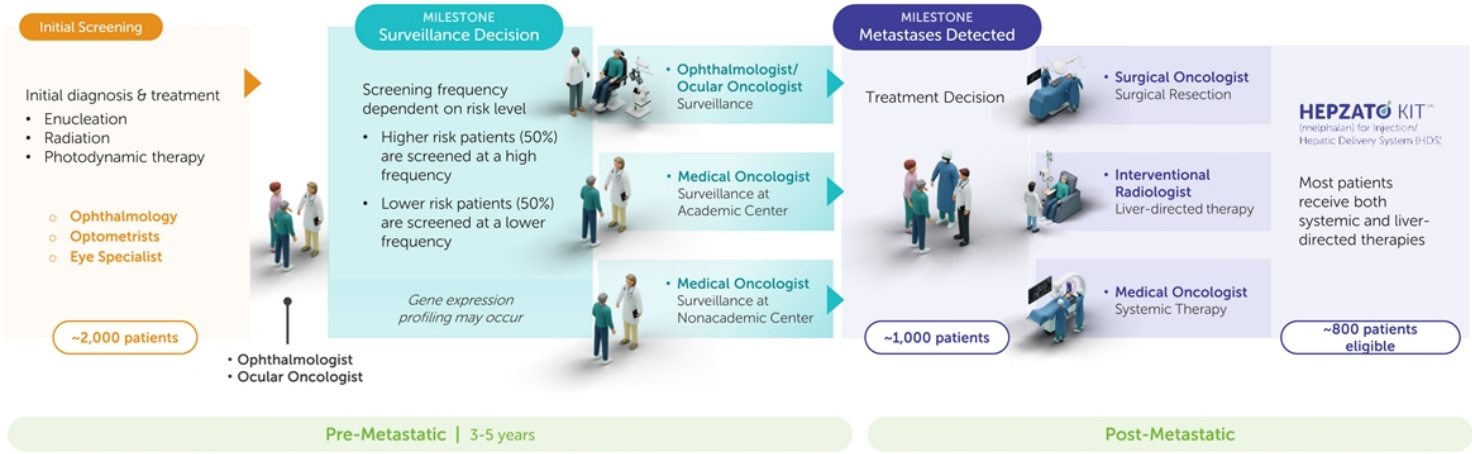
HEPZATO KIT (melphalan) for Injection/Hepatic Delivery System

HEPZATO KIT is indicated as a liver-directed treatment for adult patients with uveal melanoma 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.

- Indicated Patient Population Includes:
  - No HLA genotype restrictions
  - Treatment naïve and previously treated patients

Metastatic Uveal Melanoma (mUM)

Patient Journey



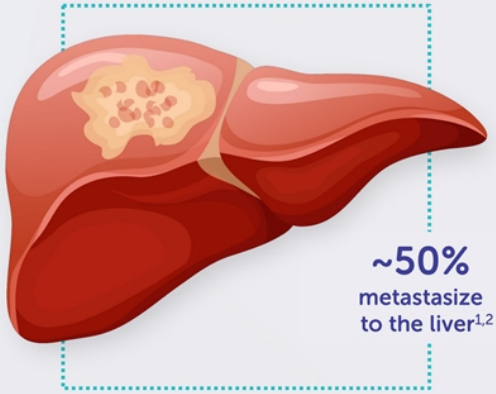
~2,000 per Year (US)[2]

~1,000 per Year (US)[2]

[2] Xu L, T, Funchain P, F, Bena J, F, Li M, Tarhini A, Berber E, Singh A, D: Uveal Melanoma Metastatic to the Liver: Treatment Trends and Outcomes. Ocul Oncol Pathol 2019;5:323-332. doi: 10.1159/000495113.

mUM: Beachhead Market Opportunity

- **Liver involved in >90% of cases** of metastatic disease (**1,000 mUM patients**)[2,3]
- In 50% of mUM patients, the liver is the only site of metastasis[5,6]
- Most patients with mUM die **from liver failure**[6]
  - **1-year OS rate** of patients with metastatic disease in the liver is **13%**
  - Median survival ranging from **4 to 15 months**[2,7]



[3] Lane AM, Kim IK, Gragoudas ES. Survival Rates in Patients After Treatment for Metastasis From Uveal Melanoma. JAMA Ophthalmol. 2018 Sep 1;136(9):981- 986.
[5] Krantz BA, et al. Uveal Melanoma: Epidemiology, Etiology, and Treatment of Primary Disease. Clin Ophthalmol. 2017;11:279-289.
[6] Eschelman DJ et al. Transhepatic Therapies for Metastatic Uveal Melanoma. Semin Intervent Radiol. 2013;30(1):39-48.
[7] Carvajal RD, et al. Metastatic Disease from Uveal Melanoma: Treatment Options and Future Prospects. Br J Ophthalmol. 2017;101(1):38-44.

Competitive Landscape

- 55% of patients have no approved systemic treatment option
- Most patients treated with multiple lines of therapy

Primary Systemic Competitors

- Kimmtrak (tebentafusp) for HLA + (~45% of patients)
- IPI/NIVO (in combination) for HLA –

Competitive Positioning

- Ideally all patients will receive a Liver Directed Therapy (LDT) as either 1st or 2nd line
- Currently, a growing minority of Oncologists/MDs believe LDT as a 1st line is critical
- For others we stress that patients die of liver failure – treat the liver before its too late (have a specific plan for LDT as 2nd line)

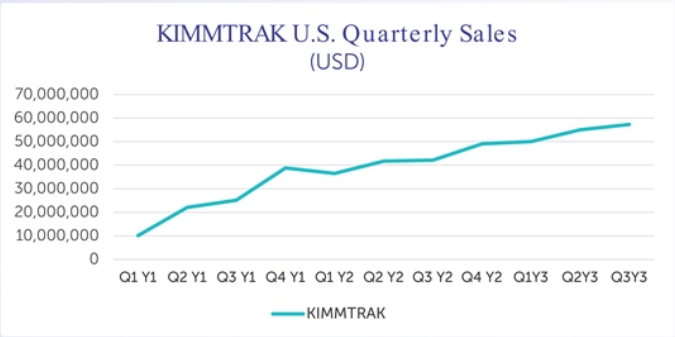
Primary LDT Competitors

- TACE (limited efficacy data, not suited for diffuse disease)
- SIRT (limited to two treatments, not suitable for multi-lobar disease)

Competitive Positioning

- 1st line for all that believe in LDT 1st line
- Whole liver treatment vs. targeted treatment is necessary
- PHP leaves options for additional LD therapies, Y90 and TACE do not

Demonstrated Demand for FDA Approved Treatment in mUM



KIMMTRAK

- Reported $57.3 million in Q3 2024 US sales ($230M annualized revenue)
- Only 45% of mUM patients (~400) are eligible for treatment due to HLA restriction

HEPZATO KIT: FDA Approved August 14, 2023 to Treat Patients with Liver-Dominant mUM

- Approximately 800 patients potentially eligible for treatment
- HEPZATO has no HLA genotype restrictions
- Patients often receive both systemic and liver-directed treatment

Mean HEPZATO treatment vs. mean treatment duration of KIMMTRAK
(per pivotal trials)

DRUG	DOSE COST*	MEAN TREATMENTS #**	TOTAL COST
KIMMTRAK	$20,480	41 weeks	$839,680
HEPZATO	$187,500	4.1 kits	$768,750

*Dose Cost ASP calculated using CMS payment allowance limit
** Mean from published phase 3 trials

HEPZATO KIT:

Commercialization

Delivering an Innovative Treatment with a Well-Trained Team

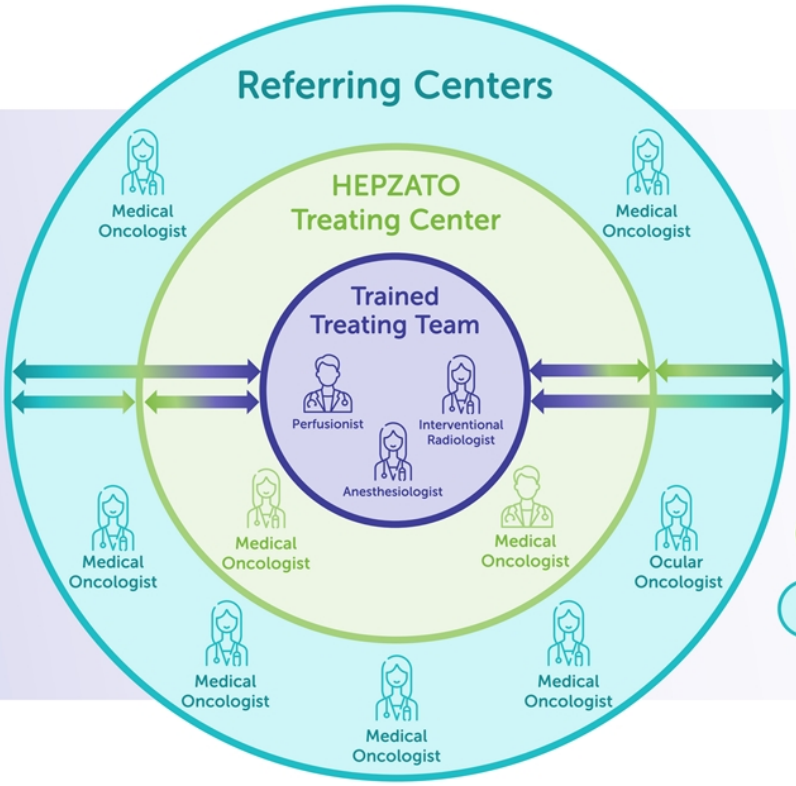
Treatment with HEPZATO KIT involves training and a team approach. The team members below complete a preceptorship and proctorship as well as a risk evaluation and mitigation strategy (REMS) training.

Interventional radiologist leads and performs the vascular interventional procedure

Perfusionist establishes, monitors, and controls the extracorporeal pump and veno-venous bypass circuit

Anesthesiologist manages sedation, analgesia, and respiratory and cardiovascular support

All REMS materials are available at www.HEPZATOKITREMS.com or by calling the REMS Coordinating Center at 1-833-632-0457.



Specialized, Targeted Sales Teams

Three Complementary Representatives:

- Clinical Specialists
- Liver-Directed Therapy Representatives
- Oncology Managers

Current and Pending Commercial Centers

As of 01/09/2025

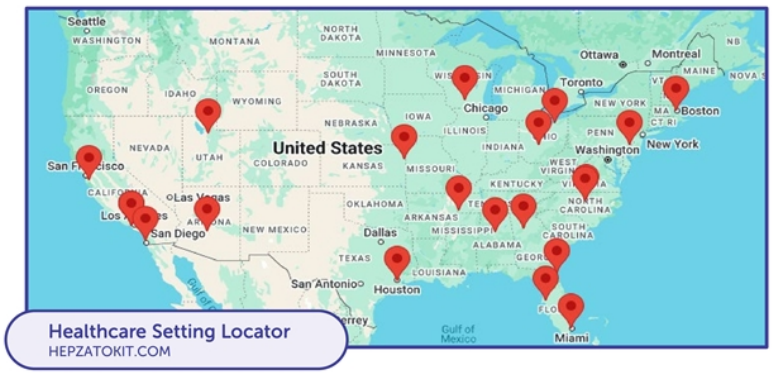
First commercial use of **HEPZATO KIT**
January 12, 2024 at Moffitt

22 sites are accepting referrals

14 sites active as of December 31, 2024

20+ additional sites in active conversations

30 active center target for end of 2025



Healthcare Setting Locator
HEPZATOKIT.COM

Cleveland Clinic Main Campus - Cleveland, OH *
Duke Cancer Center - Durham, NC
HonorHealth Scottsdale Shea - Scottsdale, AZ
Massachusetts General Hospital - Boston, MA
Mayo Clinic - Jacksonville, FL
MD Anderson Cancer Center - Houston, TX *
Moffitt Cancer Center - Tampa, FL
Northwestern University – Chicago, IL*
Ohio State University - Columbus, OH
Piedmont Atlanta - Atlanta, GA *
Providence Saint John's Health Center - Santa Monica, CA *
Regional One Health - Memphis, TN
Stanford Health Care - Stanford, CA
Thomas Jefferson University Hospital - Philadelphia, PA
UC San Diego Health - San Diego, CA
UCLA Health - Santa Monica, CA
UNC Health Medical Center - Chapel Hill, NC
University of Alabama - Birmingham, AL *
University of Miami Hospital - Miami, FL *
University of Utah Hospital - Salt Lake City, UT
University of Kansas Cancer Center – Kansas, KS *
University of Wisconsin Hospital – Madison, WI

*Sites accepting referrals; not yet REMS certified

HEPZATO KIT:

Reimbursement & Pricing

Reimbursement

Medicare Patients

- J-Code assigned and active April 1, 2024
- Majority of patients expected to be outpatient
  - Drug directly covered by Medicare as pass through

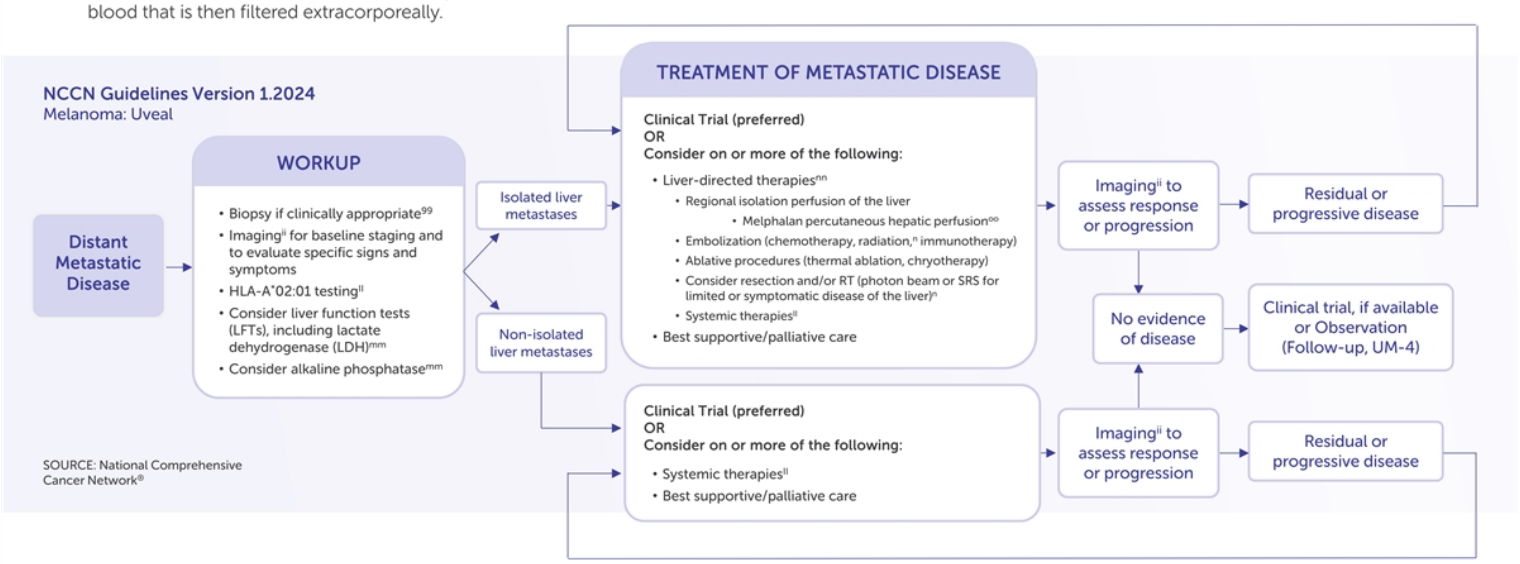
Private Payer Patients

- Follow Medicare guidelines
  - For rare disease
  - Patients to be treated as outpatients
- Medical Prior-Authorization of patients likely required
  - Delcath has engaged a hub service to assist with benefit verification and navigation
- Centers of Excellence (Prospective Payment System (PPS) exempt and NCI designated Cancer Centers) have the leverage to negotiate favorable rates and reimbursement terms
  - ~50% of target sites are PPS exempt or NCI Cancer Centers

PHP is Already Part of Current NCCN Guidelines for mUM

Regional Isolation Perfusion

Methods include isolated hepatic infusion (IHP), percutaneous hepatic perfusion (PHP), HAI, and embolization techniques. **PHP is a simpler, less invasive alternative to IHP that can be repeated.** It uses a double-balloon catheter inserted into the inferior vena cava to isolate hepatic venous blood that is then filtered extracorporeally.



SOURCE: National Comprehensive Cancer Network®

Components of Hospital Reimbursement

Assuming Outpatient Pass Through Status with J-Code

HEALTHCARE FACILITY FEE

- The existing CPT codes should capture all steps of the procedure
- Believe the existing codes will provide payment competitive with other interventional procedures

"PHYSICIAN" PAYMENT

- MDs primarily on salary but physician payments and associated RVUs are still relevant
- The existing CPT codes should capture all steps of the procedure
- Believe the existing codes will provide payment competitive with other interventional procedures

DRUG

- ASP+6% (CMS)
- Likely similar for commercial payers

CPT Code mapping complete
No meaningful impact on treatment decisions

NEXT STEPS:

Future Indications

Clinical Rationale for Broad Development Effort

Melphalan has demonstrated clinical activity in multiple tumor types

Promising ORR, DCR and PFS signals seen across multiple tumor types with CHEMOSAT in Europe and in earlier studies with IHP

In many solid tumor patients, liver metastases are often life limiting

HEPZATO is currently the only liver-directed treatment that can repeatedly treat the whole liver

Potential for significant improvement in survival

Converting unresectable liver metastases into resectable metastases and adjuvant usage to prevent recurrence

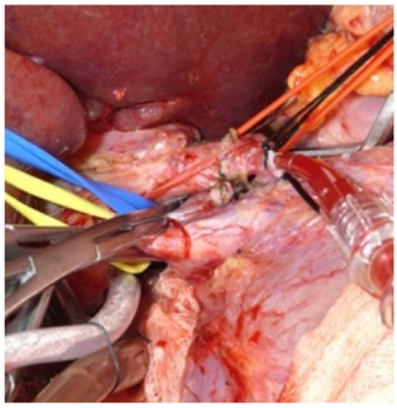
Potential for sequential usage with Immune-Oncology (I/O) agents

Liver metastases reduce I/O therapy efficacy due to the tumor microenvironment inducing immune tolerance, HEPZATO may reduce this effect

Strong Correlation of IHP and PHP Efficacy in mUM Patients

IHP activity in CRC and NET

Meta-analysis of 8 mUM clinical studies [15]		
Endpoint	**IHP (%)**	**PHP (%)**
mOS	17.1	17.3
mPFS	7.2	9.6
hPFS	10	9.5
Complications	39.1	23.8
Mortality	5.5	1.8



IHP / Melphalan in mCRC	
Van Iersel[16]	N=154 ORR 50% mPFS 7.4 months mOS 24.8 months
Alexander[17]	N=120 ORR 61% mOS 17.4 months 2-year survival 34%

IHP in mNET	
Grover[18]	ORR 50% DOR 15 months mhPFS 7 months mOS 48 months

IHP, or Intrahepatic Perfusion, is an invasive surgical technique for delivering high doses of chemotherapy to the liver; procedure related mortality and morbidity prevented common usage. **PHP is a minimally invasive, safer procedure** which accomplishes the same goals as IHP and **can be performed up to 6 times**.

[15] Bethlehem MS et al. Meta-Analysis of Isolated Hepatic Perfusion and Percutaneous Hepatic Perfusion as a Treatment for Uveal Melanoma Liver Metastases. Cancers (Basel). 2021 Sep 21;13(18):4726.
[16] Van Iersel LB, Gelderblom H, Vahrmeijer AL, et al. Isolated hepatic melphalan perfusion of colorectal liver metastases: outcome and prognostic factors in 154 patients. Ann Oncol. 2008;19:1127–34Grover A et al. Isolated Hepatic Perfusion with 200 mg Melphalan for Advanced Noncolorectal Liver Metastases. Surgery. (2005). 136. 1176-82.
[17] Alexander HR Jr, Bartlett DL, Libutti SK, et al. Analysis of factors associated with outcome in patients undergoing isolated hepatic perfusion for unresectable liver metastases from colorectal center. Ann Surg Oncol. 2009;16:1852–9
[18] Grover AC, Libutti SK, Pingpank JF, Helsabeck C, Beresnev T, Alexander HR. Isolated hepatic perfusion for the treatment of patients with advanced liver metastases from pancreatic and gastrointestinal neuroendocrine neoplasms. Surgery. 2004;136(6):1176-1182. doi:https://doi.org/10.1016/j.surg.2004.06.044

Rationale for Combining HEPZATO with IO Therapy

Liver Metastases Suppress IO Therapy Efficacy

nature medicine

Article | Published: 04 January 2021

Liver metastasis restrains immunotherapy efficacy via macrophage-mediated T cell elimination

Science Immunology

SCIENCE IMMUNOLOGY · 30 Oct 2020 · Vol 5, Issue 52 · DOI: 10.1126/sciimmunol.aba0759

Regulatory T cell control of systemic immunity and immunotherapy response in liver metastasis

HBSN HEPATOBILIARY SURGERY AND NUTRITION

Hepatobiliary Surg Nutr. 2021 Aug; 10(4): 526–529. PMCID: PMC8351020
doi: 10.21037/hbsn-21-215 PMID: 34430535

Liver metastases "siphon" off immunotherapy response

frontiers in Oncology

Front Oncol. 2021; 11: 728018. PMCID: PMC8419351
Published online 2021 Aug 23. doi: 10.3389/fonc.2021.728018 PMID: 34497771

From Immunogenic Cell Death to Immunogenic Modulation: Select Chemotherapy Regimens Induce a Spectrum of Immune-Enhancing Activities in the Tumor Microenvironment

HEPATOLOGY AASLD

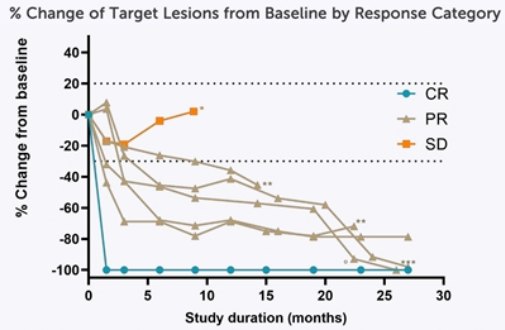
ORIGINAL ARTICLE

Enhancing the therapeutic efficacy of programmed death ligand 1 antibody for metastasized liver cancer by overcoming hepatic immunotolerance in mice

First published: 03 December 2021 | https://doi.org/10.1002/hep.32266 | Citations: 2

Encouraging Signal of Efficacy for PHP and I/O Drug Combination

From Phase 1b Part of the Chopin Trial



- N=7 in Phase 1b portion of the trial[19]
- RP2D: IPI 1mg/kg and NIVO 3mg/kg.
  Well tolerated, no DLTs or deaths.
- 1CR, 6 PR and 1 PD (85.7% ORR, 100% DCR) – meta-analysis of prior IO trials has shown ORR<<10%
- As of 11/15/22 the median follow-up was 29.1 months, the median PFS was 29.1 months, and the median duration of response was 27.1 months.
- 3 of 4 patients who subsequently experienced PD continued with treatment in the form of repeated Melphalan Chemosat treatments
- Ongoing randomized Phase 2 (control is Chemosat) has recruited and enrolled all 76 patients, Primary endpoint is 1 Yr PFS and results expected in Fall of 2025

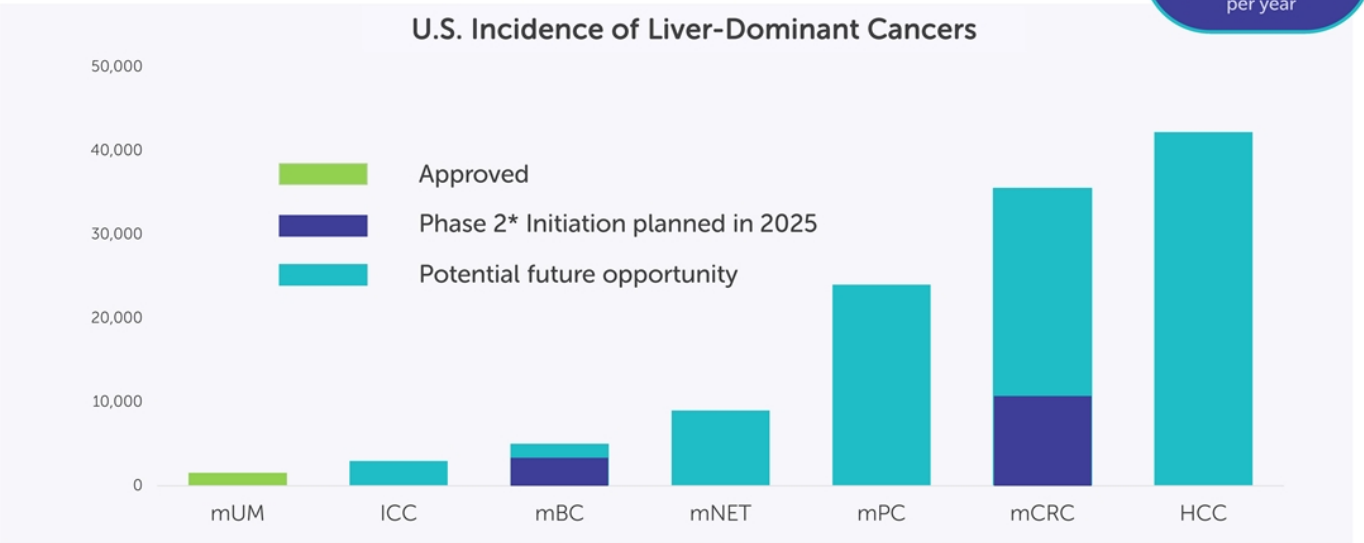
*c1: 1+1mg/kg, c2: 1+3mg/kg

[19] Tong TML et al. Combining Melphalan Percutaneous Hepatic Perfusion with Ipilimumab Plus Nivolumab in Advanced Uveal Melanoma: First Safety and Efficacy Data from the Phase Ib Part of the Chopin Trial. Cardiovasc Intervent Radiol. 2023 Mar;46(3):350-359.

Planned Market Expansion

Potential Significant Upside

U.S. TAM
>$1B
per year



*mBC and mCRC planned trials will address 3rd line liver-dominant metastatic patients

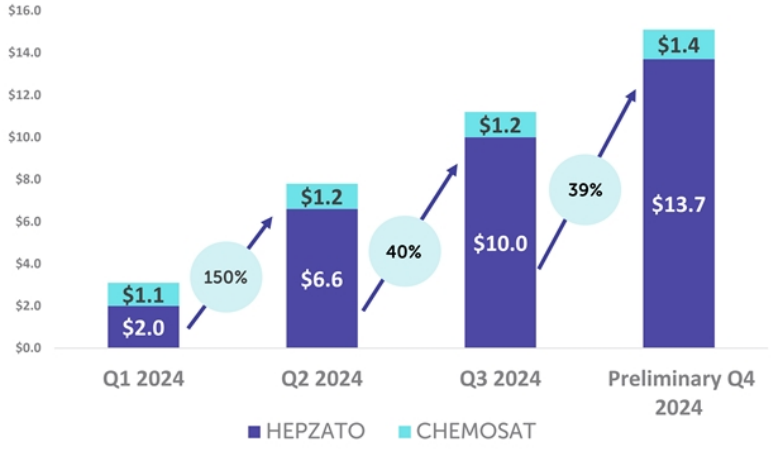
DELCATH:

Financials

Financial Metrics (unaudited)

Total revenues: quarterly progression

($ in millions)



Highlights – Preliminary Q4 and YE 2024 (unaudited)

- Fourth Quarter Revenue to be Approximately $15.1 Million
- Full Year Total Revenue to be Approximately $37.2 Million
- Revenue growth driven primarily by HEPZATO site activation
- Gross Margins expected to be 80-85%
- Expected Cash and Investments of $53.2M
- No outstanding debt obligations

($ in millions)	Q1 2024	Q2 2024	Q3 2024	Preliminary Q4 2024
Revenue				
HEPZATO	$2.0	$6.6	$10.0	$13.7
CHEMOSAT	$1.1	$1.2	$1.2	$1.4
Operating Cash Burn	($9.6)	($4.5)	($3.6)	TBD

Capital Structure and Share Information

Capitalization	DCTH (NASDAQ)
Shares Outstanding[a]	36.2M
Warrants Outstanding[b]	1.8M
Stock Options Outstanding	5.8M
Fully Diluted Shares	43.8M
52 Week Low - High[c]	$3.72 - $12.67
30d Average Daily Volume[d]	342k

a. As of December 31, 2024; includes 33.0M of Common plus; 1.8M Preferred E, E-1 and F Series & 1.4M Pre-funded Warrants as converted.

b. 1.8M warrants at a $10 exercise price (expiring May 2025).

c. Used NASDAQ closing price information starting on January 1, 2024 to December 31, 2024.

d. 30-day average calculated between November 20, 2024 to December 31, 2024.

Multi-Disciplinary, Experienced Leadership Team

Gerard Michel
CHIEF EXECUTIVE OFFICER

- 30+ yrs. pharma/medtech experience
- C-suite roles at Vericel Corp, Biodel, & NPS
- M.S. Microbiology, B.S. Biology & Geology from the Univ. of Rochester School of Medicine
- M.B.A. Simon School of Business & Leadership

Martha S. Rook, PhD
CHIEF OPERATING OFFICER

- 25+ yrs. molecular bio., process dev., manufacturing, supply chain and quality experience
- Senior roles at insitro, Sigilon Therapeutics, and MilliporeSigma
- Ph.D. Biochemistry from MIT, B.S. in chemistry from Texas A&M
- Postdoctoral studies at Harvard Medical School

David Hoffman
GENERAL COUNSEL, CORP SECRETARY & CHIEF COMPLIANCE OFFICER

- 20+ yrs. advising biotech companies with a focus on the commercialization of therapies
- Previously Associate General Counsel and Chief Compliance Officer at Vericel Corporation

Vojislav Vukovic, MD PhD
CHIEF MEDICAL OFFICER

- Oncology dev. exec, global clinical expertise
- Former CMO at Aileron, Taiho, Synta
- MD, Univ. of Sarajevo | MSc, PhD, Univ. of Toronto
- Published, AACR, ASCO, ASH, ESMO member

Kevin Muir
GENERAL MANAGER, INTERVENTIONAL ONCOLOGY

- 20+ yrs. medtech/bioTx sales & marketing experience
- Senior leadership roles at BTG, ClearFlow, Aragon Surgical, Kensey Nash Corporation, and Kyphon
- Field Artillery officer, U.S. Army
- B.S. in Management Systems Engineering, U.S. Military Academy at West Point

Sandra Pennell
SVP, FINANCE

- 20+ years' biotech financial oversight experience
- Manages global financial affairs, U.S. GAAP compliance
- Led finance at Invivyd
- VP at Vericel Corp
- MSc, Accountancy, Univ. of Illinois

Board of Directors

John R. Sylvester, Chairman
Bridget Martell, MA, MD, Director
Elizabeth Czerepak, Director
Steven Salamon, Director
Dr. Gil Aharon, Ph.D., Director
Gerard Michel, CEO


FOCUS
U.S. Registration Trial for the
Treatment of Patients with mUM

Summary of Efficacy Results[9]

Endpoints	HEPZATO KIT (N=91)
ORR, n	33 (36.3%)
DOR, Median in months	14.0
DCR, n	67 (73.6%)
PFS, Median in months	9.0
OS, Median in months	20.53

- Full analysis with **final data cut pending publication**
- HEPZATO Tx **every 6-8 weeks** up to a maximum of **6 cycles**
- Prescribing Information includes **ORR, DOR** and **response categories**
- Trial powered to show an **ORR advantage over a meta-analysis of Best Alternative Care**
  - Checkpoint inhibitors, chemotherapy, other liver-directed therapy
- Lower bound of **FOCUS ORR (26.4%) is significantly higher** than the upper bound of the meta-analysis (8.3%)

[9] DOI: 10.1200/JCO.2022.40.16_suppl.9510 Journal of Clinical Oncology 40, no. 16_suppl (June 01, 2022) 9510-9510.

Published mUM Prospective and Retrospective Studies*

Clinical Study/Publication	Study Type	Treatment	N	Median OS (months)	1 year OS	Median PFS (months)
FOCUS	Single-Arm	HEPZATO	91[AL]	20.53	80%	9.03
Khoja et al 2019[10]	Meta-Analysis	systemic and liver-directed therapies	912	10.2	NA	3.3
Rantala et al 2019[11]	Meta-Analysis	systemic and liver-directed therapies	2,494	12.84	NA	NA
Piulats et al 2021[12]	Single-Arm	ipi plus nivo	52[TN]	12.7	NA	3.0
Heppt et al 2019[13]	Single-Arm	ipi plus (pembro or nivo)	64[AL]	16.1	NA	3.0
Nathan et al 2021[14]	Randomized	tebentafusp	252[TN]	21.7	73%	3.3
		control	126[TN]	16	59%	2.9

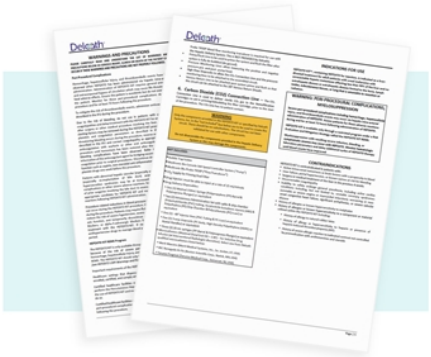
TN = Treatment Naïve, AL = Any Line

Ipi = ipilimUMab, nivo = nivolumab, pembro = pemUMab

*Studies from 2019 or later with >50 patients

[10] Khoja L, et al. Meta-analysis in metastatic uveal melanoma to determine progression free and overall survival benchmarks: an international rare cancers initiative (IRCI) ocular melanoma study. Ann Oncol 2019 Aug 1, 30(8): 1370-1380.
[11] Ranjala, E, et al. Overall survival after treatment for metastatic uveal melanoma: a systematic review and meta-analysis. Melanoma Res. 2019 Dec; 29(6): 561–568
[12] Piulats, J, et al. Nivolumab Plus Ipilimumab for Treatment-Naïve Metastatic Uveal Melanoma: An Open-Label, Multicenter, Phase II Trial by the Spanish Multidisciplinary Melanoma Group (GEM-1402). Journal of Clinical Oncology 39, no. 6 (February 20, 2021) 586-598.
[13] Heppt, M, et al. Combined immune checkpoint blockade for metastatic uveal melanoma: a retrospective, multi-center study. J Immunotherapy Cancer. 2019 Nov 13;7(1):299.
[14] Nathan, P, et al. Overall Survival Benefit with Tebentafusp in Metastatic Uveal Melanoma. N Engl J Med 2021; 385:1196-1206

Adverse Events



Adverse reactions are described further in the HEPZATO KIT PI.

- Most hematological side effects result from melphalan
- Side effect profile similar to standard melphalan use

	Adverse Reactions Related to Study Treatment Occurring in ≥10% of Patients (N=95)	
	ALL GRADES (%)	GRADES 3 OR 4 (%)
Thrombocytopenia*	64	55
Leukopenia*	44	34
Anemia*	61	33
Neutropenia*	35	29
International normalized ratio increased	29	8
Activated partial thromboplastin time prolonged	26	8
Aspartate aminotransferase increased	27	3
Hypocalcemia	12	3
Blood bilirubin increased	11	3
Alanine aminotransferase increased	31	2
Blood alkaline phosphatase increased	25	2
Troponin I increased	12	2
Abdominal pain upper	18	1
Dyspnea	11	1
Nausea	47	0
Fatigue	43	0
Vomiting	27	0
Contusion	16	0
Asthenia	13	0
Back pain	13	0
Decreased appetite	13	0
Abdominal pain	12	0
Lethargy	12	0
Groin pain	11	0
Headache	11	0

Anemia includes anemia, febrile bone marrow aplasia, hemoglobin decreased, normochromic normocytic anemia, red blood cell count decreased. Leukopenia includes leukopenia, lymphocyte count decreased, lymphopenia, and white blood cell count decreased. Neutropenia includes neutropenia and neutrophil count decreased. Thrombocytopenia includes thrombocytopenia and platelet count decrease.


Delcath
Thank You
38

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13. Heppt, M, et al. Combined immune checkpoint blockade for metastatic uveal melanoma: a retrospective, multi-center study. J Immunotherapy Cancer. 2019 Nov 13;7(1):299.
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18. Grover AC, Libutti SK, Pingpank JF, Helsabeck C, Beresnev T, Alexander HR. Isolated hepatic perfusion for the treatment of patients with advanced liver metastases from pancreatic and gastrointestinal neuroendocrine neoplasms. Surgery. 2004;136(6):1176-1182. doi:https://doi.org/10.1016/j.surg.2004.06.044
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