UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): March 27, 2023

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

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

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

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

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $.01 par value	DCTH	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On March 27, 2023, Delcath Systems, Inc. (the "Company") updated its corporate presentation. A copy of the slides used in the presentation are attached hereto as Exhibit 99.1. The furnishing of the attached corporate presentation is not an admission as to the materiality of any information therein. The information contained in the slides is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures. For important information about forward looking statements, see the slide titled "Forward Looking Statements" in Exhibit 99.1 attached hereto.

The information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto 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 or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 and in the presentation attached as Exhibit 99.1 to this Current Report shall not be incorporated by reference into any filing with the SEC made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1	Delcath Systems, Inc. Corporate Presentation Dated March 27, 2023
104	Cover Page Interactive File (the cover page tags embedded within the Inline XBRL document)

SIGNATURE

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

DELCATH SYSTEMS, INC.

Date: March 27, 2023

By: /s/ David Hoffman
Name: David Hoffman
Title: General Counsel

Exhibit 99.1

Delcath

Corporate Presentation

(NASDAQ: DCTH)

March 26, 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 news release contains forward-looking statements, which are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to, uncertainties relating to: actions by the FDA relating to the application; the ability of the Company to respond to FDA queries related to the application; the Company's successful inspections by the FDA or foreign regulatory agencies; 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 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; the Company's ability to successfully commercialize the HEPZATO and the potential of the HEPZATO KIT/CHEMOSAT system as a treatment for patients with primary and metastatic disease in the liver; our ability to obtain reimbursement for commercialized product in various markets; the Company's ability to successfully enter into strategic partnership and distribution arrangements and the timing and revenue, if any, of the same; uncertainties relating to the timing and results of research and development projects; and uncertainties regarding the Company's ability to obtain financial and other resources for any research, development, clinical trials and commercialization activities. These factors, and others, are discussed from time to time in our filings with the Securities and Exchange Commission. You should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. We undertake no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.

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

FOCUS pivotal trial
- Metastatic Ocular Melanoma (mOM)
- Primary endpoint met
- NDA resubmitted

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

PDUFA Date: 8/14/23

LARGE MARKET OPPORTUNITY

Near-term (mOM)
- >$600 TAM in US/EU
- Unsurpassed 1 year survival data

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

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[15]

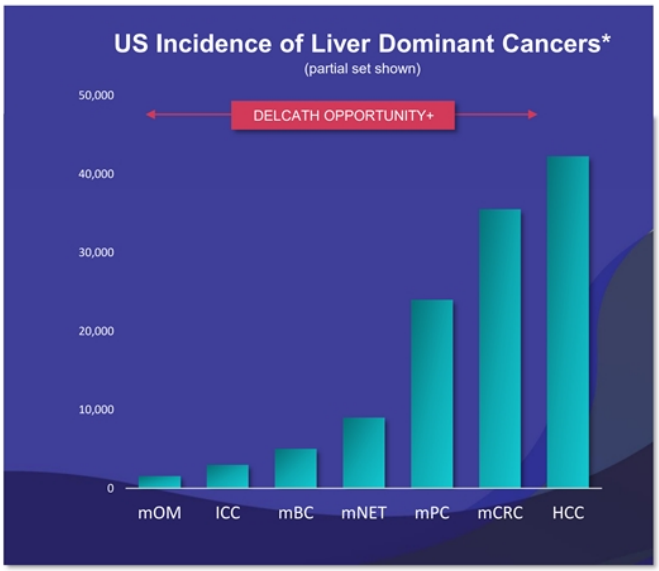
Liver: Common Site of Metastases

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



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*Metastatic Ocular Melanoma (mOM)[1,2], Cholangiocarcinoma (ICC)[3,4], Liver-dominant Breast Cancer (mBC)[7-10], Metastatic Neuroendocrine Tumors (mNET)[6,7] Metastatic Pancreatic Cancer (mPC)[7,13], Metastatic Colorectal Cancer (mCRC)[11,12], Hepatocellular carcinoma (HCC)[15]

Limitations of Current Liver-Directed Therapies

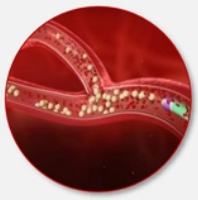
Majority of Treatment

Trans Arterial Chemo Embolization (TACE)[17]

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

Y90[16]

- 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

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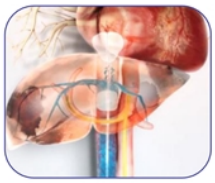
HEPZATO™ Kit: Enables Percutaneous Hepatic Perfusion (PHP)

Repeatable, safe & effective liver-focused disease control

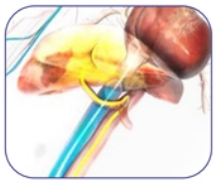
ISOLATION

Hepatic venous flow is isolated, enabling 12x increased dose



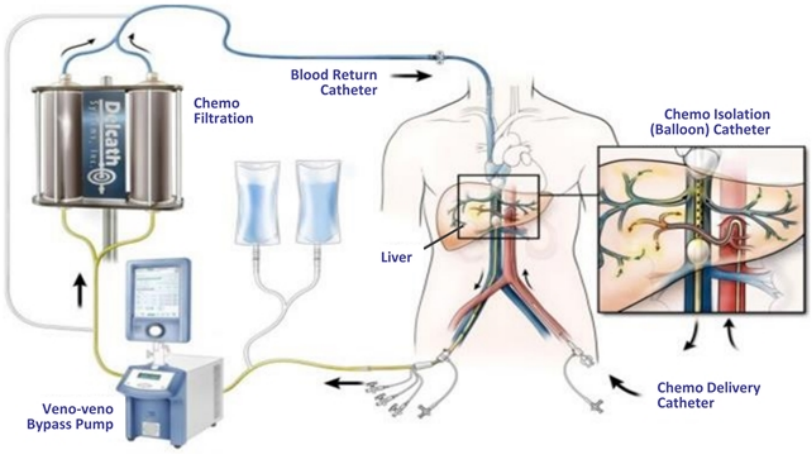
SATURATION

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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mOM: Beachhead Market Opportunity

High Unmet Need, Favorable Reimbursement Environment

Unmet Need

- >5,000 cases of primary ocular melanoma per year in the US/EU[12,34], ~50% metastasize to the liver[2,35]
- US TAM ~800 patients, Europe ~1,200 patients
- Median survival up to 12 months.[36]
- 55% of patients have no approved treatment option, most patients treated with multiple lines of therapy

Low Risk Opportunity

- FOCUS pivotal trial has met primary endpoints to support approval in mOM[37]
- Significantly improved safety profile over Gen 1 filter technology
- Real world safety and efficacy demonstrated in EU

High Barrier to Entry

- Orphan indication status allows for extended exclusivity
- HEPZATO is a combination drug device regulated by CDER – no ANDA pathway
- IP prevents simple 505(B)(2) follow-on

Favorable US Commercial Economics

- Favorable US reimbursement environment for ultra orphan outpatient MD administered drugs
- Kimmtrak (approved for ~45% of mOM population) priced at an average of $800K per patient and ended 1st year at >$150M run rate in the US
- 20 US treatment centers = ~80% patients

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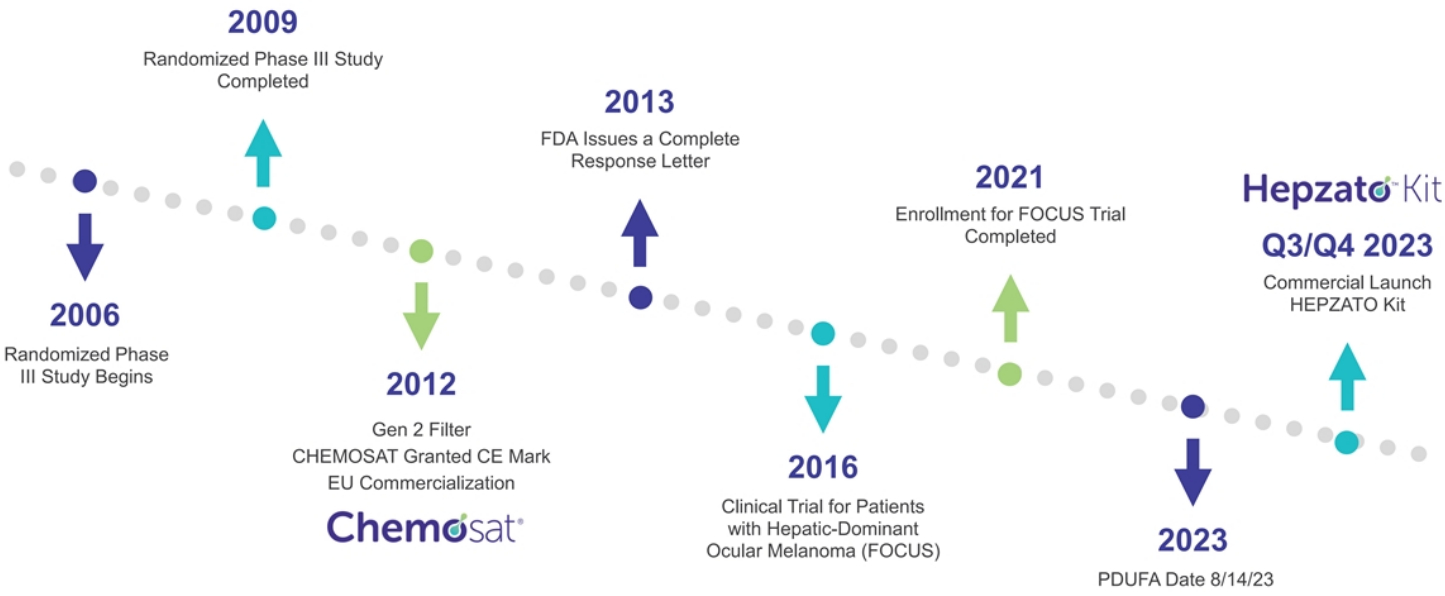
History of HEPZATO Kit Development



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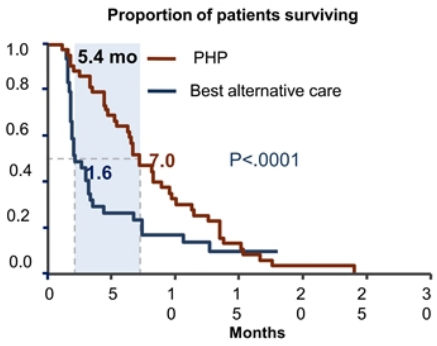
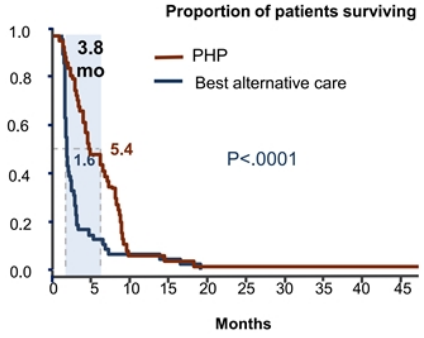
First Phase 3 RCT Results* - Primary Efficacy Endpoint Met

Hepatic Progression Free Survival (IRC Assessment)



Hazard Ratio (95% CI) = 0.39

Overall Progression Free Survival (INV Assessment)



Hazard Ratio (95% CI) = 0.42

Response Rates (ITT population)

Cohort	PHP (N=44)	BAC (N=49)	P-Value
hOR	36.4%	2.0%	<0.001
ORR	27.3%	4.1%	=0.003

Crossover design confounded overall survival analysis – most subjects in BAC arm [57.1%] crossed over to PHP arm

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*Mix of mOM and metastatic melanoma with >90% patients diagnosed with mOM - NDA 201848 Clinical Study Report dated 15 August 2012.

Safety Issues from 1st Phase 3 and Resulting Improvements

Safety Issues Primarily Due to Filter

Hematological toxicities led to 3 patient deaths

Adverse Event G3/4	Gen 1 Hughes 2016[28]	
	%	n
Anemia	62.9%	44
Neutropenia	85.7%	60
Thrombocytopenia	80.0%	56

Inappropriate patient selection and procedural issues led to 1 patient death and other AE's

- ~90% liver involvement causing tumor lysis syndrome

Improvement

Gen 2 Filter introduced in 2013

Adverse Event G3/4	Gen 2 Karydis 2018[33]		% Improvement Gen 1 → 2
	%	n	
Anemia	29.4%	15	53% ↓
Neutropenia	31.3%	16	64% ↓
Thrombocytopenia	31.3%	16	61% ↓

- Protocol amendments were put in place for patient selection
- Training improved

FDA required these issues be addressed prior to the start of the FOCUS trial

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FOCUS Trial

2nd Registration Clinical Trial for Patients with mOM

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 subjects 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
- Initially a RCT against Best Alternative Care (BAC)
  - Subsequently modified with FDA agreement to single-arm trial
  - FDA will view the comparisons with the 32 patient BAC arm as supportive exploratory analyses

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2020 –'23 Initial Approvals Using ORR in Single-Arm Oncology Trials

Product	Indication	N	ORR
Gavreto (pralsetinib)	Metastatic *RET* NSCLC	114	naïve = 70%, exp. = 57%
Monjuvi (tafasitamab-cxix)	Relapsed or refractory large B-cell lymphoma	71	39%
Tazverik (tazemetostat)	Lymphoma positive for EXH2 mutation	95	mutant = 69%, wild-type = 34%
Zepzelca (lurbinectedin)	Metastatic SMLC 2nd Line	105	35%
Tabrecta (capmatinib)	mNSCLC with mutation MET exon 14 skipping	97	naive = 68%' exp. = 41%
Trodelvy (sacituzumab)	3rd Line Metastatic triple-negative BC	108	33.3%
Koselugo (selumetinib)	Neurofibromatosis Type 1	50	66%
Ayvakit (avapritinib)	mGIST with PDGFRA exon 18 mutation	43	84%
Pemazyre (pemigatinib)	Previously treated ICC with FGFR2 fusion	107	36%
Fyarro (sirolimus)	Malignant perivascular epithelioid cell tumor	31	39%
Tivdak (tisotumab vedotin-tftv)	2nd Line cervical cancer	101	24%
Exkivity (mobocertinib)	mNSCLC w/ EGF mutations	114	28%
Jemperli (dostarlimab-gxly)	MMRD recurrent or advanced solid tumors – 2nd line	209	41.6%
Welireg (belzutifan)	von Hippel-Lindau disease +RCC, blastomas, or NET	61	49%
Truseltiq (infigratinib)	2nd Line ICC with a FGF 2 fusion	108	23%
Lumakras (sotorasib)	KRAS G12C mutated mNSCLC	124	36%
Rybrevant (amivantamab-vmjw)	mNSCLC with EGFR exon 20 insertion mutations	81	40%
Jemperli (dostarlimab-gxly)	MMRD endometrial cancer, 2nd Line.	71	42.3%
Libtayo (cemiplimab-rwlc)	Metastatic BCC	112	meta. = 21%, adv. = 29%
Tepmetko (tepotinib)	mNSCLC w/ met exon 14	152	43%
Lunsumio (mosunetuzumab)	Relapsed or refractory follicular lymphoma	90	80%
Krasati (adagrasib)	KRAS G12C-mutated NSCLC	112	38.4%
Elahere (mirvetuximab soravtansine-gynx)	FRα positive, ovarian, fallopian tube, or primary peritoneal	106	31.7%
Jaypirca (pirtobrutinib)	Relapsed/refractory mantle cell lymphoma	120	50%

Focus Trial Success Criteria - Informed By FDA Interactions

Critical Single Arm Efficacy End Points*

- "Clinically Meaningful" ORR**
  - » Trial powered to show an advantage over immuno-oncology (IO) agents
  - » Lower bound at 95% Confidence Interval needed to exceed 8.3%
- "Clinically Meaningful" DOR***
  - » >6 months

Overall Risk Benefit Assessment

- Significantly improved safety relative to first pivotal trial
- Positive trends in exploratory BAC comparisons (ORR, DOR, DCR, PFS and OS)

Best Alternative Care (BAC) Arm	Enrolled N=42	Treated N=32
Dacarbazine	1	0
Ipilimumab	7	1
Pembrolizumab	8	6
TACE	26	25

* Per FDA and SAP ORR is the primary endpoint and per FDA primary analysis population will be treated patient population (SAP defined ITT as primary analysis population)

** FDA did not object to using a meta-analysis of checkpoint inhibitors "to provide support for a clinically meaningful ORR" (476 patients from 16 publications, 95% Confidence Interval for ORR of 3.6% - 8.3%)

*** FDA specified that DOR would be the critical secondary endpoint and requested that patients be followed for at least 6 months to assess durability of response

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FOCUS Trial Analysis: Prespecified Endpoint Met*

ORR Advantage Coupled With Meaningful Duration of Response

ORR and DCR in the Treated Population

Efficacy Endpoint	PHP (n=91)	BAC (n=32)	*p* Value†
ORR, n (%)	33 (36.3)	4 (12.5)	0.0133
[95% CI]	[26.44, 47.01]	[3.51, 28.99]	
DCR, n (%)	67 (73.6)	12 (37.5)	0.0005
[95% CI]	[63.35, 82.31]	[21.10, 56.31]	

† Fisher's Exact Test

26.44% >> 8.3% prespecified threshold**
Exploratory comparison versus BAC supportive

DOR in the Treated Population

	PHP (n=91)	BAC (n=32)
Median DOR, months	14	NC
[95% CI]	[8.31-17.74]	[6.93-NC]
Patients with confirmed CR or PR	33 (7 CR, 26 PR)	4 (all PR)
Patients with subsequent PD, n (%)	16 (48.5)	1 (25.0)
Censored, n (%)	17 (51.5)	3 (75.0)

14 Month Duration of Response
7 Complete Responses

* 02-Dec-2022 data cut, data continues to mature and patients will be followed at least through May, 2023

* * Meta-analysis of checkpoint inhibitors (476 patients,16 publications) calculated a 95% Confidence Interval for ORR of 3.6% - 8.3%

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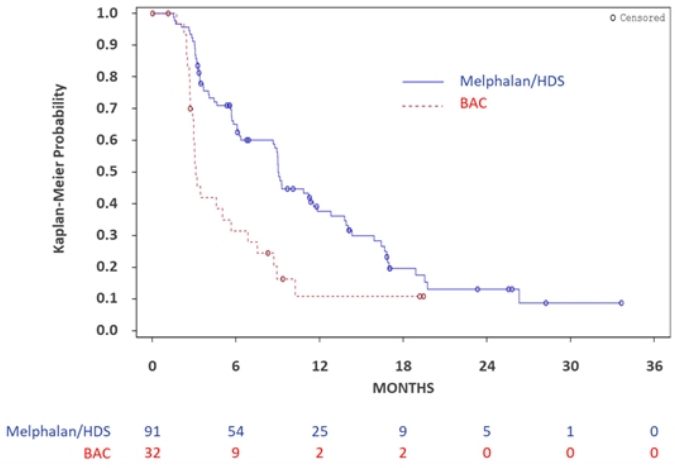
Progression Free Survival

Kaplan Meier Curves in Treated Populations*



Melphalan/HDS	91	54	25	9	5	1	0
BAC	32	9	2	2	0	0	0

* 02-Dec-2022 data cut, data continues to mature and patients will be followed at least through May, 2023

Pre-Specified Exploratory Analyses*

Secondary Endpoint	PHP (n=91)	BAC (n=32)	*p* Value
Median PFS, months	9.03	3.12	0.0003†
[95% CI]	[6.34, 11.56]	[2.89, 5.65]	
PFS status, n (%) Events	67 (73.6)	25 (78.1)	
Censored	24 (26.4)	7 (21.9)	
Hazard Ratio Estimate	0.39		0.0002‡
[95% CI]	[0.23, 0.63]		

†Log-Rank test.

‡Chi-Square test.

Exploratory comparison versus BAC supportive

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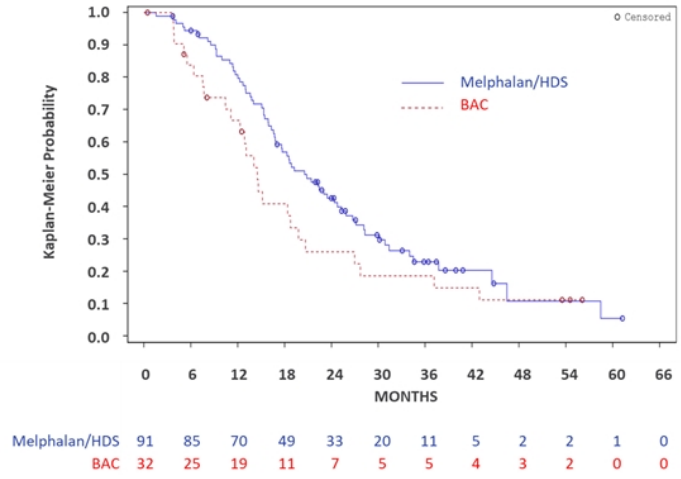
Overall Survival

Kaplan Meier Curves in Treated Populations*



** 02-Dec-2022 data cut, data continues to mature and patients will be followed at least through May, 2023

Pre-Specified Exploratory Analyses*

Secondary Endpoint	PHP (n=91)	BAC (n=32)	*p* Value
Median OS, months	20.53	14.49	0.1077†
[95% CI]	[16.79, 25.26]	[11.10, 19.78]	
OS status, n (%) Events	67 (73.6)	25 (78.1)	
Censored	24 (26.4)	7 (21.9)	
Hazard Ratio Estimate	0.68		0.1110‡
[95% CI]	[0.42, 1.09]		

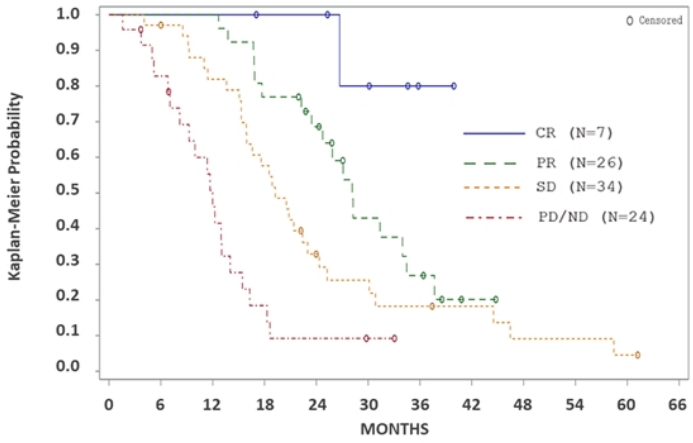
†Log-Rank test.

‡Chi-Square test.

Exploratory comparison versus BAC supportive

Overall Survival Comparison by Best Overall Response

Kaplan Meier Curves in Treated Populations*



CR	7	7	7	6	6	4	1	0			
PR	26	26	26	20	16	8	5	1	0		
SD	34	33	27	19	9	7	5	4	2	2	1
PD/ND	24	19	10	4	2	1	0				

Post Hoc 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, data continues to mature and patients will be followed at least through May, 2023

Analysis Supports that ORR is Clinically Meaningful

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Adverse Events Are Predictable and Manageable

Related Serious Adverse Events Occurring in >5% of PHP Patients

Category, n (%)	FOCUS Trial (n=95)
Thrombocytopenia*	14 (14.7%)
Neutropenia†	10 (10.5%)
Febrile neutropenia	7 (7.4%)
Leukopenia‡	5 (5.3%)

*Thrombocytopenia includes thrombocytopenia (8, 8.4%) and platelet count decreased (6, 6.3%)
†Neutropenia includes neutropenia (8, 8.4%) and neutrophil count decreased (2, 2.1%)
‡Leukopenia includes leukopenia (4, 4.2%) and white blood cell count decreased (1, 1.1%)

Hematological Toxicities - Comparison with Previous Trials*

Grade 3 or higher Adverse Events, Post-procedural	FOCUS Trial* (n=91)	Hughes 2016 (n=70)
Anemia	8 (8.8%)	44 (62.9%)
Thrombocytopenia	27 (29.7%)	56 (80.0%)
Neutropenia†	27 (29.7%)	60 (85.7%)

Hematological AE's consistent with European experience

*Data cut on 02-Dec-2022

† In the FOCUS Trial, "febrile neutropenia" was included under the category of "neutropenia." In Hughes 2016, "febrile neutropenia" was considered its own category; 12 patients (17.1%) experienced febrile neutropenia.

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FOCUS Trial – Safety Comparison with Previous Trials*

Category	FOCUS Trial (N=95)	Pooled Analysis of Prior Studies (N=121)
Patients who Withdrew due to an AE or SAE	17 (17.9%)	46 (38%)
Patients who Received a Reduced Dose due to an AE or SAE	12 (12.6%)	27 (22.3%)
Average Number of Cycles	4.1	2.8

Improvement in tolerability led to a larger number of treatments

* Data cut on 02-Dec-2022

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FOCUS Trial Comparison to Other Published Studies*

Clinical Study/Publication	Study Type	Treatment	N	Median OS (months) (95% CI)	Median PFS (months) (95% CI)
FOCUS	Single-Arm	Hepzato	91[AL]	20.53 (16.79 to 25.26)	9.03 (6.34 to 11.56)
Khoja et al 2019[13] (based on 29 articles)	Meta-Analysis	systemic and liver-directed therapies	912	10.2 (9.5 to 11.0)	3.3 (2.9 to 3.6)
Rantala et al 2019[14] (based on 78 articles)	Meta-Analysis	systemic and liver-directed therapies	2494	12.84 (12.00 to 13.56)	-
Piulats et al 2021[11]	Single-Arm	ipilimumab plus nivolumab	52[TN]	12.7 (7.1 to 18.3)	3.0 (2 to 4.1)
Heppt et al 2019	Single-Arm	ipilimumab + (pembrolizumab or nivolumab)	64[AL]	16.1	3.0
Nathan et al 2021[9]	Randomized	tebentafusp	252[TN]	21.7 (18.6 to 28.6)	3.3 (3 to 5)
		control	126[TN]	16 (9.7 to 18.4)	2.9 (2.8 to 3)

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

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Expanded Access Program (EAP)

Institution	City	Principal Investigator	Status
Moffitt Cancer Center	**Tampa, Florida**	**Dr. Jonathan Zager**	**Open and Enrolling**
Duke University	**Durham, North Carolina**	**Dr. Georgia Beasley**	**Open and Enrolling**
University of Tennessee	**Memphis, Tennessee**	**Dr. Evan Glazer**	**Open and Enrolling**
Thomas Jefferson University	**Philadelphia, Pennsylvania**	**Dr. Marlana Orloff**	**Contract and budget are under review with the site**
Stanford University	**Stanford, California**	**Dr. Sunil Reddy**	**Contract and budget are under review with the site**
Ohio State University	**Columbus, Ohio**	**Dr. Aslam Ejaz**	**Contract and budget are under review with the site**
Mayo Clinic Hospital	**Jacksonville, Florida**	**Dr. Roxana Dronca / Dr. Yiyi Yan**	**Contract and budget discussions initiated**
Emory University	Atlanta, Georgia	Dr. Mike Lowe	Interested to participate in EAP; need additional time to start activities
University of Miami	Miami, Florida	Dr. Jose Lutzky	Interested to participate in EAP; need additional research staff before participating

mOM Beachhead Market Strategy

BEACHHEAD MARKET | mOM | LIVER DISEASE

SIGNIFICANT REVENUE OPPORTUNITY:

- Oncologists* believe ~80% of mOM patients would be HEPZATO candidates - ~800 patients
- Considered a significant advancement
- Payer & hospital finance stakeholders suggest pricing expectations in the range of IO agents
- Tebentafusp is priced at an estimated ~$820 per patient** and generated $50M in global revenue in the 3rd full quarter post launch
- May be positioned as a first-line treatment due to limited efficacy of available therapies.

US TAM

>$450M

per year

*Source: Boston Health Associates primary research n=13 physicians, ** $400K consensus estimates from Immunocore's covering analysts assuming treatment until progression, $1M annualized cost assuming treatment through progression (25% longer duration than pivotal trial)

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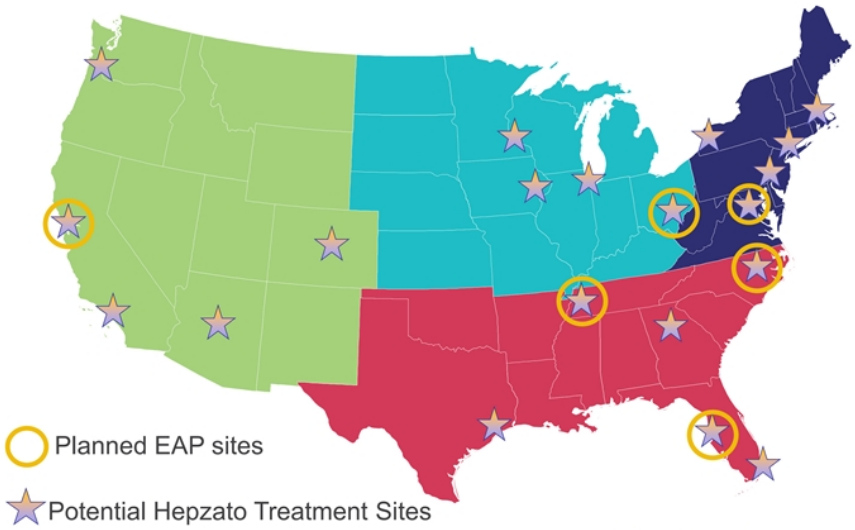
Specialized, Targeted Sales Team

Leveraging EAP and Longitudinal Data

EAP (FDA Approved) – Up to 8 Sites
- Provide immediate access to patients
- First Commercial Sites
- Train new medical teams to use Hepzato after launch

Regional Based Sales Team
- Experienced, Oncology focused
- Upon launch, placed in key geographies
- Supplement with Clinical Support Specialist

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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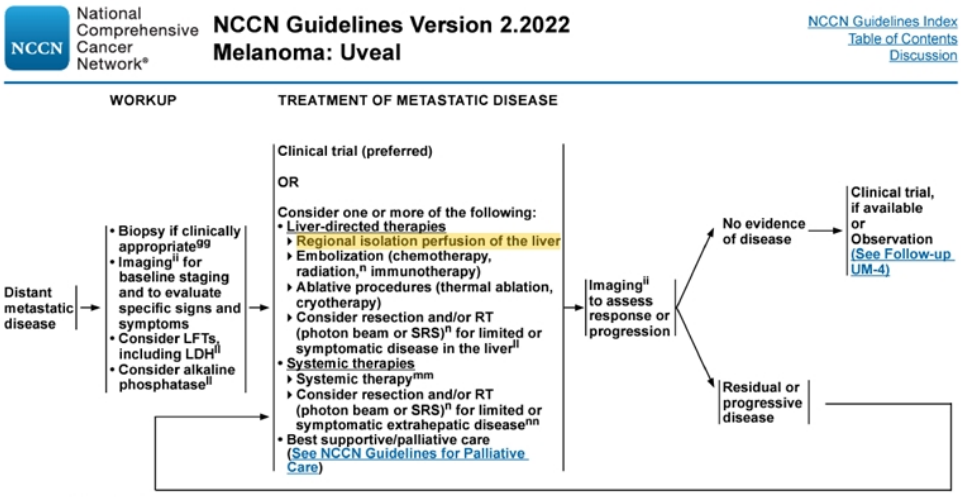
Reimbursement

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 (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 mOM



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 underway – while important, it will not have a meaningful impact on drug pricing decision

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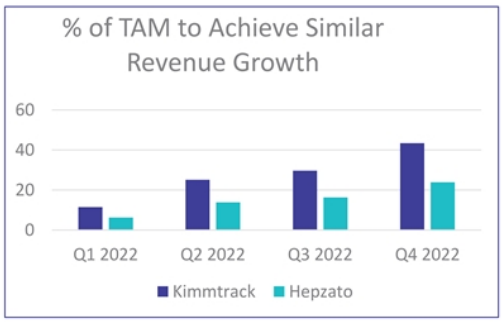
Hepzato vs. Kimmtrak Cost of Treatment Comparisons

At First Assessment (first time to discontinue treatment because of progression)			
Drug	Dose Cost	Treatments #	Total cost
Kimmtrak	$20,261	24	$486,264
Hepzato	t.b.d.	2	t.b.d.

Mean Hepzato treatment vs. mean treatment duration of Kimmtrak			
Drug	Dose Cost	Mean Treatments #	Total cost
Kimmtrak	$20,261	41	$830,701
Hepzato	t.b.d.	4.1	t.b.d.

Rapid Uptake for FDA Approved Treatment in mOM



** Assuming $150K per treatment and 4 treatments per patient.*

- Demonstrated demand for FDA approved treatments for mOM
  - Kimmtrak - $38 million in Q4 2022 US sales ($152M annualized revenue)
  - Only 45% of mOM patients are eligible for treatment with Kimmtrak (unique MOA)
  - Kimmtrak has an estimated 40% share of eligible patients in less than 12 months
- Hepzato Kit submitted for FDA approval 14 February 2023
  - 100% of mOM patients are eligible for treatment with Hepzato
  - Hepzato will require <20% of eligible patients to achieve similar 4 quarter growth*
- Hepzato Kit is well positioned to generate rapid uptake
  - Hepzato is more of a complement than a competitor to Kimmtrak for patients eligible for Kimmtrak
  - Hepzato can treat all mOM patients and will be the **only** FDA approved drug for 55% of patients
  - 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 V2.2022*

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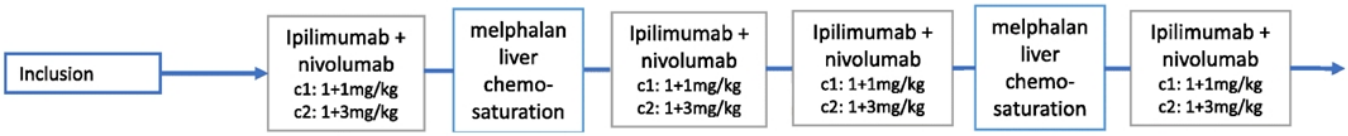
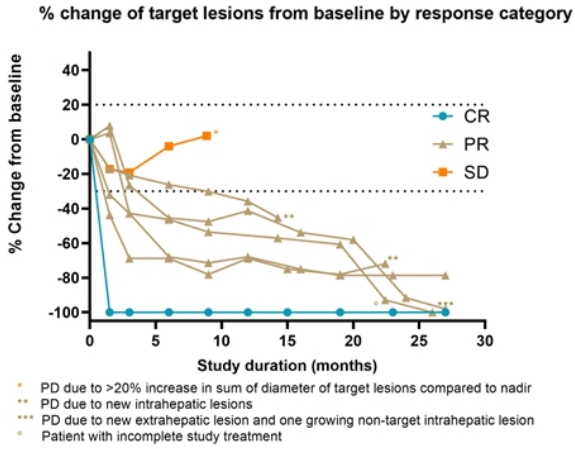
IO Combination Proof of Principal – Ongoing CHOPIN Trial





- N=7 in Phase 1b portion of the trial (mOM patients)
- 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 (range 8.9 – 30.2), **the median PFS was 29.1 months** (95% CI 11.9 – 46.3) and the **median duration of response was 27.1 months** (range 7.4 – 28.5)
- All patients are still alive
- 3 of 4 patients who subsequently experienced PD continued with treatment in the form of repeated Melphalan Chemosat treatments
- The safe treatment dose was established at IPI 1mg/kg and NIVO 3mg/kg.
- Both cohorts were tolerated with no dose-limiting toxicities or deaths
- Ongoing randomized Phase 2 (control is Chemosat) has recruited 50% of N=76 patients and will provide an interim analysis at N=40 patients

Published 09 January 2023 in Cardiovascular and Interventional Radiology: https://doi.org/10.1007/s00270-022-03338-1

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The Local Hepatic Myeloablative Effect May Improve IO Efficacy

nature medicine

Article | Published: 04 January 2021

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

Nat Med. 2021 Jan; 27(1): 152–164. PMID: 33398162
Published online 2021 Jan 4. doi: 10.1038/s41591-020-1131-x

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

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

frontiers in Oncology

Front Oncol. 2021; 11: 728018. PMCID: PMC8419
Published online 2021 Aug 23. doi: 10.3389/fonc.2021.728018 PMID: 34497

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

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

EU – Broad Reimbursement Pending Focus Trial Data; Demonstrated Interest Across Multiple Indications

- CE Marked - available in ~23 centers in 4 countries
- Delcath resumed direct sales on 3/1/22

- NICE (UK) upgraded status from "Research" to "Special Status"
- German reimbursement based on annual hospital special request ("ZE" process)

- Strong interest to fuel additional indications driven by HCP's

- 1,343 commercial Chemosat kits shipped to the EU
- Queensbury facility has been inspected 21 times by the Notified Bodies LRQA and BSI, Health Authorities FDA and ANVISA

CHEMOSAT Used In 13 Tumor Types

~70%: Metastatic Ocular Melanoma (mOM)

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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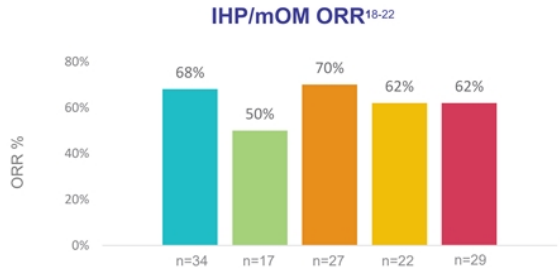
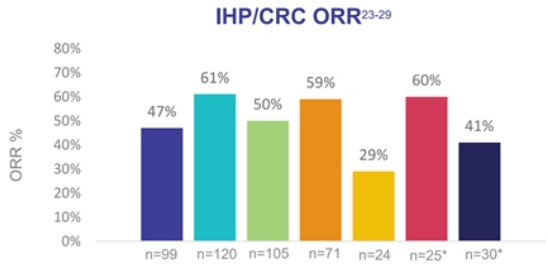
IHP Results in mOM Provided Rationale for PHP in mOM and Provides Rationale for CRC and Other Tumor Types





IHP Studies in other disease states

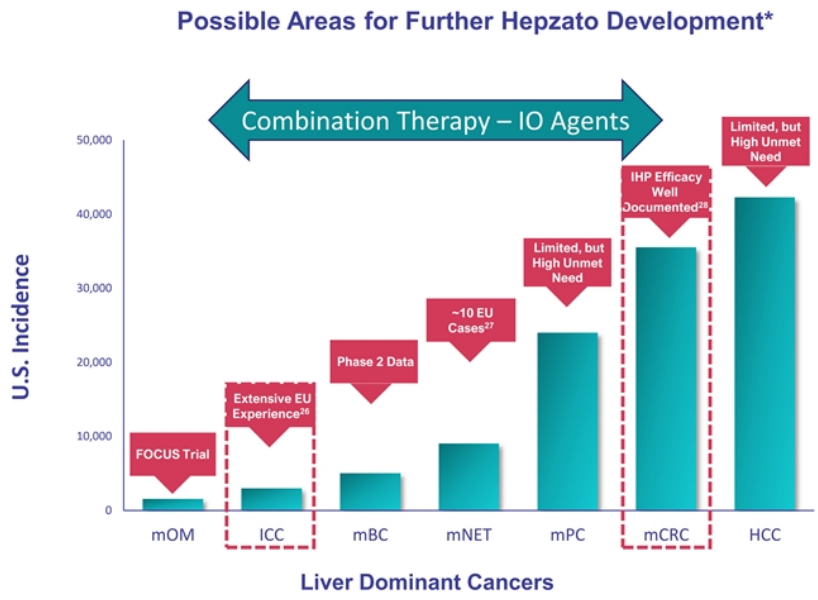
- Primary HCC and ICC utilizing IHP (melphalan +/- TNF alpha). ORR = 67% (N=13) with a median actuarial survival of 16.3 months.[30]
- Unresectable GEP-NET utilizing IHP (melphalan +/- TNF alpha). ORR = 50% (N=13) with a median actuarial survival of 48 months.[31]

*Hepatic arterial infusion used adjunctively.

Clinical Rationale for Broad Development Effort

"Broad-spectrum" alkylating agent given at 12X normal systemic doses	• Promising ORR and DCR signals seen across multiple tumor types in Europe and in earlier studies with IHP
Liver mets are often life limiting and reduce I/O efficacy	• When the liver is the life limiting organ, systemic chemotherapy can be paused and HEPZATO added to prolong survival • Early data supports that combination with I/O agents is safe and effective
PHP treats the entire liver and is not dependent on tumor location	• For patients at high risk of liver mets based on tumor characteristics or ctDNA, adjuvant therapy is logical

Market Expansion: Significant Investigator Interest



US TAM

>$1B

Per Year

*Metastatic Ocular Melanoma (mOM)[1,2], Cholangiocarcinoma (ICC)[3,4], Liver-dominant Breast Cancer (mBC)[7-10], Metastatic Neuroendocrine Tumors (mNET)[6,7] Metastatic Pancreatic Cancer (mPC)[7,13], Metastatic Colorectal Cancer (mCRC)[11,12], Hepatocellular carcinoma (HCC)[15]

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

JOHNNY JOHN, MD
SVP Clinical Development & Medical Affairs

- 15+ yrs. experience in oncology drug development and clinical trials
- 11 years of personal clinical practice
- Received M.D. from Mangalore University, India; post-grad training at the University of IL

KEVIN MUIR
VP, Commercial Operations

- 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

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

Capital Structure and Share Information

	12/31/22	Material One Time Q1 Events Incremental (+/-) Changes[1, 2]
Shares Outstanding	12.72[3]	+7.58[1]
Cash and Cash Equivalents	$11.8M	+$23.5M[1] -$4M[2]
Warrants Outstanding	3.61M[4]	+11.94M[1]
Stock Options Granted	2.34M	NA
2022 Cash Burn	$25.0M	NA
Debt	$16.9M[5]	-$4M[1]
52 week Low – High	$2.59 - $7.95[6]	NA
30d Average Daily Volume	22,960[7]	NA

[1] Includes a $4M prepayment of debt
[2] Includes $25M PIPE financing for 7.58 Series F Pfd shares, 7.78M Tranche A warrants for an aggregate exercise price $34.9 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 $24.9 million exercisable until the earlier of 3/31/2026 or 21 days following recording at least $10 million in quarterly U.S. revenue.
[3] As of December 31, 2022; includes 10.0M of Common plus 1.1M, Preferred E & E-1 & 1.5M Pre-funded Warrants as converted
[4] $10 exercise price
[5] Includes $5.0M of notes convertible at $11.98 per common share equivalent
[6] Used NASDAQ price information starting on January 1, 2022- December 31, 2022
[7] 30-day average calculated between November 17, 2022 - December 30, 2022

Delcath: Investment Summary

- 3Q approval in mOM likely due to strong pivotal data and real-world experience
- Kimmtrak proving out significant commercial opportunity ($200M run rate) with 45% of the HEPZATO TAM
- Rapid uptake likely due to favorable reimbursement environment, NCCN guidelines including PHP and equivalent OS as Kimmtrack in more advance patient population
- Management team experienced in commercializing high value, specialty products
- Multiple 2023 catalysts (AdCom, Approval, CHOPIN data)
- High value follow-on indications and strategic interest creates significant upside

THANK YOU

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