UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 14, 2023

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)

(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, $0.01 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 7.01. Regulation FD Disclosure.

On August 14, 2023, Delcath Systems, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") approved the Company's HEPZATO Kit™ ("HEPZATO") for the treatment of adult patients with unresectable hepatic-dominant metastatic uveal melanoma. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On August 14, 2023, the Company released an updated corporate presentation on the "Events & Presentations" section of the Company's website at https://delcath.com/investors/events-presentations/. The Company has scheduled a conference call to take place on August 15, 2023, relating to the FDA approval of HEPZATO. A copy of the corporate presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 7.01, including Exhibits 99.1 and 99.2, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), or otherwise subject to the liabilities of that Section, and shall not be deemed incorporated by reference in any registration statement or other filing pursuant to the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise expressly stated in such filing.

Item 8.01. Other Events.

On August 14, 2023, the FDA approved HEPZATO for the treatment of adult patients with unresectable hepatic-dominant metastatic uveal melanoma.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 14, 2023.
99.2	Corporate Presentation.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

DELCATH SYSTEMS, INC.

Date: August 15, 2023

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

Exhibit 99.1

Delcath Systems, Inc. Announces FDA Approval of HEPZATO KIT™ for the Treatment of Adult Patients with Unresectable Hepatic-Dominant Metastatic Uveal Melanoma

HEPZATO KIT is the only FDA approved liver-directed therapy to treat metastatic uveal melanoma

Approval includes treatment naïve and previously treated patients and is not limited by HLA genotype

Delcath to hold Business Update Call on August 15, 2023 at 8:00 a.m. Eastern Time

NEW YORK, August 14, 2023/PRNewswire/ - Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, announced that today the US Food and Drug Administration (FDA) approved HEPZATO KIT (melphalan/Hepatic Delivery System) 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.

mUM is a rare and aggressive form of metastatic cancer with a US incidence of approximately 1,000 cases per year. Ninety percent of mUM involves the liver, and liver failure is often the cause of death. National Comprehensive Cancer Network (NCCN) guidelines recommend liver-directed therapies for mUM patients with liver metastases. HEPZATO KIT is the only liver-directed therapy approved by the FDA for the treatment of mUM and percutaneous hepatic perfusion (PHP), the procedure enabled by HEPZATO KIT, is already included in the NCCN guidelines.

“FDA approval of HEPZATO KIT marks the beginning of a new chapter for Delcath and the culmination of the Company’s commitment to bring this treatment option to patients suffering from metastatic uveal melanoma,” said Gerard Michel, Delcath’s Chief Executive Officer. “We look forward to partnering with cancer centers across the country to build a network of treatment sites trained in the use of this novel therapy.”

The Company plans to have commercial product available in the fourth quarter, and patients will continue to be enrolled and treated at Expanded Access Program (EAP) sites.

The approval of HEPZATO KIT was based primarily on the results of the FOCUS Study (NCT02678572), a Phase 3, single arm, multicenter, open label study, which administered HEPZATO (melphalan) via the hepatic delivery system (HDS) during a PHP procedure. Ninety-one (91) patients received treatment every 6 to 8 weeks, for up to 6 treatments. The main efficacy endpoints were objective response rate (ORR) and

duration of response (DoR) as assessed by an independent review committee using RECIST v1.1. ORR was 36.3% (95% CI: 26.4, 47.0) and median DoR was 14 months (95% CI: 8.3, 17.7). The Disease Control Rate (DCR) observed in treated patients was 73.6% (95% CI: 63.3, 82.3) with 7 complete responses (7.7%), and 26 (28.6%) partial responses.

The patient population enrolled in the FOCUS Study included patients with hepatic and extra-hepatic lesions subject to a treatment plan, as well as both treatment naïve (56.0%) and previously treated (44.0%) patients, irrespective of HLA genotype.

The HEPZATO KIT prescribing information has a boxed warning, which includes three sections: toxicity related to the procedure, myelosuppression and a Risk Evaluation and Mitigation Strategy program, commonly known as REMS, to manage and mitigate these risks. Serious adverse events associated with the PHP procedure with the HEPZATO KIT, such as hemorrhage, hepatocellular injury, and thromboembolic events, occurred in less than 5% of treated patients. Myelosuppressive adverse events including thrombocytopenia, anemia, and neutropenia, are well-known and predictable side effects of melphalan and are routinely managed with standard supportive care measures.

The HEPZATO KIT REMS is designed to ensure consistent conduct of the PHP procedure and that only treatment teams who have received appropriate training perform the PHP procedure.

“HEPZATO KIT is the only liver-directed therapy that can treat the whole liver,” said Vojislav Vukovic, Delcath’s Chief Medical Officer. “Scientific literature supports that HEPZATO KIT may have broad applicability in other tumor types, and we intend to expand our development efforts beyond uveal melanoma given the high incidence of unresectable hepatic dominant tumors.”

The approval effectively triggers the second tranche of financing tied to the previously announced March 29, 2023 Private Investment in Public Equity (PIPE) financing. Participants in the PIPE have 21 days to exercise their Tranche A warrants, translating to up to approximately $34.9 million of additional funding to Delcath. In addition, upon the Company’s announcement of recording at least $10.0 million in quarterly U.S. revenue from the commercialization of HEPZATO KIT, participants in the PIPE will have 21 days to exercise their Tranche B warrants, resulting in up to an additional $24.9 million in funding to Delcath.

About HEPZATO KIT

HEPZATO KIT is a combination product that administers HEPZATO (melphalan), a well-known and long-approved chemotherapeutic agent, directly to the liver through Delcath’s novel device delivery system, the Hepatic Delivery System (HDS), which permits higher drug exposure in target tissues while limiting systemic toxicity. The use

of the HDS allows a healthcare provider team to surgically isolate the liver while the hepatic venous blood is filtered during melphalan infusion and subsequent washout during a Percutaneous Hepatic Perfusion (PHP) procedure. PHP, which can only be performed with Delcath's HDS, results in loco-regional delivery of a relatively high melphalan dose.

About Hepatic-Dominant Metastatic Uveal Melanoma

Uveal melanoma is a very rare form of cancer that affects melanocytes in the eye with approximately 5% of all melanomas being uveal. The US incidence of primary uveal melanoma is approximately 2,000 cases per year. While surgical or radiation therapy of the primary tumor is generally successful, approximately half of all patients with uveal melanoma will develop metastatic disease, primarily due to this inability to treat early micro-metastases of the primary tumor. The metastases occur predominantly in the liver (~90% of patients), and less commonly in the lungs and bones.

Prior to the approval of HEPZATO KIT, there was no approved liver-directed therapy for patients with metastatic uveal melanoma. There is one systemic therapy, KIMMTRAK® (tebentafusp-tebn), approved for a subset of mUM patients withHLA-A*02:01-positive unresectable or metastatic uveal melanoma. Because most patients, regardless of HLA-A*02:01 status, eventually progress, there is a need for both first line treatment ofHLA-A*02:01- negative patients and second line treatment for HLA-A*02:01-positive patients.

The treatment of liver metastases is critical since liver failure is most often the cause of death for patients with metastatic uveal melanoma. Because of this, National Comprehensive Cancer Network guidelines recommends liver-directed therapies for patients with metastases to the liver, including embolization (i.e., transarterial chemoembolization, radioembolization or immunoembolization), ablative procedures (i.e., thermal ablation, cryotherapy) as well as PHP which can only be performed with the HEPZATO KIT. It is noteworthy that PHP was already on guidelines prior to FDA approval.

Metastatic uveal melanoma tumors in the liver tend to have a miliary pattern of spread where there are numerous radiographically evident and microscopically occult metastases in the liver. Therefore, an effective treatment should ideally treat the entire liver and allow for retreatment. None of the embolization or ablation treatments fulfill these requirements nor have any of these techniques been studied in prospective multi-center trials. The PHP procedure utilizing the HEPZATO KIT saturates the entire liver, regardless of the location or imageability of the lesions and most patients are able to undergo multiple treatments.

Please see the full Prescribing Information, including BOXED WARNING for the HEPZATO KIT.

Delcath will hold a business update conference call August 15, 2023, at 8:00 AM Eastern Time to discuss the FDA approval.

Conference Call Information

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

Event Date: Tuesday, August 15, 2023

Time: 8:00 AM Eastern Time

Participant Numbers: Toll Free: 1-833-630-1960

International: 1-412-317-1841

Webcast: https://app.webinar.net/rE345LOXL6b

CONFERENCE REPLAY

US Toll Free:	1-877-344-7529
International Toll:	1-412-317-0080
Replay Access Code:	4657227
End Date:	August 21, 2023

Important Safety Information

Patients eligible for HEPZATO should NOT have any of the following medical conditions:

- Active intracranial metastases or brain lesions with a propensity to bleed
- Liver failure, portal hypertension, or known varices at risk for bleeding
- Surgery or medical treatment of the liver in the previous 4 weeks
- Active cardiac conditions including unstable or severe angina or myocardial infarction), worsening ornew-onset congestive heart failure, significant arrhythmias, or severe valvular disease
- History of allergies or known hypersensitivity to melphalan or a component or material utilized within the HEPZATO KIT including natural rubber latex, heparin, and severe hypersensitivity to iodinated contrast not controlled by antihistamines and steroids

Most common adverse reactions or laboratory abnormalities occurring with HEPZATO treatment are thrombocytopenia, fatigue, anemia, nausea, musculoskeletal pain, leukopenia, abdominal pain, neutropenia, vomiting, increased alanine aminotransferase, prolonged activated partial thromboplastin time, increased alkaline phosphatase, increased aspartate aminotransferase and dyspnea.

Severe peri-procedural complications including hemorrhage, hepatocellular injury, and thromboembolic events may occur via hepatic intra-arterial administration of HEPZATO. HEPZATO is available only through a restricted program under a Risk Evaluation and Mitigation Strategy called the HEPZATO KIT REMS. Myelosuppression with resulting severe infection, bleeding, or symptomatic anemia may occur with HEPZATO. Additional cycles of HEPZATO therapy will be delayed until blood counts have improved.

Please see the full Prescribing Information, including BOXED WARNING for the HEPZATO KIT.

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 products, HEPZATO KIT™ (melphalan hydrochloride 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.

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: 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.

Contact:

Investor Relations Contact:
Ben Shamsian
Lytham Partners
646-829-9701
shamsian@lythampartners.com

Exhibit 99.2

Delcath

Corporate Presentation

(NASDAQ: DCTH)

August 14, 2023

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 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: 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, and 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.

Delcath

Executive Summary

Delcath aims to be the leader in targeted, safe and highly-effective minimally-invasive treatments for patients with cancers of the liver.

UNMET NEED LIVER CANCER

Incidence US/EU
- >200K primary and metastatic liver tumors per year[1-14]

Current local/regional treatments
- Cannot treat the whole liver
- Targeted to visible and accessible tumors
- Limited in their ability to retreat

HEPATIC DELIVERY SYSTEM (HDS)

HDS + Melphalan enables the Percutaneous Hepatic Perfusion (PHP) Procedure
- Delivers high dose chemotherapy to the entire liver
- Limits systemic exposure
- Minimally invasive, repeatable and well-tolerated

US: HEPZATO KIT (Melphalan/HDS)
EU: CHEMOSAT (HDS)

COMPANY & CLINICAL PROGRAM

FDA Approved 8/14/23
- Metastatic Ocular Melanoma (mUM)
- Liver failure #1 cause of death in mUM
- Response rates >36%
- 1 Year OS** = 80%

Real World Evidence
- **>1k** commercial treatments in EU
- Multiple single center publications

Launch Expected Q4 '23

LARGE MARKET OPPORTUNITY

Near-term (mUM)*
- Ultra orphan pricing dynamic
- >$600M TAM in US/EU

Longer Term (CRC, ICC, Pancreatic, etc.)
- >>$1B TAM
- Investigator interest in more than 10 other indications

** mUM – metastatic Uveal Melanoma, also known as metastatic Ocular Melanoma **Exploratory endpoint in FOCUS trial*

Limitations of Current Liver-Directed Therapies

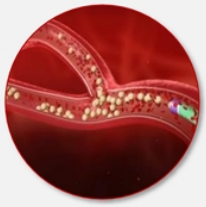
Majority of Treatment

Trans Arterial Chemo Embolization (TACE)[1]

- Beads obstruct blood flow to tumor and elute chemo
- **50-60k treatments** per year in US (and growing)

Y90[2]

- Radioactive beads delivered into the tumor
- **10-15k treatments per year** in US (and growing)



⊗ Effective, but tumors recur & retreatment limited due to damaged vasculature

⊗ Diffuse disease: cannot be treated with a tumor-by-tumor modality

⊗ Many tumors are not imageable – micro-metastases are common

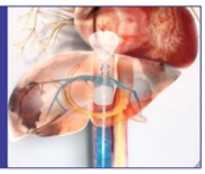
Delcath

HEPZATO KIT™: Enables Percutaneous Hepatic Perfusion (PHP)

Repeatable, safe & effective liver-focused disease control

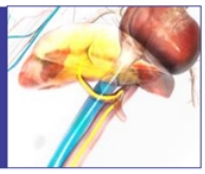
ISOLATION

Hepatic venous flow is isolated, enabling 12x increased dose



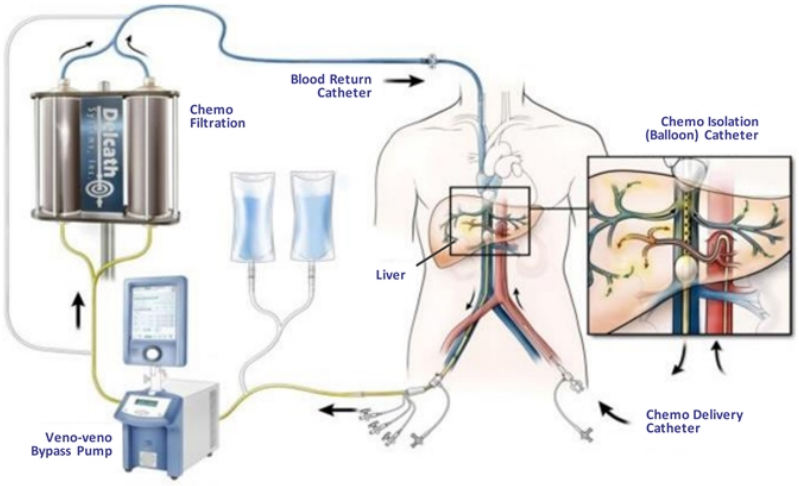
SATURATION

Melphalan (chemo) treats micro and macro lesions simultaneously



FILTRATION

Proprietary filters remove greater than 85% of chemo from the body[33]



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Liver-Dominant Cancers

High incidence with poor prognosis

Up to

80%

Many patients with liver metastases are not amenable to surgical resection largely due to extensive tumor burden[17]

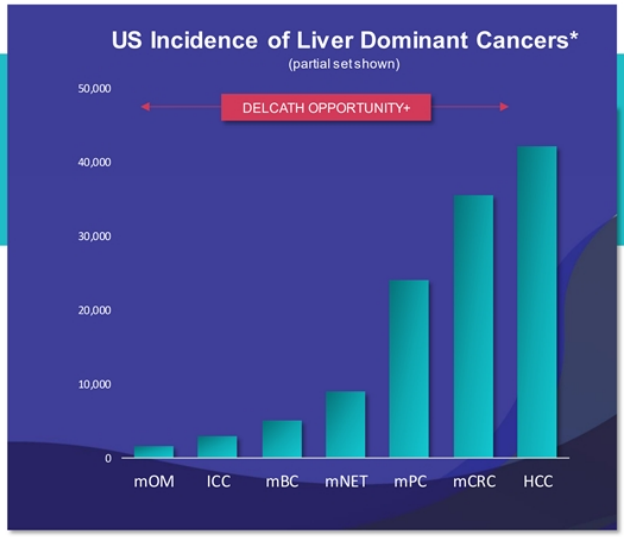
Liver: Common Site of Metastases

Limited Effective Systemic Treatments

- Systemic therapies - low efficacy
- Immuno-oncology agents - become less effective in the presence of metastases

Limited Overall Survival – Unresectable Liver Cancer

- Often the life-limiting organ



*Metastatic Ocular Melanoma (mUM)[3,4], Cholangiocarcinoma (ICC)[5,6], Liver-dominant Breast Cancer (mBC)[9-12], Metastatic Neuroendocrine Tumors (mNET)[8,9] Metastatic Pancreatic Cancer (mPC)[9,15], Metastatic Colorectal Cancer (mCRC)[13,14], Hepatocellular carcinoma (HCC)[17]

mUM: Beachhead Market Opportunity

High Unmet Need, Favorable Reimbursement Environment

Unmet Need

- >5,000 cases of primary ocular melanoma per year in the US/EU [18] ~50% metastasize to the liver [4,19]
- US TAM ~800 patients, Europe ~1,200 patients
- Median survival up to 12 months.[20]
- 55% of patients have no approved treatment option, most patients treated with multiple lines of therapy

Low Risk Commercial Opportunity

- FDA Approved 8/14/23
- Commercial launch 4Q '23
- Commercial team led by TheraSphere (BSX) veterans
- Focused commercial effort: 20 US treatment centers @ 2 patients/week = ~70% TAM

High Barrier to Entry

- Orphan indication status allows for extended exclusivity
- HEPZATO is a combination drug device regulated by CDER – no traditional ANDA pathway
- IP around HEPZATO limits any 505(b)(2) follow-on

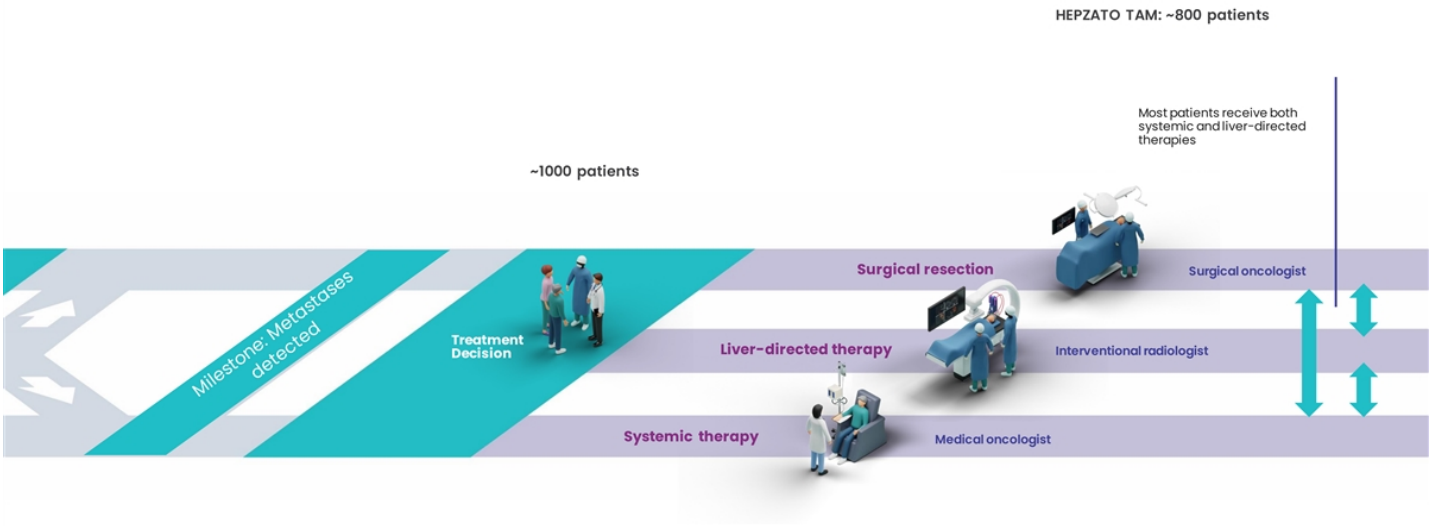
Favorable US Commercial Economics

- Favorable US reimbursement environment for ultra orphan outpatient MD administered drugs
- KIMMTRAK® (tebentafusp-tebn) (approved 1Q '22 for ~45% of mUM population) priced at an average of $790K per patient, reported $41.7M in 2Q '23

Delcath

Patient Journey (Pre- Metastatic)

Patient Journey (Post Metastatic)



Liver metastases: a significant clinical problem in mUM

Half of all patients with UM develop systemic metastases [21,22]

- The liver is involved in 90% of cases of metastatic disease [21,22]
- In 50% of mUM patients, the liver is the only site of metastasis [21,22]
- Most patients with mUM die from liver failure [22]
- 1-year OS rate of patients with metastatic disease in the liver is 13%; mOS with median survival ranging from 4 to 15 months [24,25]

mUM patients have micrometastases with or without the presence of radiologically visible metastases [23]

Liver directed treatment, such as Isolated Hepatic Infusion* (IHP), achieves better efficacy (ORR, PFS, PFS) compared to systemic therapy [26]

IHP 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.

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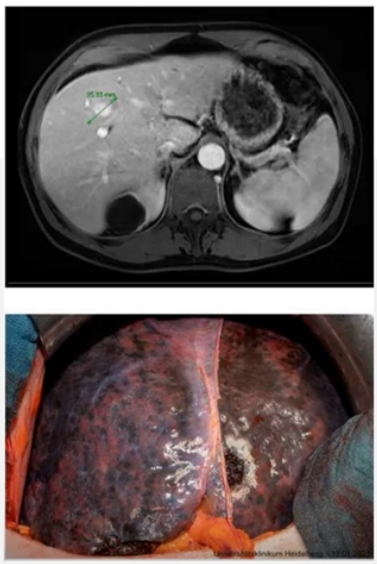
Diffuse/Miliary Metastatic Pattern in mUM

Diffuse disease is difficult to treat with current options

- Solitary liver lesions are often treated with surgery or ablation
- Radiographically metastatic Uveal Melanoma can initially present only as focal lesions
- As is often the case, the true nature of the disease may only be seen upon visual confirmation
- Traditional liver directed therapy mechanism of action is not ideal if a whole liver treatment is needed
- Whole organ therapy delivers medication to a specific organ or tissue through its blood supply, then filters out the medication to minimize systemic exposure



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

* Data on File

Estimated 80%+ of mUM Patients Are Eligible

1 INDICATIONS AND USAGE

HEPZATO for injection, as a component of the 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 ▶

- *Treatment naïve and previously treated patients*
- *No HLA genotype restrictions*

Box Warnings Managed By REMS

Risk **E**valuation and **M**itigation **S**trategy Program

= *Training & Monitoring*

WARNING: PERI-PROCEDURAL COMPLICATIONS, MYELOSUPPRESSION

- **Severe peri-procedural complications including hemorrhage, hepatocellular injury, and thromboembolic events may occur via hepatic intra-arterial administration of HEPZATO. Assess patients for these adverse reactions during and for at least 72 hours following administration of HEPZATO** ***[see Warnings and Precautions (5.1)]*****.**
- **HEPZATO is available only through a restricted program under a Risk Evaluation and Mitigation Strategy called the HEPZATO KIT REMS** ***[see Warnings and Precautions (5.2)]*****.**
- **Myelosuppression with resulting severe infection, bleeding, or symptomatic anemia may occur with HEPZATO. Monitor hematologic laboratory parameters and delay additional cycles of HEPZATO therapy until blood counts have improved.** ***[see Warnings and Precautions (5.3)]***

European experience has shown that the procedure can be safely conducted by Interventional Radiology team after appropriate training

REMS program goals are to standardize training, ensure consistent treatment methodology and monitor outcomes

Myelosuppression is a black box warning for generic melphalan, the management of which is standard practice for oncologists

FOCUS Trial

Registration Clinical Trial for Patients with mUM

FOCUS

- Multinational, multicenter, single-arm trial
- Efficacy Endpoints:
  - Primary: Objective Response Rate (ORR) compared to meta-analysis of IO therapy
  - Secondary: Duration of Response (DOR), Disease Control Rate (DCR), Overall Survival (OS), Progression Free Survival (PFS)
- 102 patients enrolled, 91 completed treatments at 23 centers in the US and EU
- HEPZATO Tx every 6-8 weeks up to a maximum of 6 cycles

Delcath

FOCUS Trial

Single Arm Trial Efficacy Data in PI

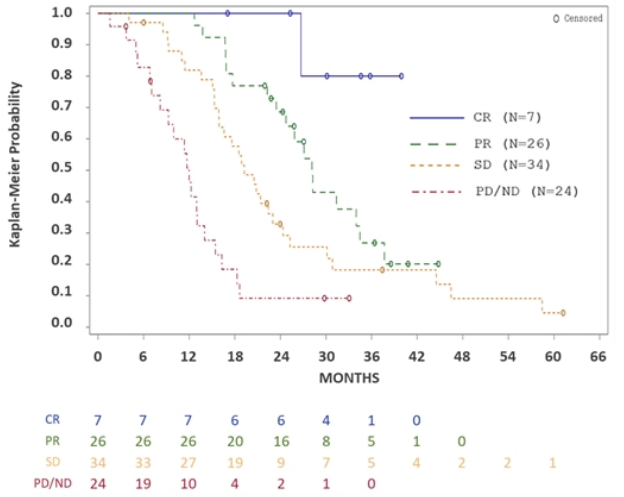
Efficacy Endpoint	N (%)
ORR, n (%)	33 (36.3)
[95% CI]	[26.44, 47.01]
Median DOR, months	14
[95% CI]	[8.31-17.74]
DCR, n (%)	67 (73.6)
[95% CI]	[63.35, 82.31]

- 91 treated patients
- 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%)
- Prescribing Information includes ORR, DOR and response categories
- Full analysis with final data cut pending publication – manuscript in process

Delcath

HEPZATO Response Predicts Survival

Kaplan Meier Curves in Treated Populations*



Exploratory Analyses*

	CR (N=7)	PR (N=26)	SD (N=34)	PD/ND (N=24)
Status of OS, N (%)				
Events	1 (14.3)	17 (65.4)	29 (85.3)	20 (83.3)
Censored	6 (85.7)	9 (34.6)	5 (14.7)	4 (16.7)
Median OS (Months)†	NC	28.16	19.25	11.99
95% CI	[26.71, NC]	[23.46, 34.46]	[15.90, 23.00]	[8.18, 14.03]
p-value‡	**<0.0001**			

CR=complete response, PR=partial response, SD=stable disease, PD=progressive disease, ND=not done, BOR=best overall response
Note: NC = Not calculable, due to the number of events within the stratum (n=1)

† Kaplan-Meier estimates.

‡ Log-Rank test.

* 02-Dec-2022 data cut, patients followed through May, 2023

Analysis Supports that ORR is Clinically Meaningful

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OS and PFS Trend Favorable Relative to Historical Results

Pre-Specified Exploratory Analyses*

Secondary Endpoint	N (%)
Median OS, months	**20.53**
[95% CI]	[16.79, 25.26]
1 Year OS, K-M Probability Point Estimate	**0.80**
[95% CI]	[0.70, 0.87]
Median PFS, Months	**9.03**
[95% CI]	[6.34, 11.56]

* 02-Dec-2022 data cut, patients followed through May, 2023

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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[33]	Meta-Analysis	systemic and liver-directed therapies	912	10.2	NA	3.3
Rantala et al 2019[34]	Meta-Analysis	systemic and liver-directed therapies	2,494	12.84	NA	NA
Piulats et al 2021[35]	Single-Arm	ipi plus nivo	52[TN]	12.7	NA	3.0
Heppt et al 2019[36]	Single-Arm	ipi plus (pembro or nivo)	64[AL]	16.1	NA	3.0
Nathan et al 2021[37]	Randomized	tebentafusp	252[TN]	21.7	73%	3.3
		control	126[TN]	16	59%	2.9

TN = Treatment Naïve, AL = Any Line
*Studies from 2019 or later with >50 patients

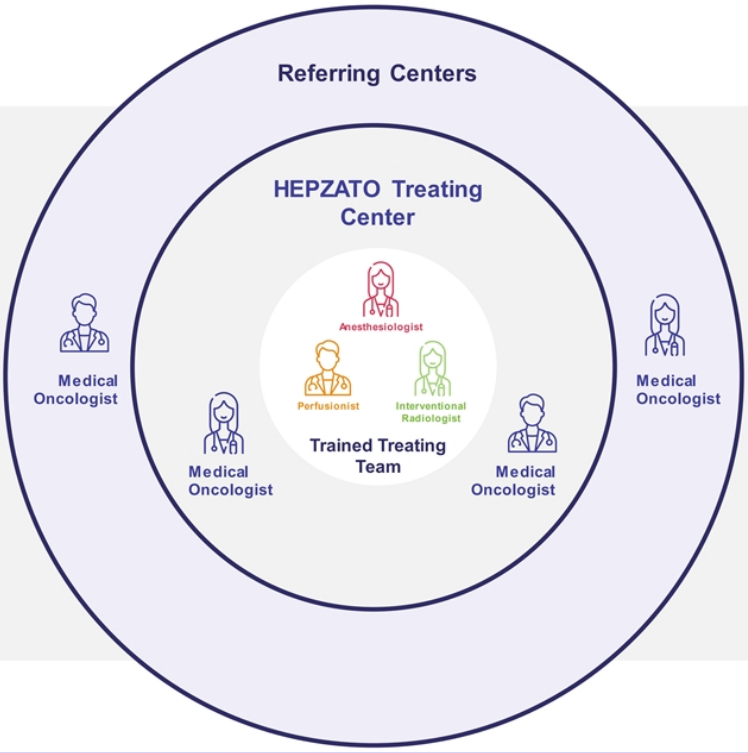
Ipi = ipilimUMab, nivo = nivolumab, pembro = pemUMab

	All Adverse Reactions N=95	
	All Grades (%)	Grades 3 or 4 (%)
Hypotension	13	3
Dyspnea	23	2
Abdominal Pain	39	1
Diarrhea	17	1
Musculoskeletal Pain	46	1
Hemorrhage	15	1
Nausea	57	0
Vomiting	35	0
Fatigue	65	0
Pyrexia	16	0
Groin Pain	11	0
Cough	15	0
Headache	19	0
Lethargy	12	0
Dizziness	11	0
Contusion	17	0
Decreased appetite	16	0

Adverse Events Primarily Hematological

Most hematological side effects result from melphalan

Side effect profile similar to other cytotoxics commonly Used By Oncologists



Patients Referred to Multidisciplinary Treatment Teams

Oncologists Are Generally the Decision Makers

Training Key to Expanding Number of Treating Sites and Capacity

Multidisciplinary Teams to Be Expanded To Increase Both Training Capacity and Patient Flow

Plan To Launch at 10 Treating Sites

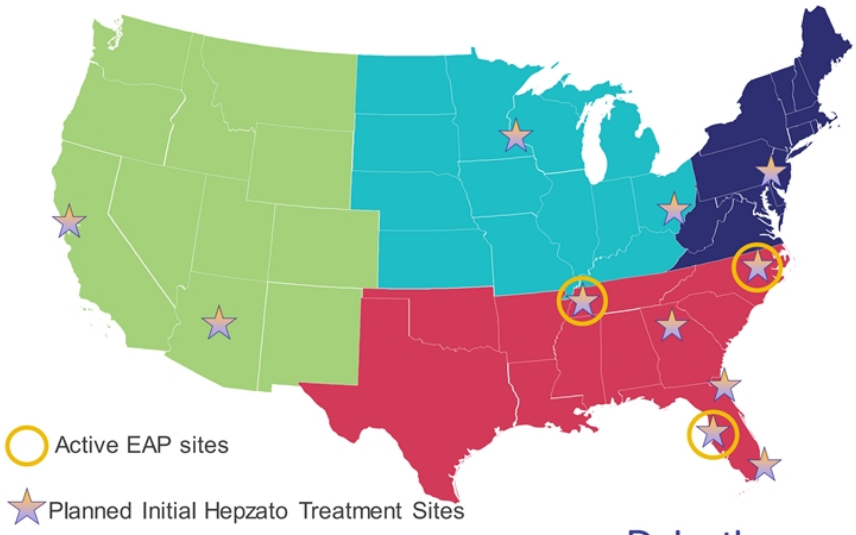
Leveraging EAP and Longitudinal Data to Build Referral Networks

EAP – Currently 3 Sites

- Provide immediate access to patients
- First Commercial Sites
- Train new medical teams to use Hepzato after launch

Leverage Longitudinal Data

- Partnered with data provider to access patient level longitudinal data with 3-week refresh
- Accurately map and quantify surveillance, referral and treatment patterns at the patient and MD level



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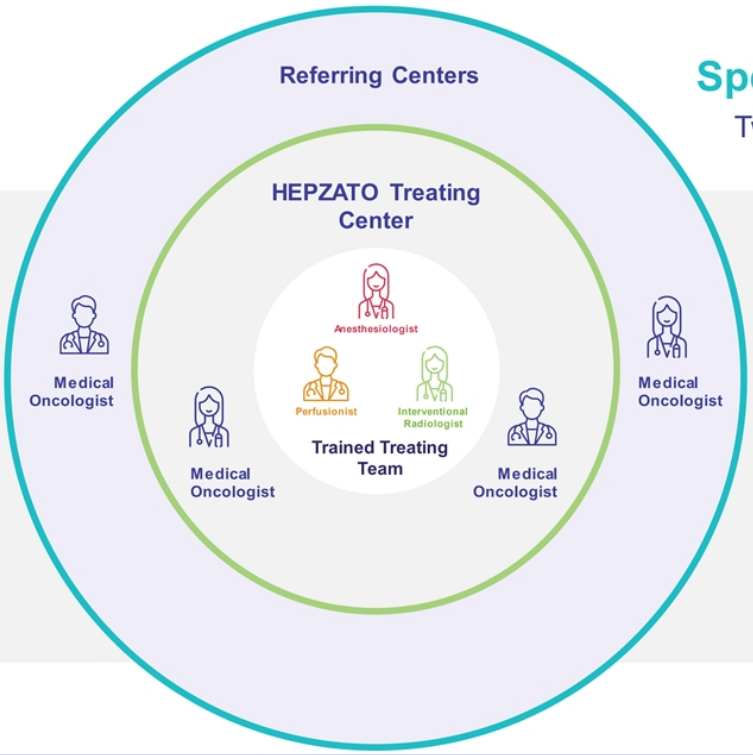
Treating Centers – Current Targets for Launch

Institution	City	Status
Moffitt Cancer Center	Tampa, Florida	EAP - Open and Enrolling
Duke University	Durham, North Carolina	EAP - Open and Enrolling
University of Tennessee	Memphis, Tennessee	EAP - Open and Enrolling
Stanford University	Stanford, California	EAP - Plans to join
Ohio State University	Columbus, Ohio	EAP - Plans to join
Mayo Clinic Hospital	Jacksonville, Florida	EAP - Plans to join
HonorHealth	Scottsdale, Arizona	Confirmed interest in being a treating center
Thomas Jefferson University	Philadelphia, Pennsylvania	Confirmed interest in being a treating center
University of Miami	Miami, Florida	Confirmed interest in being a treating center

Specialized, Targeted Sales Team

Two Complementary Teams of Representatives



Hospital Representative

Responsibilities

- Manage Treating Centers Including VAC/Formulary
- Support Treating Teams
- Facilitate REMS Compliance
- Generate Intra-Center Referrals
- Prospect and Open New Centers with Oncology Representative

Oncology Representative

Responsibilities

- Generate Inter-Center Referrals
- Support Hospital Rep / Generate Intra-Center Referrals
- Prospect and Open New Centers with Hospital Representative

Reimbursement

HEPZATO will be billed as a drug with a J-Code

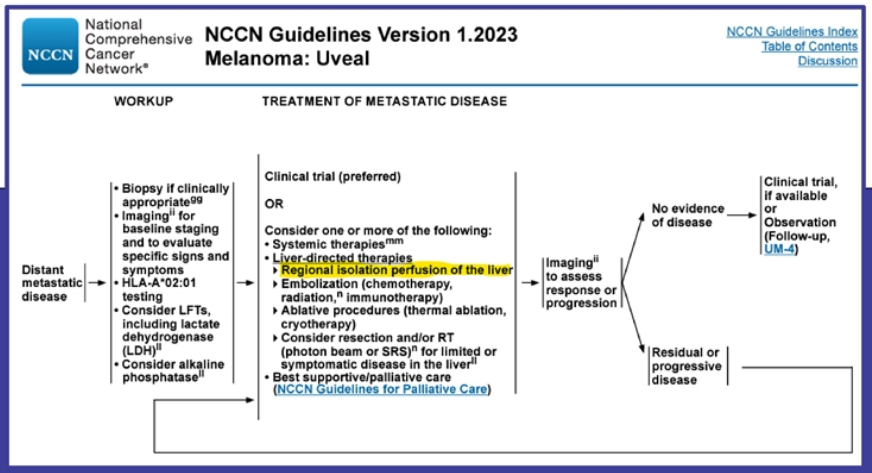
Medicare Patients

- Initially a C-Code
- Majority of patients will be outpatient (2 midnight rule) with the drug directly covered by Medicare

Private Payer Patients

- Private Payers for rare disease generally follow Medicare guidelines and we expect these patients to be treated as outpatients
- Prior-Authorization of patients might be needed, we are planning to contract out a hub service
- Centers of Excellence (Prospective Payment System (PPS) exempt and NCI designated Cancer Centers) have the leverage to negotiate favorable rates and reimbursement terms (our target sites are all either 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.

Components of Hospital Reimbursement

Assuming Outpatient Pass Through Status with C Code

Drug

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

Healthcare Facility Fee

- Highly variable based on coding – we do not "map" to any existing code
- Using existing codes is advised and should provide the hospital adequate payment

"Physician" payment

- Actually goes to hospital but still matters to MD
- Highly variable based on coding – we do not "map" to any existing code
- Using existing codes is advised and should provide the hospital adequate payment

CPT Code mapping complete – while important, it will not have a meaningful impact on drug pricing decision

HEPZATO vs. KIMMTRAK Cost of Treatment Comparisons

At First Assessment (first time to discontinue treatment because of progression)			
Drug	Dose Cost*	Treatments #	Total cost
Kimmtrak	$19,289	24	$462,936
Hepzato	t.b.d.	2	t.b.d.

Mean HEPepzato treatment vs. mean treatment duration of Kimmtrak			
Drug	Dose Cost	Mean Treatments #	Total cost
Kimmtrak	$19,289	41	$790,849
Hepzato	t.b.d.	4.1	t.b.d.

Annual Hepzato treatment vs. Annual treatment duration of Kimmtrak			
Drug	Dose Cost	Mean Treatments #	Total cost
Kimmtrak	$19,289	52	$1,003,028
Hepzato	t.b.d.	6	t.b.d.

**Dose Cost ASP calculated using 7/2023 CMS payment allowance limit*

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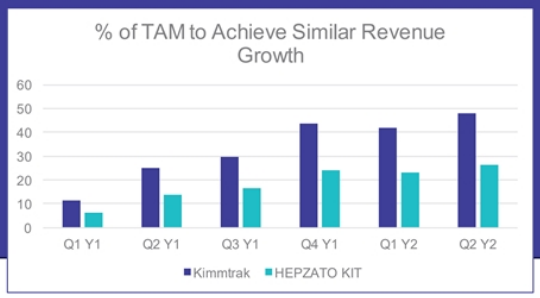
Rapid Uptake for FDA Approved Treatment in mUM



Demonstrated demand for FDA approved treatments for mUM

- KIMMTRAK - $41.7 million in Q2 2023 US sales ($167M annualized revenue)
- Only 45% of mUM patients are eligible for treatment with KIMMTRAK (unique MOA)
- KIMMTRAK captured an estimated 40% share of eligible patients within12 months

HEPZATO KIT approved August 14, 2023 to treat patients with liver dominant mUM

- mUM patients with liver involvement of <50% are eligible for treatment with HEPZATO
- HEPZATO would require <20% of eligible patients to achieve similar 4 quarter growth*
- HEPZATO has no HLA genotype restrictions and will be the only FDA approved drug for 55% of all mUM patients, as well as for KIMMTRAK failure patients

HEPZATO KIT is well positioned to capture a similar share of its TAM

- HEPZATO is more of a complement than a competitor to KIMMTRAK for patients eligible for KIMMTRAK
- HEPZATO EAP patients have included: 1st line stand alone treatment, 1st line treatment for those intending to receive KIMMTRAK, as 2nd line treatment, and as a 3rd line palliative treatment
- NCCN Guidelines currently state "regional isolation perfusion of the liver" as a recommended treatment
- "If disease is confined to the liver, regional therapies…should be considered. Since tebentafusp-tebn response rates are low, symptomatic patients may be better palliated by liver-directed treatment first…." NCCN Guidelines Melanoma Uveal V1.2023

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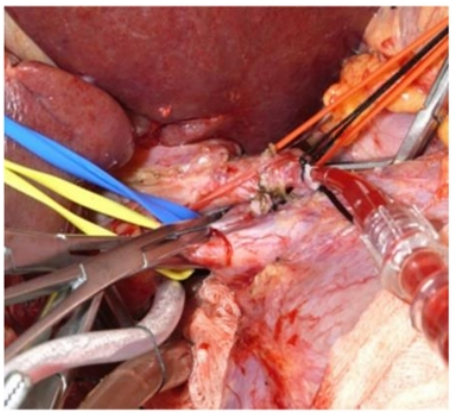
Clinical Rationale for Broad Development Effort

PHP treats the entire liver and is not dependent on tumor location or number of lesions	Promising ORR, DCR and PFS signals seen across multiple tumor types with CHEMOSAT in Europe and in earlier studies with IHP
Liver mets are often life limiting and reduce I/O efficacy	HEPZATO is the only liver directed treatment which can repeatedly treat the whole liver Early data supports that combination with I/O agents is safe and effective
Converting unresectable liver metastases into resectable	Potential for significant improvement in survival

Strong Correlation of IHP and PHP Efficacy in mUM Patients

IHP activity in CRC and NET

Meta-analysis of 8 mUM clinical studies [27]		
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 in mCRC	
Van Iersel [28]	ORR 50% mPFS 7.4 months mOS 24.8 months
Magge [29]	ORR 82% 1-year OS rate 91% 2-year OS rate 72%
Rothbart [30]	ORR 59% mTTP 7.7 months mOS 28.8 months
Bartlett [31]	ORR 76% DOR 8.5 months mOS 16 months
IHP in mNET	
Grover[32]	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.

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Chemosat Has Been Used Across Multiple Tumor Types

- CE Marked - available in ~23 centers in 4 countries
- Delcath resumed direct sales on 3/1/22
- ~1,400 commercial Chemosat kits shipped to the EU

- Strong interest to fuel additional indications driven by HCP's
- Results from over 20 retrospective and prospective trials published by independent investigators

- NICE (UK) upgraded status from "Research" to "Special Status"
- German reimbursement based on annual hospital special request ("ZE" process)
- Broader usage pending FOCUS trial publication to support reimbursement

CHEMOSAT Used In 13 Tumor Types

~70%: Metastatic Ocular Melanoma (mUM)

Other Types Treated:

- Intrahepatic Cholangiocarcinoma (ICC)
- Hepatocellular Carcinoma (HCC)
- Metastatic Colorectal Cancer (mCRC)
- Metastatic Breast (mBreast)
- Pancreatic
- Metastatic Neuroendocrine Tumors (mNET)
- Metastatic Cutaneous Melanoma (mCM)

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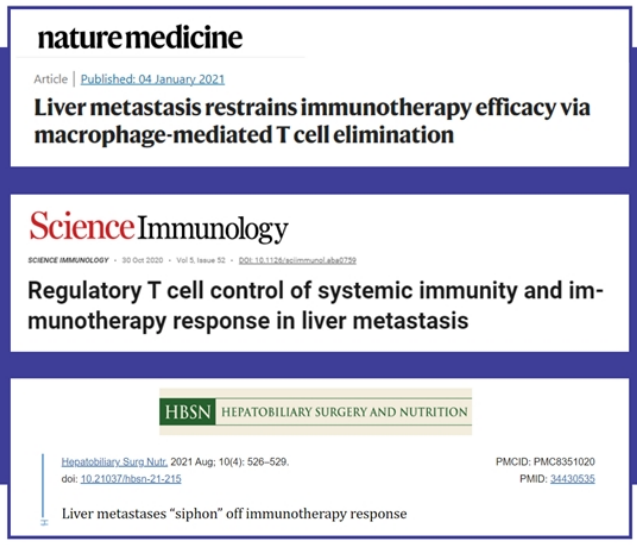
Rationale for Combining HEPZATO with IO Therapy

Liver Metastases Suppress IO Therapy Efficacy



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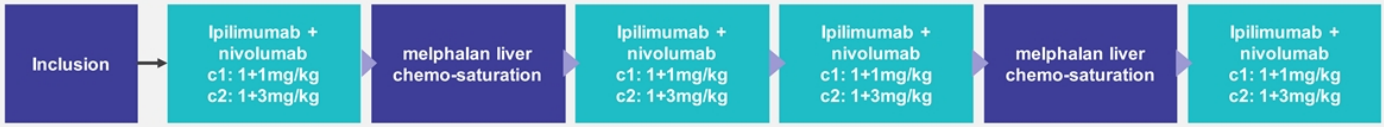
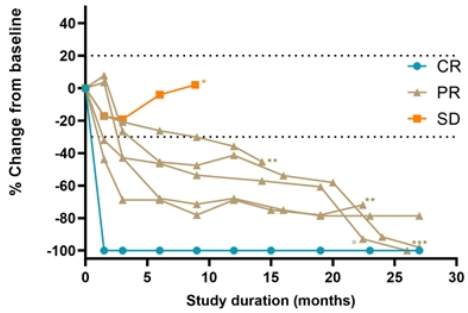
CHOPIN: Phase mUM 1b/2 randomized study of PHP vs PHP+IO



% change of target lesions from baseline by response category



* PD due to >20% increase in sum of diameter of target lesions compared to nadir
** PD due to new intrahepatic lesions
*** PD due to new extrahepatic lesion and one growing non-target intrahepatic lesion
° Patient with incomplete study treatment

- N=7 in Phase 1b portion of the trial[38]
- 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.** All patients are still alive.
- 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 50% of N=76 patients and will provide an interim analysis at N=40 patients

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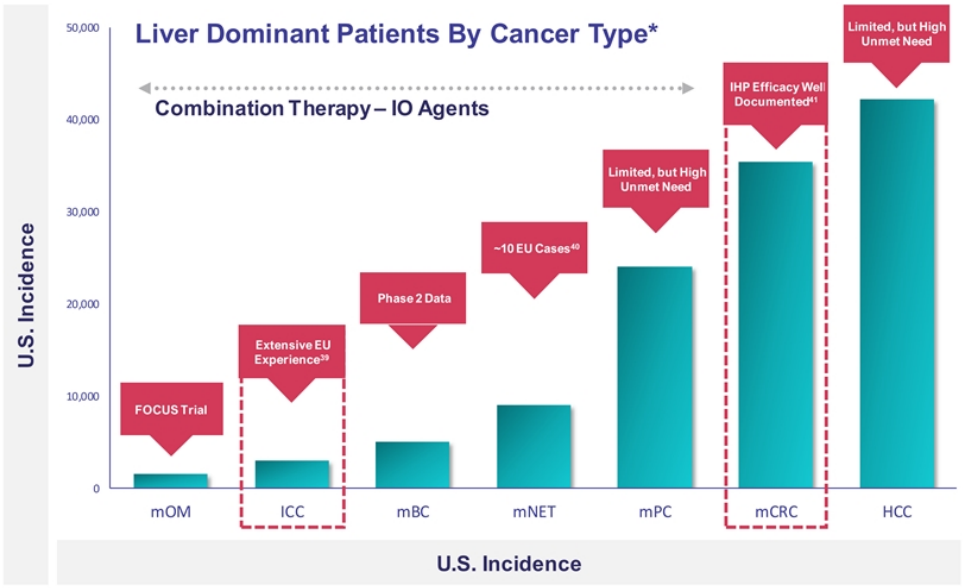
Market Expansion: Significant Investigator Interest



US TAM

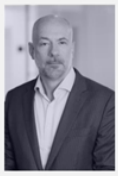
>$1B

Per Year

*Metastatic Ocular Melanoma (mUM)[1-4], Cholangiocarcinoma (ICC)[5-6], Liver-dominant Breast Cancer (mBC)[8-12], Metastatic Neuroendocrine Tumors (mNET)[8,9] Metastatic Pancreatic Cancer (mPC)[8,15], Metastatic Colorectal Cancer (mCRC)[13,14], Hepatocellular carcinoma (HCC)[17]

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

JOHN PURPURA
Chief Operating Officer

- Past VP and Exec Director roles of Reg. Affairs for Bracco Diagnostics
- Held senior roles Sanofi-Aventis, Bolar Pharma, Luitpold Pharma & Eon Labs
- M.S. Mgmnt. & Policy and B.S. Chemistry and Biology at the State University of NY at Stony Brook

BOARD OF DIRECTORS

John R. Sylvester	*Chairman*
Dr. Roger G. Stoll, Ph.D.	*Director*
Elizabeth Czerepak	*Director*
Steven Salamon	*Director*
Dr. Gil Aharon, Ph.D.	*Director*
Gerard Michel	*CEO*

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. of medtech/bioTx sales & marketing experience.
- Held senior leadership roles at BTG, ClearFlow, Aragon Surgical, Kensey Nash Corporation, and Kyphon.
- Field Artillery officer in the U.S. Army
- B.S. in Management Systems Engineering at the 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

Capital Structure and Share Information

Share Listing - Current	*DCTH (NASDAQ)*
Shares Outstanding [a]	20.3M
Cash and Cash Equivalents [b]	$14.6M
Warrants Outstanding [c]	15.56M
Stock Options Granted	2.9M
2023 Q2 Cash Burn [d]	$9.6M
Debt [e]	$9.8M
52 week Low – High [f]	$2.59 - $7.96
30d Average Daily Volume [g]	72,722

a. As of June 30, 2023; includes 15.3M of Common plus 1.1M Preferred E & E-1, 2.9M of Preferred F-2 & 1.0M Pre-funded Warrants as converted

b. As of June 30, 2023; (10-Q filing on August 9, 2023)

c. As of June 30, 2023; 3.6M warrants at a $10 exercise price, 7.78M Tranche A warrants for an aggregate exercise price $35 million exercisable until the earlier of 3/31/2026 or 21 days receipt of FDA approval for HEPZATO; and 4.17M Tranche B warrants for an aggregate exercise price $25 million exercisable until the earlier of 3/31/2026 or 21 days following recording at least $10 million in quarterly U.S. revenue.

d. Q2 Net cash used in operating activities (increase from Q1 2023 due to pay down of accrued liabilities)

e. Includes $5.0M of notes convertible at $11.98 per common share equivalent,

f. Used NASDAQ closing price information starting on July 1, 2022 – June 30, 2023

g. 30-day average calculated between May 18, 2023,- June 30, 2023

Delcath: Investment Summary

- 4Q launch in mUM
- KIMMTRAK proving out significant commercial opportunity (~$167M run rate) with 45% of the HEPZATO TAM
- High penetration likely due to NCCN guidelines including PHP and equivalent OS as KIMMTRAK in more advance patient population
- Management team experienced in commercializing high value, specialty products
- Multiple 2023/2024 catalysts (Launch, CHOPIN data, Revenue Build)
- Potential high value follow-on indications and strategic interest creates significant upside

THANK YOU

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