UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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 5, 2024

DELCATH SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

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

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

Registrant's telephone number, including area code: (212) 489-2100

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 (see General Instruction A.2. below):

☐ 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	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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 January 5, 2024, Delcath Systems, Inc. (the "Company") 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 99.1 and incorporated by reference in this Item 7.01.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any of the Company's filings with the Securities and Exchange Commission under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such a filing, except as otherwise expressly stated in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Corporate Presentation dated January 5, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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 hereunto duly authorized.

DELCATH SYSTEMS, INC.

Date: January 8, 2024

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

Exhibit 99.1

Delcath

Corporate Presentation

NASDAQ: DCTH

January 2024

Table of Contents

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: 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.

Delcath Investment Summary

HEPZATO KIT
- FDA approval for mUM* 8/14/23
- 1Q 2024 US Launch

Commercial Opportunity
- Ultra orphan pricing
- Focused call points
- US mUM TAM ~$600M

High Penetration
- Included in NCCN Guidelines
- First and only FDA approved whole-liver directed therapy

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

Significant upside beyond mUM
- Strong efficacy signals in multiple other tumor types
- Unique interventional oncology asset

Multiple 2024 Catalysts
- Launch
- Revenue build
- CHOPIN enrollment completion
- Initiate trials in other indications

** metastatic Uveal Melanoma (mUM)*

HIGH UNMET NEED:

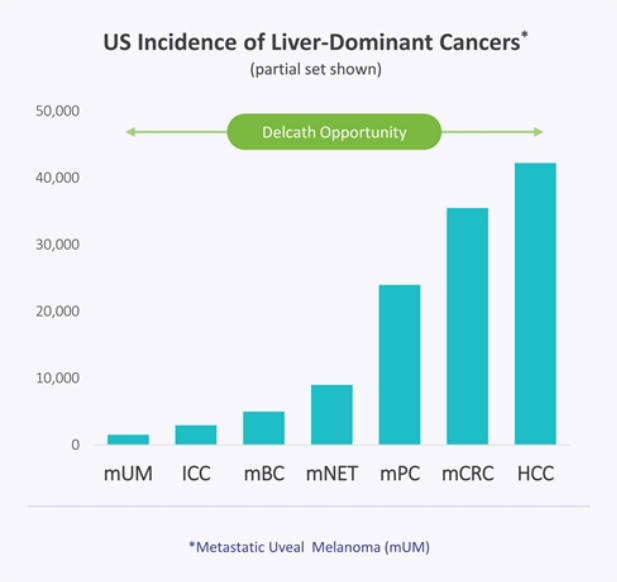
Liver-Dominant Cancers

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.

Current 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

SIRT (Y90)[3]

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

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

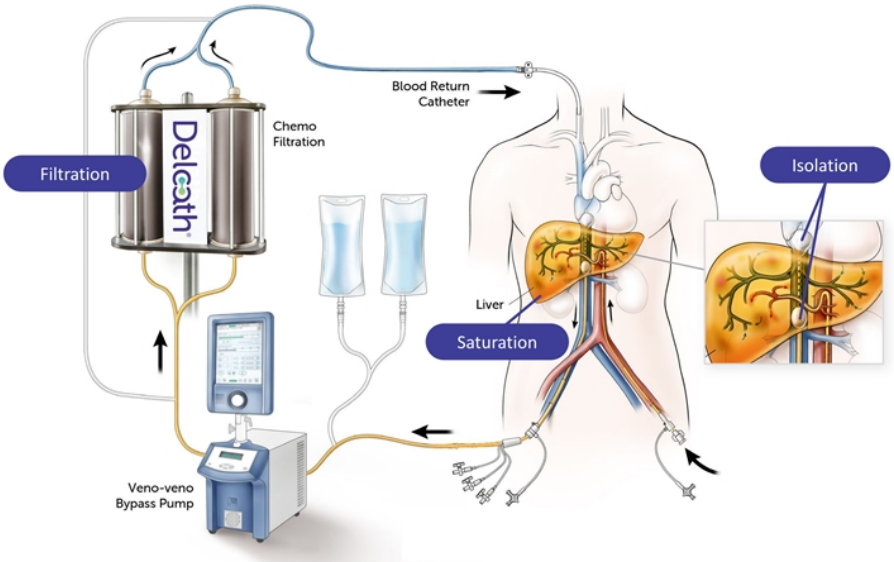
Hepatic venous flow is isolated, enabling >6X greater local concentration of chemo

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

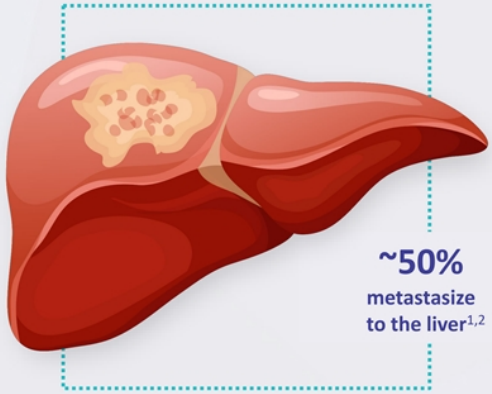
HEPZATO KIT is indicated as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation.

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

Metastatic Uveal Melanoma (mUM)

mUM: Beachhead Market Opportunity

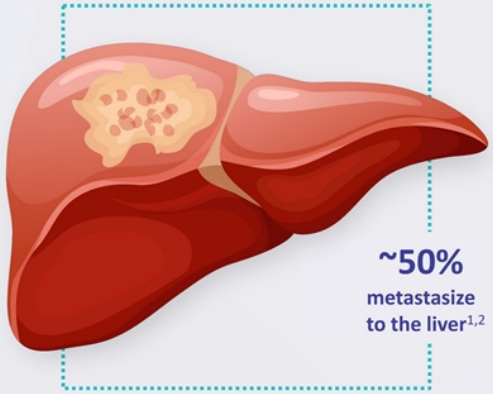
- **~2,000 newly diagnosed cases** of primary uveal melanoma per year in the US[2]
- 50% metastasize with the **liver involved in >90% of cases** of metastatic disease[5,6] **(1,000 mUM patients)**[2,3]
- **1-year OS rate** of patients with metastatic disease in the liver is **13%**
  - median survival ranging from **4 to 15 months**[2,7]



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

mUM: Beachhead Market Opportunity

- Most patients with mUM die **from liver failure**[6]
- In 50% of mUM patients, the liver is the only site of metastasis[5,6]
- **Liver-directed treatment achieves better efficacy** compared to systemic therapy[8]
- **55%** of patients have **no approved systemic treatment** option
- Most patients treated with **multiple lines of therapy**

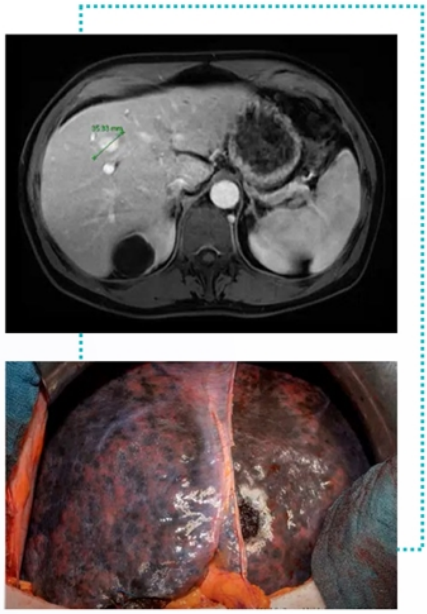


[1] Reddy S, et al. Isolated hepatic perfusion for patients with liver metastases, Ther Adv Med Oncol. 2014 Jul; 6(4): 180-194.
[2] Xu L, T, Funchain P, F, Bena J, F, Li M, Tarhini A, Berber E, Singh A, D: Uveal Melanoma Metastatic to the Liver: Treatment Trends and Outcomes. Ocul Oncol Pathol 2019;5:323-332. doi: 10.1159/000495113.
[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.
[8] Olofsson BR, et al. Isolated Hepatic Perfusion With Melphalan for Patients With Isolated Uveal Melanoma Liver Metastases: A Multicenter, Randomized, Open-Label, Phase III Trial (the SCANDIUM Trial). J Clin Oncol. 2023 Jun 1;41(16):3042-3050

Diffuse/Miliary Metastatic Pattern in mUM

Diffuse Disease is Difficult to Treat with Other Liver Directed Options

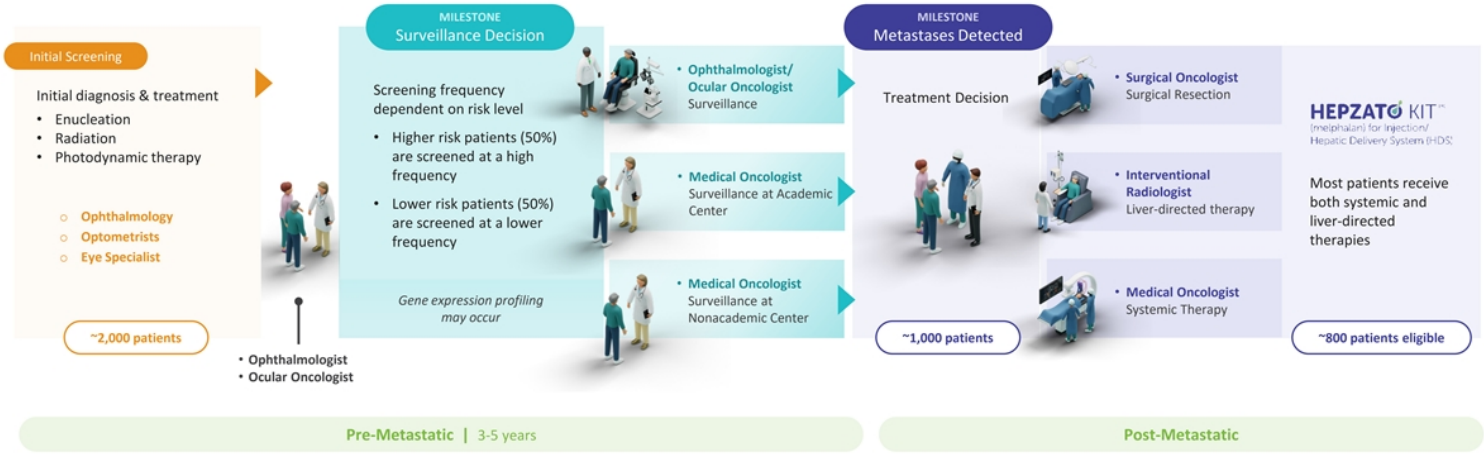
- Solitary **liver lesions** are often treated with **surgery or ablation**.
- True nature of the disease may **only be seen upon visual confirmation**.
- Radiographically, metastatic Uveal Melanoma can **initially present** only as **focal lesions**.
- Traditional **liver-directed therapy** mechanism 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 patient sent for a liver resection based upon radiographic diagnosis*

* Data on File

Patient Journey




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

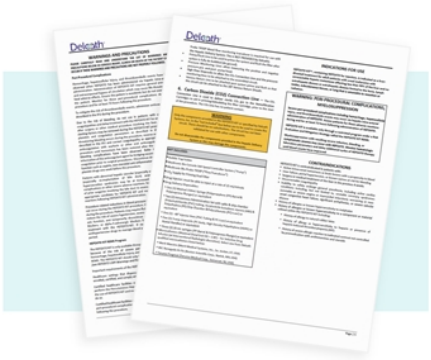
TN = Treatment Naïve, AL = Any Line

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

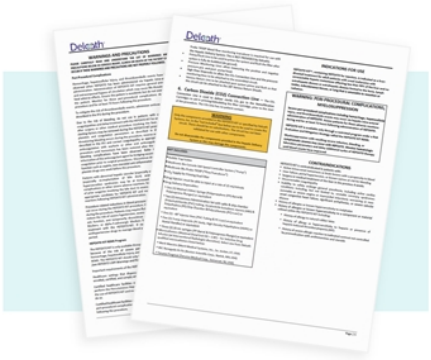


- Most hematological side effects result from melphalan
- Side effect profile similar to standard melphalan use

	Adverse Reactions (N=95) >10%	
	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 reactions are described further in the HEPZATO KIT PI.

Adverse Events



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

Adverse reactions are described further in the HEPZATO KIT PI.

	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.*

HEPZATO KIT:

Commercialization

Delivering an Innovative Treatment with a Well-Trained Team

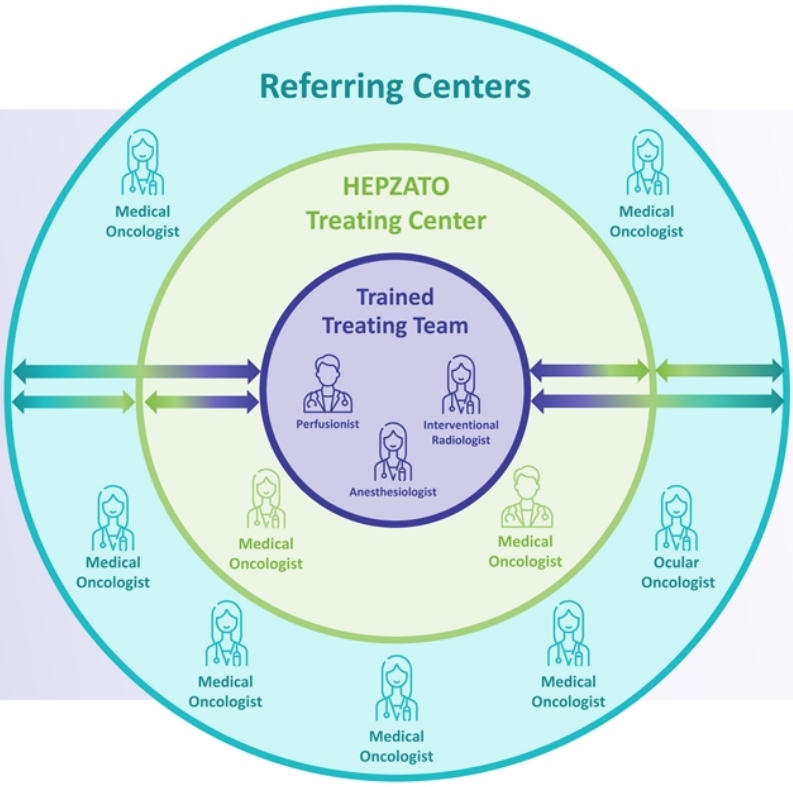
Treatment with HEPZATO KIT involves training and a team approach. The team members below complete a preceptorship and proctorship as well as a risk evaluation and mitigation strategy (REMS) training.

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

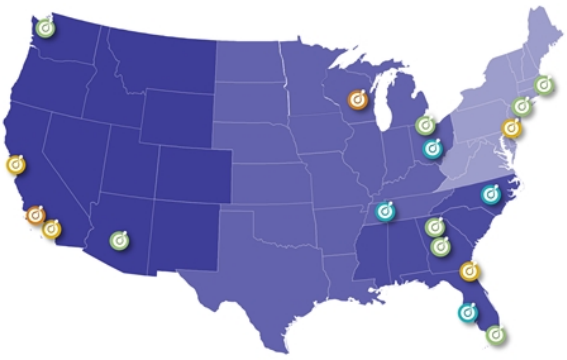
Three Complementary Teams of Representatives:

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

Treatment Sites

Interest from 20+ sites

- Focused on a subset of sites to ensure we achieve our planned activation targets throughout the year



Fully Trained
Pending Preceptorship
Pending Proctorship
Strong Interest/Commitment

CENTER	CITY	STATE
FULLY TRAINED		
Duke University	Durham	NC
Moffitt Cancer Center	Tampa Bay	FL
Ohio State University	Columbus	OH
University of Tennessee	Memphis	TN
PENDING PROCTORSHIP		
Mayo Clinic Jacksonville	Jacksonville	FL
Stanford University	Stanford	CA
Thomas Jefferson University	Philadelphia	PA
University of California, Los Angeles	Los Angeles	CA
PENDING PRECEPTORSHIP		
St. John (Cedars)	Los Angeles	CA
University of Wisconsin	Madison	WI
STRONG INTEREST/COMMITMENT		
Cleveland Clinic	Cleveland	OH
Emory University	Atlanta	GA
Honor Health	Scottsdale	AZ
Massachusetts General Hospital	Boston	MA
Memorial Sloan Kettering	New York	NY
Piedmont Healthcare	Atlanta	GA
University of Miami	Miami	FL
University of Washington Fred Hutchinson Cancer Center	Seattle	WA

Status as of January 2024

Demonstrated Demand for FDA Approved Treatment in mUM

KIMMTRAK

- $42.1 million in Q3 2023 US sales ($168M annualized revenue)
- Captured an estimated 40% share of eligible patients within 12 months
- Approximately 360* patients are eligible for KIMMTRAK
- Only 45%* of mUM patients 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
- Only FDA approved drug for 100% of all mUM patients, with appropriate liver involvement

*Due to HLA genotype restrictions

HEPZATO KIT:

Reimbursement & Pricing

Reimbursement

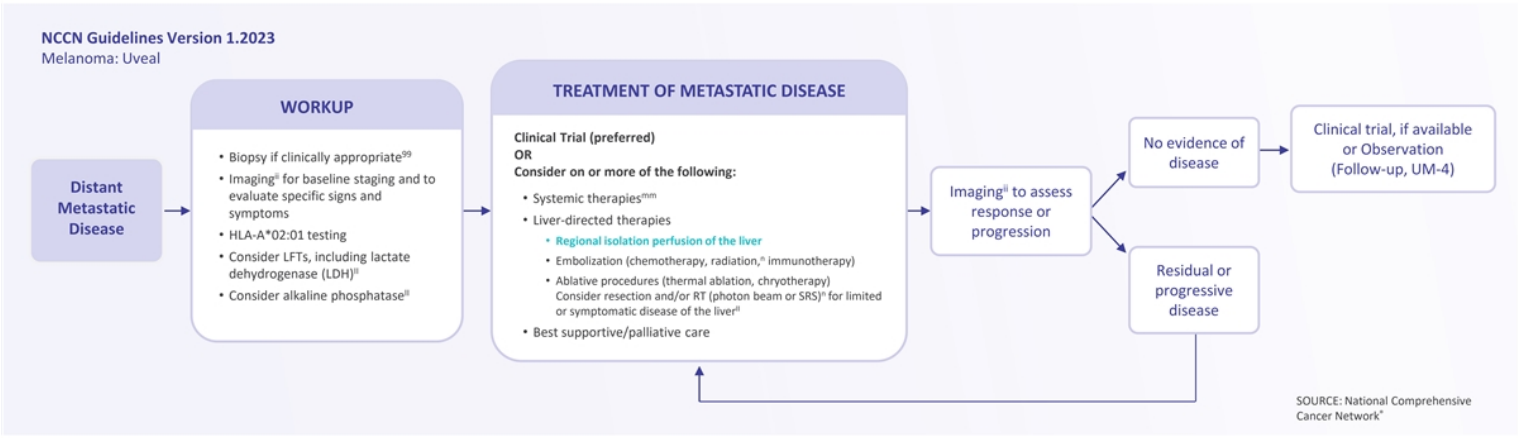
Medicare Patients

- **C-Code and J-Code under review and expected 2024 H1**
- **Majority of patients will be outpatient**
  - Drug directly covered by Medicare as pass through

Private Payer Patients

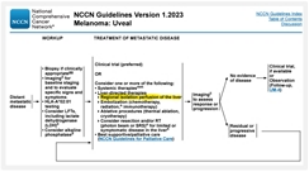
- **Follow Medicare guidelines**
  - For rare disease
  - Patients to be treated as outpatients
- **Medical Prior-Authorization of patients likely required**
  - Delcath has engaged a hub service to assist with benefit verification and navigation
- **Centers of Excellence (Prospective Payment System (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.



Components of Hospital Reimbursement

Assuming Outpatient Pass Through Status with C-Code

DRUG

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

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

CPT Code mapping complete
No meaningful impact on treatment decisions

HEPZATO KIT Pricing

Consistent with Only Other Approved mUM Therapy

At First Assessment (first time to discontinue treatment because of progression)			
DRUG	**DOSE COST***	**TREATMENTS #****	**TOTAL COST**
KIMMTRAK	$19,289	24	$462,936
HEPZATO	$182,500	2	$365,000

Mean HEPZATO treatment vs. mean treatment duration of KIMMTRAK (per pivotal trials)			
DRUG	**DOSE COST***	**MEAN TREATMENTS #*****	**TOTAL COST**
KIMMTRAK	$19,289	41	$790,849
HEPZATO	$182,500	4.1	$748,250

*Dose Cost ASP calculated using 7/2023 CMS payment allowance limit
** Minimum treatments prior to determining progression based on trial protocols
*** Mean from published phase 3 trials

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 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

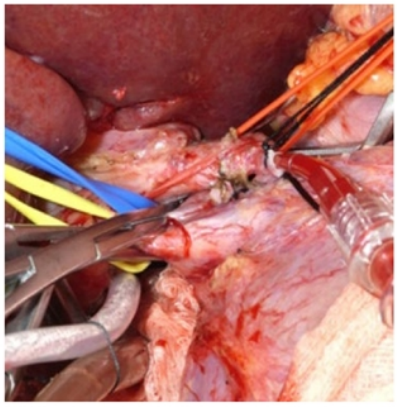
Potential for sequential usage with Immune-Oncology (I/O) agents

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

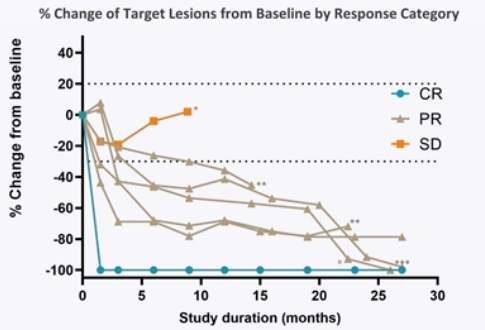
ORIGINAL ARTICLE

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

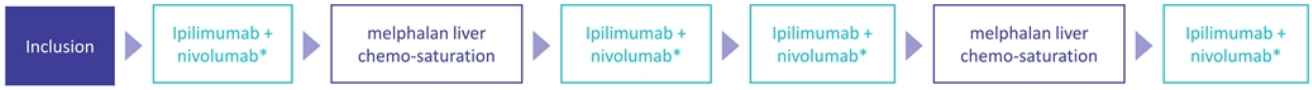
First published: 03 December 2021 | https://doi.org/10.1002/hep.32266 | Citations: 2

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. 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



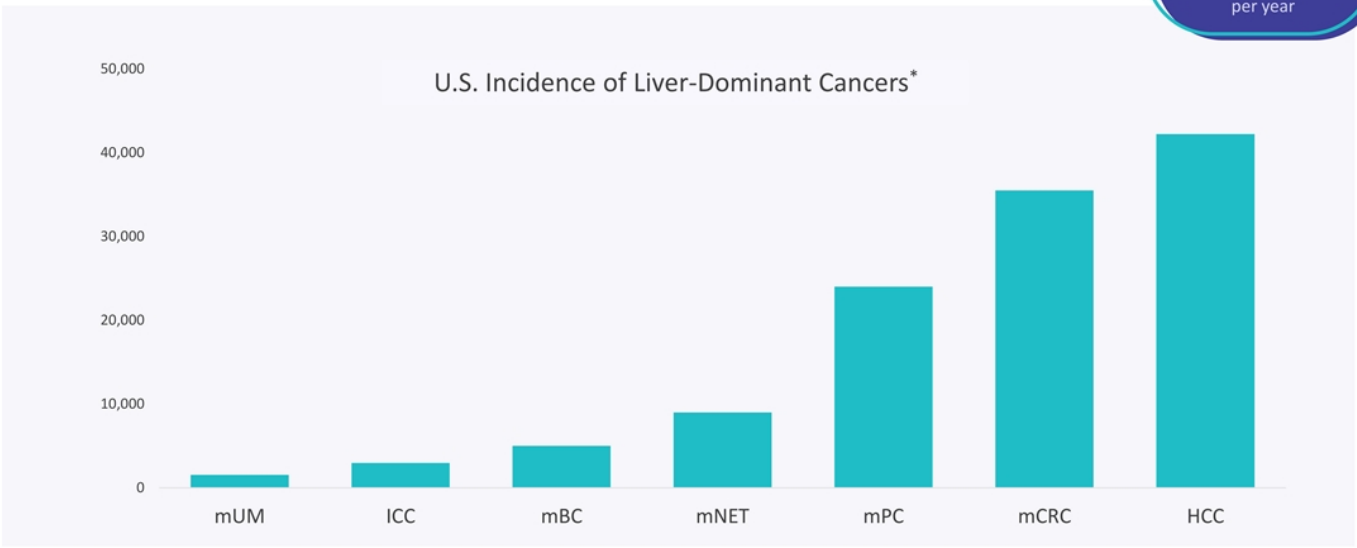
*c1: 1+1mg/kg, c2: 1+3mg/kg

[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.

Market Expansion

Significant Upside

U.S. TAM
>$1B
per year



*Metastatic Uveal Melanoma (mUM)

HEPZATO KIT:

Financials and Team

Capital Structure and Share Information

Share Listing - Current	DCTH (NASDAQ)
Shares Outstanding [a]	28.6M
Cash and Cash Equivalents [b]	$40.5M
Warrants Outstanding [c]	7.8M
Stock Options Granted	4.1M
2023 Q3 Cash Burn [d]	$9.7M
Debt [e]	$9.8M
52 week Low – High [f]	$2.25 - $7.99
30d Average Daily Volume [g]	351,474

a. As of September 30, 2023; includes 19.7M of Common plus; 1.1M Preferred E & E-1, 1.5M of Preferred F-2; 4.8M of Preferred F-3; Conversion of convertible notes .5M; & 1.0M Pre-funded Warrants as converted. Does not include Tranche B Outstanding Warrants.

b. As of September 30, 2023; (10-Q filing on November 13, 2023) which includes $35M received from Tranche A warrants exercised 21 days after receipt of FDA approval for HEPZATO;

c. As of September 30, 2023; 3.6M warrants at a $10 exercise price 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. Q3 Net cash used in operating activities

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

f. Used NASDAQ closing price information starting on December 20, 2022 – December 20, 2023

g. 30-day average calculated between on December 4, 2023 – January 4, 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

John Purpura
CHIEF OPERATING OFFICER

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

BOARD OF DIRECTORS

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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. 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


Delcath
Thank You

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