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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2023
Or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____
Commission File Number: 001-16133

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

Delaware	**06-1245881**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1633 Broadway, Suite 22C
New York, NY 10019
(Address of principal executive offices)
(212) 489-2100
(Registrant's telephone number, including area code)

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 per share	**DCTH**	**The NASDAQ Capital Market**

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
		Emerging growth company	o

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 Securities Act. o
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x
As of August 3, 2023, 15,276,487 shares of the Company's common stock, $0.01 par value, were outstanding.

DELCATH SYSTEMS, INC.

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DELCATH SYSTEMS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share data)

	June 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 14,540	$ 7,671
Restricted cash	50	4,151
Accounts receivable, net	127	366
Inventory	2,480	1,998
Prepaid expenses and other current assets	2,275	1,969
Total current assets	19,472	16,155
Property, plant and equipment, net	1,403	1,422
Right-of-use assets	175	285
Total assets	$ 21,050	$ 17,862
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 966	$ 2,018
Accrued expenses	5,546	4,685
Lease liabilities, current	92	186
Loan payable, current	4,510	7,846
Total current liabilities	11,114	14,735
Warrant liability	3,780	—
Other liabilities, non-current	1,146	1,144
Loan payable, non-current	411	3,070
Convertible notes payable, non-current	4,841	4,772
Total liabilities	21,292	23,721
Commitments and contingencies (see note 13)		
Stockholders' equity (deficit)		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; 20,981 and 11,357 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.01 par value; 80,000,000 shares authorized; 15,250,469 shares and 10,046,571 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	153	100
Additional paid-in capital	473,355	451,608
Accumulated deficit	(473,686)	(457,484)
Accumulated other comprehensive loss	(64)	(83)
Total stockholders' equity (deficit)	(242)	(5,859)
Total liabilities and stockholders' equity	$ 21,050	$ 17,862

See accompanying Notes to Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share data)

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Product revenue	$ 495	$ 797	$ 1,092	$ 1,003
Other revenue	—	—	—	171
Total revenues	495	797	1,092	1,174
Cost of goods sold	(150)	(180)	(331)	(214)
Gross profit	345	617	761	960
Operating expenses:				
Research and development expenses	3,555	5,606	8,131	10,087
Selling, general and administrative expenses	4,787	4,497	8,952	8,699
Total operating expenses	8,342	10,103	17,083	18,786
Operating loss	(7,997)	(9,486)	(16,322)	(17,826)
Change in fair value of warrant liability	1,160	—	1,160	—
Interest expense, net	(371)	(665)	(1,059)	(1,309)
Other income (expense)	6	(8)	19	(24)
Net loss	(7,202)	(10,159)	(16,202)	(19,159)
Other comprehensive income:				
Foreign currency translation adjustments	—	(31)	19	(29)
Total other comprehensive loss	$ (7,202)	$ (10,190)	$ (16,183)	$ (19,188)
Common share data:				
Basic and diluted loss per common share	$ (0.58)	$ (1.24)	$ (1.35)	$ (2.34)
Weighted average number of basic and diluted shares outstanding	12,463,665	8,190,483	12,035,738	8,190,483

See accompanying Notes to Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(Unaudited)
(in thousands, except share data)

	Preferred Stock $0.01 Par Value		Common Stock $0.01 Par Value		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	No. of Shares	Amount	No. of Shares	Amount				
Balance at January 1, 2023	11,357	$ —	10,046,571	$ 100	$ 451,608	$ (457,484)	$ (83)	$ (5,859)
Compensation expense for issuance of stock options	—	—	—	—	1,661	—	—	1,661
Private placement -issuance of common shares, net of expenses	—	—	19,646	1	55	—	—	56
Issuance of common stock with the employee stock purchase plan	—	—	15,417	—	47	—	—	47
Net loss	—	—	—	—	—	(9,000)	—	(9,000)
Total comprehensive income	—	—	—	—	—	—	19	19
Balance at March 31, 2023	11,357	$ —	10,081,634	$ 101	$ 453,371	$ (466,484)	$ (64)	$ (13,076)
Compensation expense for issuance of stock options	—	—	—	—	1,661	—	—	1,661
Conversion of Preferred F-1 shares to common shares	—	—	4,629,539	47	11,222	—	—	11,269
Preferred F-2 Shares Issuance	9,624	—	—	—	7,099	—	—	7,099
Prefunded warrant exercise	—	—	538,828	5	—	—	—	5
Issuance of common stock related to stock option exercises	—	—	468	—	2	—	—	2
Net loss	—	—	—	—	—	(7,202)	—	(7,202)
Balance at June 30, 2023	20,981	$ —	15,250,469	$ 153	$ 473,355	$ (473,686)	$ (64)	$ (242)

	Preferred Stock $0.01 Par Value		Common Stock $0.01 Par Value		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	No. of Shares	Amount	No. of Shares	Amount				
Balance at January 1, 2022	11,357	$ —	7,906,728	$ 79	$ 432,831	$ (420,976)	$ 18	$ 11,952
Compensation expense for issuance of stock options	—	—	—	—	2,271		—	2,271
Net loss	—	—	—	—	—	(9,000)	—	(9,000)
Total comprehensive income	—	—	—	—	—	—	2	2
Balance at March 31, 2022	11,357	$ —	7,906,728	$ 79	$ 435,102	$ (429,976)	$ 20	$ 5,225
Compensation expense for issuance of stock options	—	—	—	—	2,119	—	—	2,119
Net loss	—	—	—	—	—	(10,159)	—	(10,159)
Total comprehensive income	—	—	—	—	—	—	(31)	(31)
Balance at June 30, 2022	11,357	—	7,906,728	$ 79	$ 437,221	$ (440,135)	$ (11)	$ (2,846)

See accompanying Notes to Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Six months ended June 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (16,202)	$ (19,159)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	3,322	4,390
Depreciation expense	59	31
Warrant liability fair value adjustment	(1,160)	—
Non-cash lease expense	195	234
Amortization of debt discount	388	380
Interest expense accrued related to convertible notes	80	80
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(306)	374
Accounts receivable	239	(394)
Inventory	(482)	(628)
Accounts payable and accrued expenses	132	2,667
Other liabilities, non-current	(177)	(217)
Deferred revenue	—	(170)
Net cash used in operating activities	(13,912)	(12,412)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(40)	(141)
Net cash used in investing activities	(40)	(141)
Cash flows from financing activities:		
Net proceeds from private placement	22,960	—
Proceeds from the issuance of common stock relating to the employee stock purchase plan	47	—
Repayment of debt	(6,313)	—
Proceeds from exercise of warrants	5	—
Proceeds from exercise of stock options	2	—
Net cash provided by financing activities	16,701	—
Foreign currency effects on cash	19	(46)
Net increase (decrease) in total cash	2,768	(12,599)
Total Cash, Cash Equivalents and Restricted Cash:		
Beginning of period	11,822	26,953
End of period	$ 14,590	$ 14,354
Cash, Cash Equivalents and Restricted Cash consisted of the following:		
Cash	$ 14,540	$ 10,203
Restricted Cash	50	4,151
Total	$ 14,590	$ 14,354

	Six months ended June 30,	
	2023	**2022**
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the periods for:		
Interest expense	$ 787	$ 842
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Right of use assets obtained in exchange for lease obligations	$ 84	$ —
Conversion of mezzanine equity to common shares	$ 11,269	$ —
Conversion of mezzanine equity to preferred shares	$ 7,099	$ —

See accompanying Notes to Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Notes to the Condensed Consolidated Financial Statements
(amounts in thousands, except share and per share amounts)

(1) General

The unaudited interim condensed consolidated financial statements of Delcath Systems, Inc. ("Delcath" or the "Company") as of and for the three and six months ended June 30, 2023 and 2022 should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (the "Annual Report"), which was filed with the Securities and Exchange Commission (the "SEC") on March 27, 2023 and may also be found on the Company's website (www.delcath.com). In these notes to the interim condensed consolidated financial statements the terms "us", "we" or "our" refer to Delcath and its consolidated subsidiaries.

Description of Business

The Company is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. The Company's lead product candidate, the HEPZATO® KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO, is a drug/device combination product designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, the hepatic delivery system is a stand-alone medical device having the same device components as HEPZATO but without the melphalan hydrochloride and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used at major medical centers to treat a wide range of cancers of the liver.

In the United States, HEPZATO is considered a combination drug and device product and is regulated as a drug by the United States Food and Drug Administration (the "FDA"). Primary jurisdiction for regulation of HEPZATO has been assigned to the FDA's Center for Drug Evaluation and Research. The FDA has granted Delcath six orphan drug designations (five for melphalan in the treatment of patients with ocular (uveal) melanoma, cutaneous melanoma, intrahepatic cholangiocarcinoma, hepatocellular carcinoma, and neuroendocrine tumor indications and one for doxorubicin in the treatment of patients with hepatocellular carcinoma). HEPZATO has not been approved for sale in the United States.

The Company's clinical development program for HEPZATO is comprised of the FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the "FOCUS Trial"), a global registration clinical trial that is investigating objective response rate in metastatic ocular melanoma ("mOM"), a type of primary liver cancer. The Company's most advanced development program is the treatment of mOM. The Company is currently reviewing the incidence, unmet need, available efficacy data and development requirements for a broad set of liver cancers in order to select a portfolio of follow-on indications that will maximize the value of the HEPZATO platform. In addition to HEPZATO's use to treat mOM, the Company believes that HEPZATO has the potential to treat other liver dominant cancers, such as Metastatic Colorectal Cancer and Cholangiocarcinoma, and plans to begin the study of HEPZATO to treat such conditions in the near future. The Company believes that the disease states we are investigating and intend to investigate are unmet medical needs that represent significant market opportunities.

In December 2021, the Company announced that the FOCUS Trial for HEPZATO met its pre-specified endpoint. For information on the FOCUS Trial, see "Part I, Item 1. Business—Clinical Development Program—The FOCUS Trial" in our Annual Report. On February 14, 2023, the Company filed a New Drug Application ("NDA") resubmission (the "NDA resubmission") with the FDA for the HEPZATO KIT (melphalan hydrochloride for Injection/Hepatic Delivery System) seeking approval of the HEPZATO KIT in the treatment of patients with unresectable hepatic-dominant mOM. The NDA resubmission was in response to a September 12, 2013 Complete Response Letter ("CRL") from the FDA for the NDA the Company submitted in December 2010 seeking approval of its first generation melphalan hydrochloride for injection/hepatic delivery system. The NDA resubmission contains comprehensive data and information on Generation Two HEPZATO KIT relating to the matters identified in the CRL. On March 20, 2023, the FDA determined the NDA resubmission constituted a complete response and set a Prescription Drug User Fee Act ("PDUFA") target action date of August 14, 2023. The Company continues its expanded access programs ("EAP") in the United States to make HEPZATO readily available to mOM patients. The Company is focused on continuing to treat these patients with mOM as regulatory approval is sought in the United States. There are currently patients enrolled in the Company's EAP sites.

On February 28, 2022, CHEMOSAT received Medical Device Regulation ("MDR") certification under the European Medical Devices Regulation [2017/745/EU], which may be considered by jurisdictions when evaluating reimbursement. As of March 1, 2022, the Company has assumed direct responsibility for sales, marketing and distribution of CHEMOSAT in Europe.

Risks and Uncertainties

The Company is subject to risks common to companies in the development stage including, but not limited to, dependency on the clinical and commercial success of its drug/device combination products, its ability to obtain regulatory approval of its such products in the United States and other geography markets, uncertainty of broad adoption of its approved products, if any, by physicians and consumers, and significant competition.

In addition, inflation rates have increased recently to levels not seen in decades. As a result, the U.S. Federal Reserve has raised interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. Furthermore, if, in addition to the recent bank failures of Silicon Valley Bank, Signature Bank and First Republic Bank, other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our or our partners' ability to access existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition. If the disruptions and slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could in the future negatively affect our ability to pursue our business strategy.

Liquidity and Going Concern

On June 30, 2023, the Company had cash, cash equivalents and restricted cash totaling $14.6 million, as compared to cash, cash equivalents and restricted cash totaling $11.8 million at December 31, 2022. During the six months ended June 30, 2023, the Company used $13.9 million of cash in its operating activities and $6.3 million for principal payments.

The Company's future results are subject to substantial risks and uncertainties. The Company has operated at a loss for its entire history and there can be no assurance that it will ever achieve or maintain profitability. The Company has historically funded its operations primarily with proceeds from sales of common stock, warrants and prefunded warrants for the purchase of common stock, sales of preferred stock, proceeds from the issuance of convertible debt and borrowings under loan and security agreements.

The Company believes that current cash and cash equivalents will enable the Company to have sufficient cash past our anticipated PDUFA date of August 14, 2023. If there is a substantial delay in the approval of HEPZATO, the Company expects to need to raise additional capital under structures available to the Company, including debt and/or equity offerings, which may not be on favorable terms. In a delayed approval scenario, the Company will not have sufficient funds to meet its obligations within twelve months from the issuance date of these condensed consolidated financial statements.

The Company's capital commitments over the next twelve months include (a) $6.6 million to satisfy accounts payable, accrued expenses and lease liabilities and (b) $5.1 million of loan principal payments. Additional capital commitments beyond the next twelve months include (a) $0.1 million of lease liabilities; (b) $1.0 million for settlement of litigation with medac; (c) $0.5 million of loan principal payments; and (d) $5.0 million of convertible note principal payments, if the holders do not elect to convert the notes into equity.

Basis of Presentation

These interim condensed consolidated financial statements are unaudited and were prepared by the Company in accordance with generally accepted accounting principles in the United States of America (GAAP) and with the SEC's instructions to Form 10-Q and Article 10 of Regulation S-X. They include the accounts of all wholly owned subsidiaries and all significant inter-company accounts and transactions have been eliminated in consolidation.

The preparation of interim condensed consolidated financial statements requires management to make assumptions and estimates that impact the amounts reported. These interim condensed consolidated financial statements reflect all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the Company's results of operations, financial position and cash flows for the interim periods ended June 30, 2023 and 2022; however, certain information and footnote disclosures normally included in our audited consolidated financial statements included in our Annual Report have been condensed or omitted as permitted by GAAP. It is important to note that the Company's results of operations and cash flows for interim periods are not necessarily indicative of the results of operations and cash flows to be expected for a full fiscal year or any interim period.

Significant Accounting Policies

Other than the policies listed below, there have been no material changes to our significant accounting policies as set forth in Note 3 Summary of Significant Accounting Policies to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

Warrant Liabilities

The Company determined the warrant liability was not in accordance with the provisions of ASC 480, Distinguishing Liabilities from Equity, which classifies and measures certain financial instruments with characteristics of both liability and equity. Entities must consider whether to classify contracts that may be settled in its own stock, such as warrants, as equity of the entity or as an asset or liability. If an event that is not within the entity's control could require net cash settlement, then the contract should be classified as an asset or a liability at their fair value at issuance with subsequent changes in fair value recorded in earnings.

The Company has accounted for the Preferred Warrants as derivative instruments in accordance with ASC 815, Derivatives and Hedging. The Company classified the Preferred Warrants issued in conjunction with the Preferred Purchase Agreement (defined below) and the Common Warrants issued in conjunction with the Common Purchase Agreement as a liability due to the existence of a pre-specified volatility input to the Black-Scholes calculation which would be used to calculate the repurchase price of the Preferred Warrants and Common Warrants in the event of a Fundamental Transaction, as defined.

The valuations of the warrant liability and Series F-1 Preferred Stock (defined below) were determined using option pricing models. These models use inputs such as the underlying price of the shares issued at the measurement date, volatility, risk free interest rate and expected life of the instrument. In addition, the Company used probabilities of the FDA approval of the HEPZATO KIT ("FDA Approval") and of recording at least $10 million in quarterly U.S. revenue from the commercialization of HEPZATO as inputs to determine the fair value of warrants liability and Series F-1 Preferred Stock. The Company intends to adjust the fair value of the warranty liability at the end of each reporting period.

Recently Adopted and Issued Accounting Pronouncements

We have not been required to adopt any accounting standards that had a significant impact on our consolidated financial statements in the two years ended December 31, 2022. We do not expect any recently issued accounting standards to have a significant impact on our consolidated financial statements.

Revision of Previously Issued Quarterly Financial Statements

In preparation of the Company's audited financial statements as of and for year ended December 31, 2022, the Company determined it needed to correct previously reported share-based compensation expense for each quarter during 2022. The correction for share-based compensation increased the net loss in amount of $0.8 million for the first quarter of 2022, $0.5 million for the second quarter of 2022 and $0.4 million for the third quarter of fiscal 2022. The share-based compensation adjustment is a non-cash adjustment and did not have any impact on the cash balances for the Company.

The following tables contain the financial information for the periods previously reported and have been updated to reflect the revisions of the Company's financial statements. The revisions do not have an impact on the Company's cash position. The Company has not amended its previously filed Quarterly Reports on Form 10-Q for the three quarterly periods ended September 30, 2022. The impact of the revision on the Company's financial statements for the three and six months ended June 30, 2022 is reflected in the following table:

(In thousands)	As previously reported	Adjustment	As revised
Balance Sheet for June 30, 2022 (unaudited)			
Additional paid-in capital	$ 435,922	$ 1,299	$ 437,221
Accumulated deficit	$ (438,836)	$ (1,299)	$ (440,135)
Consolidated Statement of Operations and Comprehensive Loss for the three months ended June 30, 2022 (unaudited)			
Research and development expenses	$ 5,456	$ 150	$ 5,606
Selling, general and administrative expenses	4,145	352	4,497
Total operating expenses	9,601	502	10,103
Operating loss	(8,984)	(502)	(9,486)
Net loss	(9,657)	(502)	(10,159)
Total other comprehensive loss	(9,688)	(502)	(10,190)
Basic and diluted loss per common share	$ (1.18)	$ (0.06)	$ (1.24)
Consolidated Statement of Operations and Comprehensive Loss for the six months June 30, 2022 (unaudited)			
Research and development expenses	$ 9,696	$ 391	$ 10,087
Selling, general and administrative expenses	7,791	908	8,699
Total operating expenses	17,487	1,299	18,786
Operating loss	(16,527)	(1,299)	(17,826)
Net loss	(17,860)	(1,299)	(19,159)
Total other comprehensive loss	(17,889)	(1,299)	(19,188)
Basic and diluted loss per common share	$ (2.18)	$ (0.16)	$ (2.34)
Consolidated statement of Stockholders' Equity (Deficit) for the three months ended June 30, 2022 (unaudited)			
Compensation expense for issuance of stock options	$ 1,617	$ 502	$ 2,119
Net loss	$ (9,657)	$ (502)	$ (10,159)
Consolidated statement of Stockholders' Equity (Deficit) for the six months ended June 30, 2022 (unaudited)			
Compensation expense for issuance of stock options	$ 3,091	$ 1,299	$ 4,390
Net loss	$ (17,860)	$ (1,299)	$ (19,159)
Consolidated Statement of Cash Flows for the six months ended June 30, 2022 (unaudited)			
Net loss	$ (17,860)	$ (1,299)	$ (19,159)
Stock option compensation expense	$ 3,091	$ 1,299	$ 4,390

(2) Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents that are restricted as to withdrawal or use under the terms of certain contractual agreements are recorded in Restricted Cash on the balance sheets.

Cash, cash equivalents, and restricted cash balances were as follows:

(In thousands)	June 30, 2023	December 31, 2022
Cash and cash equivalents	$ 14,540	$ 7,671
Restricted balance for loan agreement	—	4,000
Letters of credit	—	101
Security for credit cards	50	50
Total cash, cash equivalents and restricted cash shown in the statements of cash flows	$ 14,590	$ 11,822

On March 15, 2023, the Company returned to Avenue the $4.0 million held in restricted cash to pay down a portion of the outstanding Avenue Loan (defined below) balance. On March 31, 2023, the letter of credit for the sub-lease agreement for office space at 1633 Broadway, New York, NY expired.

(3) Inventory

Inventory consists of the following:

(In thousands)	June 30, 2023	December 31, 2022
Raw materials	$ 796	$ 763
Work-in-process	1,571	1,102
Finished goods	113	133
Total inventory	$ 2,480	$ 1,998

(4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(In thousands)	June 30, 2023	December 31, 2022
Clinical trial expenses	$ 1,630	$ 1,630
Insurance premiums	94	123
Professional services	389	121
Other	162	95
Total prepaid expenses and other current assets	$ 2,275	$ 1,969

(5) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

(In thousands)	June 30, 2023	December 31, 2022	Estimated Useful Life
Buildings and land	$ 1,301	$ 1,301	30 years - Buildings
Enterprise hardware and software	1,856	1,855	3 years
Leaseholds	1,781	1,774	Lesser of lease term or estimated useful life
Equipment	1,263	1,222	7 years
Furniture	201	201	5 years
Property, plant and equipment, gross	6,402	6,353	
Accumulated depreciation	(4,999)	(4,931)	
Property, plant and equipment, net	$ 1,403	$ 1,422	

Depreciation expense for the three and six months ended June 30, 2023 and 2022 was less than $0.1 million for each period.

(6) Accrued Expenses

Accrued expenses consist of the following:

(In thousands)	June 30, 2023	December 31, 2022
Clinical expenses	$ 1,769	$ 1,470
Compensation, excluding taxes	1,328	1,040
Professional fees	1,219	1,087
Interest on convertible note	633	553
Other	597	535
Total accrued expenses	$ 5,546	$ 4,685

(7) Leases

The Company recognizes right-of-use (“ROU”) assets and lease liabilities when it obtains the right to control an asset under a leasing arrangement with an initial term greater than twelve months. The Company leases its facilities under non-cancellable operating and financing leases. The Company evaluates the nature of each lease at the inception of an arrangement to determine whether it is an operating or financing lease and recognizes the ROU asset and lease liabilities based on the present value of future minimum lease payments over the expected lease term. The Company’s leases do not generally contain an implicit interest rate and therefore the Company uses the incremental borrowing rate it would expect to pay to borrow on a similar collateralized basis over a similar term in order to determine the present value of its lease payments.

For the three and six months ended June 30, 2023 and 2022, the Company recognized $0.1 million and $0.2 million, respectively, of operating lease expense in the U.S. and less than $0.1 million of operating lease expense in Ireland for the same periods.

As of June 30, 2023:

(In thousands)	U.S.	Ireland	Total
Operating cash flows for operating leases	$ 181	$ 14	$ 195
Weighted average remaining lease term	0.3	3.1	
Weighted average discount rate - operating leases	8 %	8 %	

Remaining maturities of the Company's operating leases, excluding short-term leases, are as follows:

	U.S.	Ireland	Total
Year ended December 31, 2023	$ 56	$ 18	$ 74
Year ended December 31, 2024	—	36	36
Year ended December 31, 2025	—	36	36
Year ended December 31, 2026	—	21	21
Total	56	111	167
Less present value discount	(1)	(12)	(13)
Operating lease liabilities included in the condensed consolidated balance sheets at June 30, 2023	$ 55	$ 99	$ 154

(8) Loans and Convertible Notes Payable

	June 30, 2023			December 31, 2022		
(In thousands)	Gross	Discount	Net	Gross	Discount	Net
Loan - Avenue [1]	$ 5,610	$ (689)	$ 4,921	$ 11,923	$ (1,008)	$ 10,916
Loan - Avenue [1] - Less Current Portion	(5,142)	632	(4,510)	(8,570)	724	(7,846)
Total - Loans Payable, Non-Current	$ 468	$ (57)	$ 411	$ 3,353	$ (284)	$ 3,070
Convertible Note Payable - Rosalind	2,000		2,000	2,000	—	2,000
Convertible Portion of Loan Payable - Avenue	3,000	(159)	2,841	3,000	(228)	2,772
Total - Convertible Notes Payable - Non-Current	$ 5,000	$ (159)	$ 4,841	$ 5,000	$ (228)	$ 4,772

[1] The gross amount includes the 4.25% final payment of $0.5 million.

Remaining maturities of the Company's loan and convertible note payables are as follows:

(In thousands)	Loans	Convertible Notes	Total
Year ended December 31, 2023	$ 2,221	$ —	$ 2,221
Year ended December 31, 2024	3,389	5,000	8,389
Total	$ 5,610	$ 5,000	$ 10,610

Term Loan from Avenue Venture Opportunities Fund, L.P.

On August 6, 2021, the Company entered into a Loan and Security Agreement (the "Avenue Loan Agreement") with Avenue Venture Opportunities Fund, L.P. (the "Lender," or "Avenue") for a term loan in an aggregate principal amount of up to $20.0 million (the "Avenue Loan"). The Avenue Loan bears interest at an annual rate equal to the greater of (a) the sum of 7.70% plus the prime rate as reported in The Wall Street Journal and (b) 10.95%. The interest rate at June 30, 2023

was 15.95%. The Avenue Loan is secured by all of the Company's assets globally, including intellectual property. The Avenue Loan matures on August 1, 2024.

The initial tranche of the Avenue Loan is $15.0 million, including $4.0 million that was funded into a restricted account and was released upon achievement of (a)(x) positive FOCUS trial efficacy per the trial's predefined Statistical Analysis Plan (SAP) (specifically the Overall Response Rate exceeds the pre-specified threshold for success defined in the SAP by a statistically significant amount); and (y) based on data contained within the FOCUS trial database and appropriate for use with the FDA, safety and tolerability among FOCUS trial participants is within the range of currently approved and commonly used cytotoxic chemotherapeutic agents; and (b) raising subsequent net equity proceeds of at least $20 million.

Up to $3.0 million of the principal amount of the Avenue Loan outstanding may be converted, at the option of Avenue, into shares of the Company's common stock at a conversion price of $11.98 per share.

In connection with the Avenue Loan, the Company issued to Avenue a warrant (the "Avenue Warrant") to purchase 127,755 shares of common stock at an exercise price per share equal to $0.01. The Avenue Warrant is exercisable until August 31, 2026.

On March 15, 2023, the Company returned to Avenue $4.0 million held in the restricted cash to pay down a portion of the outstanding loan balance, principal payments of $2.1 million and an incremental 4.25% of the final payment of $0.2 million. On March 31, 2023, the Company reached an agreement to amend the Avenue Loan Agreement to defer the interest only to September 30, 2023. The interest only period may be extended at the Company's option to December 31, 2023 if, by September 30, 2023, the Company has (a) received FDA approval for the HEPZATO KIT and (b) received net proceeds of at least $10 million from the sale and issuance of equity securities or exercise of existing warrants. In exchange for this extension, the Company has agreed to provide Avenue with 34,072 warrants to purchase shares of common stock. The exercise price of the warrants is $0.01.

The Avenue Loan Agreement requires the Company to make and maintain representations and warranties and other agreements that are customary in loan agreements of this type. The Avenue Loan Agreement also contains customary events of default, including non-payment of principal or interest, violations of covenants, bankruptcy and material judgments.

The Company determined that the embedded conversion option associated with the Avenue Loan did not require bifurcation and met the criteria for equity classification. In addition, the amendment was recorded under debt modification guidance. Aggregate debt discount amortization of $0.2 million and $0.4 million was recorded during the three and six months ended June 30, 2023 and 2022, respectively. Interest expense incurred was $0.3 million and $0.4 million for the three months ended June 30, 2023 and 2022, respectively and $0.8 million for both the six months ended June 30, 2023 and 2022.

Convertible Notes Payable

The Company has $2.0 million of principal outstanding related to Senior Secured Promissory Notes (the "Rosalind Notes") which bear interest at 8% per annum. Pursuant to the original terms, the Rosalind Notes were convertible into Series E Preferred Stock at a price of $1,500 per share and were to mature on July 16, 2021. Interest expense was less than $0.1 million for the three and six months ended June 30, 2023 and 2022, respectively.

On August 6, 2021, the Company executed an agreement to amend the Rosalind Notes to (i) reduce the conversion price to $1,198 per share of the Company's Series E Convertible Preferred Stock; and (ii) extend the maturity date to October 30, 2024. In addition, the holders of the Rosalind Notes agreed to subordinate all of the Company's indebtedness and obligations to Avenue and all of the holders' security interest, to the Avenue Loan and Avenue's security interest in the Company's property.

(9) Preferred Purchase Agreement

Preferred Purchase Agreement

On March 29, 2023, the Company closed the Series F Preferred Offering (defined below). Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series F Convertible Voting Preferred Stock (the "Certificate of Designation"), upon the Stockholder Approval (defined below), each share of Series F-1 Preferred Stock was automatically converted into shares of common stock and/or, if applicable (in accordance with the beneficial ownership limitations then in effect), shares of Series F-2 Preferred Stock, par value $0.01 per share (the "Series F-2 Preferred

Stock" and, together with the Series F-1 Preferred Stock, the Series F-3 Preferred Stock and the Series F-4 Preferred Stock, the "Series F Preferred Stock") in lieu of common stock.

The aggregate exercise price of the Preferred Tranche A Warrants (defined below) is approximately $34.9 million, exercisable for an aggregate of 34,860 shares of Series F-3 Preferred Stock until the earlier of 21 days following the Company's announcement of receipt of approval from the U.S. Food and Drug Administration for HEPZATO and March 31, 2026.

The aggregate exercise price of the Preferred Tranche B Warrants (defined below) is approximately $24.9 million, exercisable for an aggregate of 24,900 shares of Series F-4 Preferred Stock until the earlier of 21 days following the Company's announcement of receipt of recording at least $10 million in quarterly U.S. revenue from the commercialization of HEPZATO and March 31, 2026; provided, however, that if the FDA Approval occurs on or before February 15, 2024 and the holder of the Preferred Tranche B Warrant has not exercised its Preferred Tranche A Warrant by or before March 7, 2024, then any Series F-4 Preferred Stock not yet exercised pursuant to the Preferred Tranche B Warrant at such time shall expire.

The gross proceeds of $24.9 million were allocated first to the Preferred Warrant liabilities at their fair value of $4.9 million, with the residual of $20.0 million being allocated to the Series F-1 Preferred Stock. The Company also expensed $0.4 million of issuance costs that were allocated to the warranty liability during the three and six months ended June 30, 2023.

The Series F-2, F-3 and F-4 Preferred Stock are not mandatorily redeemable, redeemable at the holder's election or contingently redeemable at the holder's election (at this point, a Deemed Liquidation Event would potentially trigger pro rata liquidation payments to the preferred and common stockholders on a pro rata "as converted" basis). Accordingly, the Series F-2, F-3 and F-4 Preferred are now classified as permanent equity following the Stockholder Approval.

As of June 30, 2023, 15,276 shares of the Company's Series F-1 Preferred Stock were converted into 4,629,539 shares of common stock and 9,624 shares of the Company's Series F-1 Preferred Stock were converted into an equal number of shares of Series F-2 Preferred Stock.

(10) Stockholders' Equity

Public and Private Placements

Common Purchase Agreement

On March 29, 2023, the Company closed the Common Offering.

The aggregate exercise price of the Common Tranche A Warrants issued under the Common Offering is approximately $0.1 million, exercisable for an aggregate of 31,110 shares of common stock until the earlier of 21 days following the Company's announcement of receipt of FDA Approval and March 31, 2026.

The aggregate exercise price of the Common Tranche B Warrants issued under the Common Offering is approximately $0.1 million, exercisable for an aggregate of 16,666 shares of common stock until the earlier of 21 days following the Company's announcement of receipt of recording at least $10 million in quarterly U.S. revenue from the commercialization of HEPZATO and March 31, 2026; provided, however, that if the FDA Approval occurs on or before February 15, 2024 and the holder of the Common Tranche B Warrant has not exercised its Common Tranche A Warrant by or before March 7, 2024, then any warrants not yet exercised pursuant to the Common Tranche B Warrant at such time shall expire.

The Company determined that the Common Warrants should be liability-classified. See "Note 1 – Warrant Liabilities" for a discussion of the accounting treatment of the Common Warrants and Preferred Warrants.

Registration Rights for Preferred and Common Offerings

Pursuant to the Preferred Purchase Agreement and the Common Purchase Agreement (collectively, the "Purchase Agreements"), and the Stockholder Approval, the Company filed a registration statement on Form S-3 providing for the resale by the investors party thereto of the common stock issuable upon conversion of the Registrable Shares (as defined in the Purchase Agreements). The Form S-3 became effective on June 28, 2023.

The securities issued in the Series F Preferred Offering and the Common Offering have not been registered under the Securities Act of 1933, as amended (the "Securities Act"). There is no established public trading market for the Series F

Preferred Stock, the Preferred Warrants, or the Common Warrants and the Company does not intend to list such securities on any national securities exchange or nationally recognized trading system.

At-the-Market Offering

The Company has entered into a Controlled Equity Offering[SM] Sales Agreement ("ATM Sales Agreement"), with Cantor Fitzgerald & Co. (the "Sales Agent"), pursuant to which the Company may offer and sell, at its sole discretion through the Sales Agent, shares of common stock having an aggregate offering price of up to $17.0 million. To date, the Company has sold approximately $4.0 million of its common stock, prior to issuance costs, under the ATM Sales Agreement. No sales were made during the three and six months ended June 30, 2023.

Authorized Shares

Stockholders approved the amendment of the Company's Amended and Restated Certificate of Incorporation to increase the total number of shares of its common stock authorized for issuance from 40 million shares to 80 million shares. The Company is authorized to issue 80 million shares of common stock, $0.01 par value, and 10 million shares of preferred stock, $0.01 par value. As of June 30, 2023, the Company has designated the following preferred stock:

Designated Preferred Shares	June 30, 2023
Series A	4,200
Series B	2,360
Series C	590
Series D	10,000
Series E	40,000
Series E-1	12,960
Series F-1	24,900
Series F-2	24,900
Series F-3	34,860
Series F-4	24,900
Total	179,670

Preferred Stock

As of June 30, 2023, there were an aggregate of 11,357 shares of Series E and Series E-1 and 9,624 Series F-2 Convertible Preferred Stock outstanding, respectively.

Omnibus Equity Incentive Plan

On September 30, 2020, the Company's 2020 Omnibus Equity Incentive Plan (the "2020 Plan") was adopted by the Company's Board of Directors. On November 23, 2020, the Company's stockholders approved the 2020 Plan. The 2020 Plan will continue in effect until the tenth anniversary of the date of its adoption by the Board or until earlier terminated by the Board. The 2020 Plan is administered by the Board of Directors or a committee designated by the Board of Directors. On June 12, 2023, the stockholders approved the amendment to the Company's 2020 Plan to increase the number of shares of common stock available under the plan by 2.65 million shares. The 2020 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards, as well as other stock-based awards or cash awards that are deemed to be consistent

with the purposes of the plan to Company employees, directors and consultants. As of June 30, 2023, there are 5,125,000 shares of common stock reserved under the 2020 Plan, of which 1,861,160 remained available to be issued.

Stock Options

The Company values stock options using the Black-Scholes option pricing model and used the following assumptions during the reporting periods:

	Six Months Ended June 30,	
	2023	2022
Expected terms (years)	5.2-5.8	5.2-6.5
Expected volatility	129.8%-172.8%	174.8% -180.3%
Risk-free interest rate	3.88% -4.08%	1.75% - 2.90%
Expected dividends	0.00%	0.00%

The following is a summary of stock option activity for the six months ended June 30, 2023:

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2023	2,235,052	$ 10.30		
Granted	1,991,757	6.19		
Exercised	(468)	4.67		
Expired	(75,772)	9.49		
Cancelled/Forfeited	(22,637)	10.36		
Outstanding at June 30, 2023	4,127,932	$ 8.33	8.7	$ 994
Exercisable at June 30, 2023	1,741,313	$ 10.56	7.7	$ 116

The following table summarizes information for stock option shares outstanding and exercisable at June 30, 2023:

		Options Outstanding	
Range of Exercise Prices	Outstanding Number of Options	Weighted Average Remaining Option Term (in years)	Number of Options
$2.83 - $51.50	4,127,433	8.7	1,740,814
$51.50+	499	5.6	499
	4,127,932	8.7	1,741,313

The following is a summary of share-based compensation expense in the statement of operations for the three and six months ended June 30, 2023:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2023	2022	2023	2022
Selling, general and administrative	$ 911	$ 1,467	$ 2,099	$ 2,866
Research and development	651	613	1,068	1,416
Cost of goods sold	99	39	155	108
Total	$ 1,661	$ 2,119	$ 3,322	$ 4,390

At June 30, 2023, there was $10.0 million of aggregate unrecognized compensation expense related employee and board stock option grants. The cost is expected to be recognized over a weighted average period of 2.6 years.

Common Stock Warrants

The following is a summary of common stock warrant activity for the six months ended June 30, 2023:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)
Outstanding at January 1, 2023	5,153,291	$ 7.01	
Warrants issued	81,849	2.94	
Warrants exercised	(538,828)	0.01	
Outstanding at June 30, 2023	4,696,312	$ 7.74	2.1
Exercisable at June 30, 2023	4,696,312	$ 7.74	2.1

The following table presents information related to common stock warrants at June 30, 2023:

		Warrants Exercisable	
Range of Exercise Prices	Outstanding Number of Warrants	Weighted Average Remaining Warrant Term (in years)	Number of Warrants
$0.01	1,037,792	3.7	1,037,792
$4.50-$6.00	47,777	2.8	47,777
$10.00	3,610,743	1.7	3,610,743
	4,696,312	2.1	4,696,312

On April 18, 2023, there were 538,828 of $0.01 warrants exercised for 538,828 common shares.

Employee Stock Purchase Plan

In August 2021, the Company's Board of Directors, with shareholder approval in May 2022, adopted the Employee Stock Purchase Plan (the "ESPP"). The ESPP provides for a maximum of 260,295 shares of common stock to be purchased by participating employees. Employees who elect to participate in the ESPP will be able to purchase common stock at the lower of 85% of the fair market value of common stock on the first or last day of the applicable six-month offering period. In January 2023, an aggregate of 15,417 shares were purchased by participating employees for the offering period of July 1, 2022 to December 31, 2022. In July 2023, an aggregate of 26,018 shares were purchased by participating employees for the offering period of January 1, 2023 to June 30, 2023.

(11) Net Loss per Share

Basic net loss per share is determined by dividing net loss by the weighted average shares of common stock outstanding during the period, without consideration of potentially dilutive securities, except for those shares that are issuable for little or no cash consideration. Diluted net loss per share is determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as stock options and warrants calculated using the treasury stock method. In periods with reported net operating losses, all common stock options convertible preferred shares and preferred and common warrants are generally deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal.

The following potentially dilutive securities were excluded from the computation of earnings per share as of June 30, 2023 and 2022 because their effects would be anti-dilutive:

	June 30,	
	2023	2022
Common stock warrants	3,658,520	3,894,498
Assumed conversation of preferred stock warrants	11,896,667	—
Assumed conversion of preferred stock	4,051,637	1,135,721
Assumed conversion of convertible notes	488,031	488,031
Stock options	4,127,932	2,311,393
Total	24,222,787	7,829,643

At June 30, 2023, the Company had 1,037,792 pre-funded warrants outstanding. The following table provides a reconciliation of the weighted average shares outstanding calculation for the three and six months ended June 30, 2023 and 2022:

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Weighted average shares issued	11,320,450	7,906,728	10,693,762	7,906,728
Weighted average pre-funded warrants	1,143,215	283,755	1,341,976	283,755
Weighted average shares outstanding	12,463,665	8,190,483	12,035,738	8,190,483

(12) Income Taxes

As discussed in “Note 14—Income Taxes” to the notes to the consolidated financial statements contained in the Annual Report, the Company has a valuation allowance against the full amount of its net deferred tax assets. The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion or all of its deferred tax assets will not be realized. The Company has not recognized any unrecognized tax benefits in its balance sheet.

The Company is subject to income tax in the U.S., as well as various state and international jurisdictions. The federal and state tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations. Additional information regarding the statutes of limitations can be found in Note 14 Income Taxes of the Company’s Annual Report.

The Inflation Reduction Act of 2022 included tax legislation that became effective in the first quarter of 2023. Significant legislation for corporate taxpayers includes a corporate alternative minimum tax of 15% for companies with $1 billion or more in average net financial statement profits over the three previous years, as well as a 1% indirect excise tax on the repurchase of shares by a publicly traded company. The Company does not expect this legislation to have an effect on the tax provision as of June 30, 2023, however the Company will continue to evaluate the effect on the tax provision each reporting period.

(13) Commitments and Contingencies

medac Matter

In April 2021, the Company’s wholly owned subsidiary, Delcath Systems Ltd, issued to medac GmbH, a privately held, multi-national pharmaceutical company based in Germany (“medac”), an invoice for a €1 million milestone payment under a License, Supply and Marketing Agreement dated December 10, 2018 (the “medac Agreement”) between medac and the Company. The medac Agreement provided to medac the exclusive right to market and sell CHEMOSAT in certain designated countries for which the Company was entitled to a combination of upfront and success-based milestone payments as well as a fixed transfer price per unit of CHEMOSAT and specified royalties.

In response to medac’s subsequent dispute and non-payment of the invoice, on October 12, 2021, the Company notified medac in writing that it was terminating the medac Agreement due to medac’s nonpayment of the €1 million milestone

payment, with the effective date of termination of the medac Agreement being April 12, 2022. On December 16, 2021, the Company initiated an arbitration proceeding pursuant to the dispute resolution procedures of the medac Agreement for the non-payment of the invoice.

On December 30, 2022, the parties reached a final settlement of the matter and the Company agreed to pay medac either (a) a royalty on sales of CHEMOSAT units over a defined minimum for a period of five years or until a maximum payment has been reached, or (b) a minimum annual payment of $0.2 million in the event the annual royalty payment does not reach the agreed minimum payment amount. The Company has estimated the fair value of the settlement to be $1.3 million as of June 30, 2023 and recorded $1.1 million as other liabilities, non-current and $0.2 million as accrued expenses on the Company's condensed consolidated balance sheet as of June 30, 2023.

Lachman Consulting Services, Inc

On January 24, 2023, Lachman Consultant Services, Inc ("Lachman") served the Company with a Complaint alleging that Delcath owes Lachman approximately $0.9 million in unpaid consulting fees plus interest, costs and attorneys' fees. The dispute arose from a July 22, 2021 agreement between Lachman and Delcath under which Lachman provided assistance to the Company in regard to preparing for a FDA inspection and good manufacturing practices, training and support. As of June 30, 2023, the Company recorded $0.9 million as an accrued liability on the Company's condensed consolidated balance sheet. A settlement was reached on July 5, 2023, under which the Company paid Lachman $0.9 million.

(14) Fair Value Measurements

The table below presents activity within Level 3 of the fair value hierarchy, our liabilities carried at fair value for the six months ended June 30, 2023:

	Level 3		
(In thousands)	Contingent liabilities	Warrants	Total
Balance at January 1, 2023	$ 1,280	$ —	$ 1,280
Total change in foreign exchange	24		24
Fair value of the warrant liability issued	—	4,940	4,940
Warrant liability fair value adjustment	—	(1,160)	(1,160)
Balance at June 30, 2023	$ 1,304	$ 3,780	$ 5,084

Contingent liabilities are re-measured to fair value each reporting period using projected financial targets, discount rates, probabilities of payment, and projected payment dates. Projected contingent payment amounts are discounted back to the current period using a discounted cash flow model. Projected financial targets are based on our most recent internal operational budgets and may take into consideration alternate scenarios that could result in more or less profitability for the respective service line. Increases or decreases in projected financial targets and probabilities of payment may result in significant changes in the fair value measurements. Increases in discount rates and the time to payment may result in lower fair value measurements. Increases or decreases in any of those inputs in isolation may result in a significantly lower or higher fair value measurement.

As disclosed in Note 9 and Note 10 of the Company's consolidated financial statements, the Company allocated part of the proceeds of the Series F Preferred Offering to warrant liability issued in connection with the transaction. The valuations of the warrants were determined using option pricing models. The Company concluded that the Preferred Warrants were not in the scope of Accounting Standards Codification (ASC 480), Distinguishing Liabilities from Equity (ASC 480,) since the Preferred Warrants are not mandatorily redeemable; and do not have obligations to issue a variable number of shares of preferred stock. The Company determined the Preferred Warrants met the definition of a derivative in accordance with ASC 815 but were not considered indexed to the Company's common stock since the warrants require early settlement by repurchasing the preferred warrants for cash in an amount equal to the Black-Scholes value in the event of a Fundamental Transaction at pre-specified volatility of 100% as an input to the Black-Scholes calculation. The Company determined to record the Preferred Warrants at fair value with subsequent changes in fair value recorded in earnings at the end of each reporting period. For the three and six months ended June 30, 2023, the Company recorded other income of $1.2 million related to the change in fair value of the warrant liability. These models use inputs such as the underlying price of the shares issued at the measurement date, volatility, risk free interest rate and expected life of the instrument. The Company has classified the warrants as a long-term liability due to certain provisions relating to the holders' ability to exercise the warrants beyond twelve months of the reporting date.

The fair value of the preferred and common warrants at June 30, 2023 and March 29, 2023 was determined by using option pricing models assuming the following:

	March 29, 2023	June 30, 2023
Risk free interest rate	3.80% - 4.80%	4.39% - 5.29%
Expected term (years)	0.5 - 3.0	0.3 - 2.8
Expected volatility	70% - 75%	65% - 70%
Expected dividends	0.00 %	0.00 %

Additionally, the Company has determined that the warrant liability should be classified within Level 3 of the fair-value hierarchy by evaluating each input for the option pricing models against the fair-value hierarchy criteria and using the lowest level of input as the basis for the fair-value classification as called for in ASC 820. There are six inputs: closing price of the Company's stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of the Company's stock over that term; annual rate of dividends; and the risk-free rate of return. Of those inputs, the exercise price of the warrants and the remaining term are readily observable in the warrant agreements. The annual rate of dividends is based on the Company's historical practice of not granting dividends. The closing price of the Company's stock would fall under Level 1 of the fair-value hierarchy as it is a quoted price in an active market (ASC 820-10). The risk-free rate of return is a Level 2 input as defined in ASC 820-10, while the historical volatility is a Level 3 input as defined in ASC 820. Since the lowest level input is a Level 3, the Company determined the warrant liability is most appropriately classified within Level 3 of the fair value hierarchy.

The following tables present information about the Company's financial assets and liabilities that have been measured at fair value as of June 30, 2023 and December 31, 2022 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value. In general, the fair values were determined using Level 3:

(In thousands)	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	June 30, 2023
Liabilities:				
Contingent liability	$ —	$ —	$ 1,304	$ 1,304
Warrant liability	—	—	3,780	3,780
Total liabilities	$ —	$ —	$ 5,084	$ 5,084

(In thousands)	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	December 31, 2022
Liabilities:				
Contingent liability	$ —	$ —	$ 1,280	$ 1,280
Total liabilities	$ —	$ —	$ 1,280	$ 1,280

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of the financial condition and results of operations of Delcath Systems, Inc. ("Delcath" or the "Company") should be read in conjunction with the unaudited interim condensed consolidated financial statements and notes thereto contained in Item 1 of Part I of this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (the "Annual Report"), which was filed with the Securities and Exchange Commission (the "SEC") on March 27, 2023, to provide an understanding of its results of operations, financial condition and cash flows.

All references in this Quarterly Report on Form 10-Q to "we," "our," "us" and the "Company" refer to Delcath Systems, Inc., and its subsidiaries unless the context indicates otherwise.

This Quarterly Report on Form 10-Q and may include trademarks, service marks and trade names owned or licensed by us, including CHEMOFUSE, CHEMOSAT, CHEMOSATURATION, DELCATH, HEPZATO, HEPZATO KIT, PHP and THE DELCATH PHP SYSTEM. Solely for convenience and readability, trademarks, service marks and trade names, including logos, artwork and other visual displays, may appear in a non-traditional trademark usage manner, including without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks, service marks and trade names. All trademarks, service marks and trade names included in this Quarterly Report on Form 10-Q are the property of the Company or the Company's licensor, as applicable.

Disclosure Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity, and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "could," "would," "will," "may," "can," "continue," "potential," "should," and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this Quarterly Report on Form 10-Q that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in Item 3 "Quantitative and Qualitative Disclosures About Market Risk," and the risks discussed in Part II, Item 1A under "Risk Factors" and the risks detailed from time to time in our future reports filed with the SEC. These forward-looking statements include, but are not limited to, statements about:

- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- actions by the U.S. Food and Drug Administration ("FDA") relating to our New Drug Application ("NDA") resubmission;
- the ability of the Company to respond to FDA queries related to our scheduled Prescription Drug User Fee Act ("PDUFA") target action dated of August 14, 2023;
- the successful inspections by the FDA or foreign regulatory agencies of Delcath and Delcath suppliers;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- our ability to successfully commercialize CHEMOSAT and HEPZATO, generate revenue and successfully obtain reimbursement for the procedure and system;
- the initiation and success of our research and development programs;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source components of CHEMOSAT and HEPZATO and enter into supplier contracts;
- our ability to source melphalan for use in HEPZATO;
- our ability to successfully manufacture CHEMOSAT and HEPZATO;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners; and
- our estimates of potential market opportunities and our ability to successfully realize these opportunities.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

Company Overview

We are an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our lead product candidate, the HEPZATO® KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO, is a drug/device combination product designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, the hepatic delivery system is a stand-alone medical device having the same device components as HEPZATO but without the melphalan hydrochloride and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used at major medical centers to treat a wide range of cancers of the liver.

In the United States, HEPZATO is considered a combination drug and device product and is regulated as a drug by the FDA. Primary jurisdiction for regulation of HEPZATO has been assigned to the FDA's Center for Drug Evaluation and Research. The FDA has granted Delcath six orphan drug designations (five for melphalan in the treatment of patients with ocular (uveal) melanoma, cutaneous melanoma, intrahepatic cholangiocarcinoma, hepatocellular carcinoma, and neuroendocrine tumor indications and one for doxorubicin in the treatment of patients with hepatocellular carcinoma). HEPZATO has not been approved for sale in the United States.

Our clinical development program for HEPZATO is comprised of the FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the "FOCUS Trial"), a global registration clinical trial that is investigating objective response rate in metastatic ocular melanoma ("mOM"), a type of primary liver cancer. Our most advanced development program is the treatment of mOM. We are currently reviewing the incidence, unmet need, available efficacy data and development requirements for a broad set of liver cancers in order to select a portfolio of follow-on indications that will maximize the value of the HEPZATO platform. In addition to HEPZATO's use to treat mOM, we believe that HEPZATO has the potential to treat other liver dominant cancers, such as Metastatic Colorectal Cancer and Cholangiocarcinoma, and plan to begin the study of HEPZATO to treat such conditions in the near future. We believe that the disease states we are investigating and intend to investigate are unmet medical needs that represent significant market opportunities.

In December 2021, the Company announced that the FOCUS Trial for HEPZATO met its pre-specified endpoint. For information on the FOCUS Trial, see "Part I, Item 1. Business—Clinical Development Program—The FOCUS Trial" in our Annual Report.

On February 14, 2023, we filed an NDA resubmission with the FDA for the HEPZATO KIT (melphalan hydrochloride for Injection/Hepatic Delivery System) seeking approval of the HEPZATO KIT in the treatment of patients with unresectable hepatic-dominant mOM. The NDA resubmission was in response to a September 12, 2013 Complete Response Letter ("CRL"), from the FDA for the NDA submitted in December 2010 seeking approval of its first generation melphalan hydrochloride for injection/hepatic delivery system. The NDA resubmission contains comprehensive data and information on Generation Two HEPZATO KIT relating to the matters identified in the CRL. On March 20, 2023, the FDA determined the resubmission constituted a complete response and set a PDUFA target action date of August 14, 2023. We continue our expanded access programs ("EAP") in the United States to make HEPZATO readily available to mOM patients. We are focused on continuing to treat these patients with mOM as regulatory approval is sought in the United States. There are currently patients enrolled in our EAP sites.

Our preparations for the possibility of the HEPZATO KIT's commercialization includes securing the long-term supply of critical components necessary to manufacture the HEPZATO KIT under commercially reasonable terms. The drug component of the HEPZATO KIT, melphalan, is a generic drug currently approved under numerous Abbreviated New Drug Applications ("ANDAs"). We currently have an agreement with one supplier of melphalan and, with the goal of minimizing the risk of a supply interruption, are in discussions with several melphalan ANDA holders who have indicated interest in supplying melphalan to us. We are aware that the FDA issued our current melphalan manufacturer 483 observations as a result of an inspection unrelated to the HEPZATO NDA resubmission and the manufacturer is working to address these observations. The manufacturer is planning to suspend its operations beginning in December 2023 for several months to perform facility maintenance. We believe we have sufficient quantities of melphalan to meet our forecasted HEPZATO KIT demand through this shutdown period. We believe we have sufficient stock for the device components of the HEPZATO KIT to meet the first year of our forecasted

demand and intend to manage supply chain risk through stockpiled inventory and contracting with multiple suppliers for critical components.

On February 28, 2022, CHEMOSAT received Medical Device Regulation (MDR) certification under the European Medical Devices Regulation [2017/745/EU], which may be considered by jurisdictions when evaluating reimbursement. As of March 1, 2022, we have assumed direct responsibility for sales, marketing and distribution of CHEMOSAT in Europe.

Results of Operations

	Three months ended June 30,		Six months ended June 30,	
(In thousands)	**2023**	**2022**	**2023**	**2022**
Total revenues	$ 495	$ 797	$ 1,092	$ 1,174
Cost of goods sold	(150)	(180)	(331)	(214)
Gross profit	345	617	761	960
Research and development expenses	3,555	5,606	8,131	10,087
Selling, general and administrative expenses	4,787	4,497	8,952	8,699
Total operating expenses	8,342	10,103	17,083	18,786
Operating loss	(7,997)	(9,486)	(16,322)	(17,826)
Interest and other income (expense)	795	(673)	120	(1,333)
Net loss	$ (7,202)	$ (10,159)	$ (16,202)	$ (19,159)

Revenue

The decrease in total revenue for the three and six months ended June 30, 2023 compared to the same periods in 2022 was primarily due to lower demand for CHEMOSAT.

Cost of Goods Sold

The change in cost of goods sold for the three and six months ended June 30, 2023 compared to the same periods in 2022 is directly related to changes in product revenue.

Research and Development Expenses

Research and development expenses are incurred for the development of HEPZATO and consist primarily of payroll and payments to contract research and development companies. In 2022, these costs primarily related to generating pre-clinical data and the cost of manufacturing HEPZATO for clinical trials and conducting clinical trials. The decrease for the three and six months ended June 30, 2023 compared to the same periods in 2022 is due to the completing of clinical trial activities in the prior period in 2022 and higher expenses for the preparation for the pre-NDA meeting in April 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of payroll, rent and professional services such as accounting and legal services. For the three and six months ended June 30, 2023 compared to the same periods in 2022, selling, general and administrative expenses have increased due to activities to prepare for commercial launch.

Interest and other Income/Expense

Interest and other income (expense) in 2023 is primarily related to the change in fair value of the warrant liability, interest income associated with marketable securities offset by interest expense related to our debt instruments. Interest and other income (expense) in 2023 is primarily related to interest expense for our debt instruments. There was a decrease in interest expense for the three and six months ended June 30, 2023 compared to the same periods in 2022 related to the principal loan payments during the first half of 2023 as we paid $6.3 million of principal payments.

Liquidity and Capital Resources

At June 30, 2023, we had cash, cash equivalents and restricted cash totaling $14.6 million, as compared to cash, cash equivalents and restricted cash totaling $11.8 million at December 31, 2022. During the six months ended June 30, 2023, we used $13.9 million of cash for operating activities and $6.3 million for principal payments. At March 31, 2023, we had cash, cash equivalents

and restricted cash totaling $24.3 million and we used $9.7 million of cash for operating activities during the three months ended June 30, 2023.

Our future results are subject to substantial risks and uncertainties. The Company has operated at a loss for its entire history and there can be no assurance that it will ever achieve or maintain profitability. The Company has historically funded its operations primarily with proceeds from sales of common stock, warrants and prefunded warrants for the purchase of common stock, sales of preferred stock, proceeds from the issuance of convertible debt and borrowings under loan and security agreements.

We currently believe that our current cash and cash equivalents will enable us to have sufficient cash past our anticipated PDUFA date of August 14, 2023. If there is a substantial delay in the approval of HEPZATO we expect to need to raise additional capital under structures available to us, including debt and/or equity offerings, which may not be on terms favorable to us. In a delayed approval scenario, we will not have sufficient funds to meet its obligations within twelve months from the issuance date of these condensed consolidated financial statements. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves. In a delayed approval scenario, our ability to continue as a going concern depends on our ability to raise additional capital through the sale of equity or debt securities, or through partnering or licensing transactions in which we receive cash to support our future operations. If we are unable to secure additional capital or if additional capital is not available on favorable terms for us, we may be required to take measures to reduce costs in order to conserve our cash.

We also expect to use cash and cash equivalents to fund activities relating to the recent HEPZATO NDA resubmission, the possible commercialization of HEPZATO and the continued commercial support for CHEMOSAT and the any future clinical research trials and operating activities. Our future liquidity and capital requirements will depend on numerous factors, including the initiation and progress of clinical trials and research and product development programs; obtaining regulatory approvals and complying with applicable laws and regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments.

Our capital commitments over the next twelve months include (a) $6.6 million to satisfy accounts payable, accrued expenses and lease liabilities and (b) $5.1 million of loan principal payments. Additional capital commitments beyond the next twelve months include (a) $0.1 million of lease liabilities; (b) $1.0 million for settlement of litigation with medac; (c) $0.5 million of loan principal payments; and (d) $5.0 million of convertible note principal payments, if the holders do not elect to convert the notes into equity.

ATM Sales Agreement

We entered into a Controlled Equity Offering[SM] Sales Agreement (“ATM Sales Agreement”), with Cantor Fitzgerald & Co. (the “Sales Agent”), pursuant to which the Company may offer and sell, at its sole discretion through the Sales Agent, shares of common stock having an aggregate offering price of up to $17.0 million. To date, the Company has sold approximately $4.0 million of its common stock, prior to issuance costs, under the ATM Sales Agreement. No sales were made during the three and six months ended June 30, 2023.

Avenue Loan Agreement

On August 6, 2021, we entered into the Avenue Loan Agreement with Avenue Venture Opportunities Fund, L.P. (the “Lender,” or “Avenue”) for a term loan in an aggregate principal amount of up to $20 million (the “Avenue Loan”). The Avenue Loan bears interest at an annual rate equal to the greater of (a) the sum of 7.7% plus the prime rate as reported in The Wall Street Journal and (b) 10.95%. The interest rate at June 30, 2023 was 15.95%. The Avenue Loan is secured by all of our assets globally, including intellectual property. The Avenue Loan matures on August 1, 2024. On March 15, 2023, we returned to Avenue $4.0 million held in the restricted cash to pay down a portion of the outstanding loan balance, principal payments of $2.1 million and an incremental 4.25% of the final payment of $0.2 million. On March 31, 2023, we reached an agreement to amend the existing loan agreement with Avenue to defer the interest only period to September 30, 2023. The interest only period may be extended at our option to December 31, 2023 if, by September 30, 2023, we have (a) received FDA approval for the HEPZATO KIT and (b) received net proceeds of at least $10 million from the sale and issuance of equity securities or exercise of existing warrants. In exchange for

this extension, we have agreed to provide Avenue with 34,072 warrants to purchase shares of common stock. The exercise price of the warrants is $0.01.

Private Placements, Common Offering and Warrants

On March 27, 2023, we entered into a securities purchase agreement with certain accredited investors (the "Preferred Purchase Agreement"), pursuant to which we agreed to issue and sell, in a private placement (the "Series F Preferred Offering"), (i) 24,900 shares of our Series F-1 Convertible Preferred Stock, par value $0.01 per share (the "Series F-1 Preferred Stock"), (ii) tranche A warrants (the "Preferred Tranche A Warrant") to acquire shares of Series F-3 Convertible Preferred Stock, par value $0.01 per share (the "Series F-3 Preferred Stock") and (iii) tranche B warrants (the "Preferred Tranche B Warrant," together with the Preferred Tranche A Warrant, the "Preferred Warrants") for an aggregate offering price of $24.9 million before deducting the fees paid to the placement agent and the financial advisors and other financing expenses payable by us.

Also on March 27, 2023, we entered into a securities purchase agreement with the our Chief Executive Officer, Gerard Michel, pursuant to which we agreed to issue and sell, in a private placement, (i) 19,646 shares of common stock, (ii) tranche A warrants to acquire shares of common stock and (iii) tranche B warrants to acquire shares of common stock for an approximate aggregate offering price of $100,000.

On June 12, 2023, at the annual general meeting of stockholders, the stockholders approved the private placement that closed on March 29, 2023 ("Stockholder Approval") and therefore, the Preferred Warrants issued in such private placement are exercisable. The exercise of all such Preferred Warrants would generate approximately $60.0 million in proceeds. There can be no guarantee that such Preferred Warrants are ever exercised, and if so, there is no guarantee that we will ever receive the full $60.0 million in proceeds.

As of June 30, 2023, 15,276 shares of our Series F-1 Preferred Stock were converted into 4,629,539 shares of common stock and 9,624 shares of our Series F-1 Preferred Stock were converted into an equal number of shares of Series F-2 Preferred Stock.

Critical Accounting Estimates

Other than the accounting for the valuation of warrant liability and Series F-1 Preferred Stock, during the three and six months ended June 30, 2023, there were no other material changes to critical accounting estimates as reported in our Annual Report.

The valuations of the warrant liability and Series F-1 Preferred Stock were determined using option pricing models. These models use inputs such as the underlying price of the shares issued at the measurement date, volatility, risk free interest rate and expected life of the instrument. In addition, the Company used probabilities of the FDA approval and of recording at least $10 million in quarterly U.S. revenue from the commercialization of HEPZATO as inputs in the model to determine the fair value of warrants liability and Series F-1 Preferred Stock. The Company will adjust the fair value of the warranty liability at the end of each reporting period.

Application of Critical Accounting Policies

Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America. Other than the policies described in our notes Note 1 to the Notes to the Condensed Consolidated Financial Statements included elsewhere in this quarterly report on 10-Q for the three and six months ended June 30, 2023, there were no material changes to our critical accounting policies as reported in our Annual Report. A description of certain accounting policies that may have a significant impact on amounts reported in the financial statements is disclosed in "Note 3 – Summary of Accounting Policies" to the notes to the consolidated financial statements contained in the Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of June 30, 2023, our management, under the supervision of our Chief Executive Officer and our Principal Accounting Officer, performed an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Accounting Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our Chief Executive Officer and Principal Officer determined that as a result of the material weaknesses in our internal control over financial reporting previously disclosed in our Annual Report, our disclosure controls and procedures were not effective as of June 30, 2023.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended June 30, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, claims are made against the Company in the ordinary course of business, which could result in litigation. Claims and associated litigation are subject to inherent uncertainties and unfavorable outcomes could occur, such as monetary damages, fines, penalties, or injunctions prohibiting us from selling our products or engaging in other activities.

medac Matter

In April 2021, the Company's wholly owned subsidiary, Delcath Systems Ltd, issued to medac GmbH, a privately held, multi-national pharmaceutical company based in Germany ("medac"), an invoice for a €1 million milestone payment under a License, Supply and Marketing Agreement dated December 10, 2018 (the "medac Agreement") between medac and the Company. The medac Agreement provided to medac the exclusive right to market and sell CHEMOSAT in certain designated countries for which the Company was entitled to a combination of upfront and success-based milestone payments as well as a fixed transfer price per unit of CHEMOSAT and specified royalties.

In response to medac's subsequent dispute and non-payment of the invoice, on October 12, 2021, the Company notified medac in writing that it was terminating the medac Agreement due to medac's nonpayment of the €1 million milestone payment, with the effective date of termination of the medac Agreement being April 12, 2022. On December 16, 2021, the Company initiated an arbitration proceeding pursuant to the dispute resolution procedures of the medac Agreement for the non-payment of the invoice.

On December 30, 2022, the parties reached a final settlement of the matter and the Company agreed to pay medac either (a) a royalty on sales of CHEMOSAT units over a defined minimum for a period of five years or until a maximum payment has been reached, or (b) a minimum annual payment of $0.2 million in the event the annual royalty payment does not reach the agreed minimum payment amount. The Company has estimated the fair value of the settlement to be $1.3 million as of June 30, 2023 and recorded $1.1 million as other liabilities, non-current and $0.2 million as accrued expenses on the Company's condensed consolidated balance sheet as of June 30,2023.

Lachman Consulting Services, Inc

On January 24, 2023, Lachman Consultant Services, Inc ("Lachman") served the Company with a Complaint alleging that Delcath owes Lachman approximately $0.9 million in unpaid consulting fees plus interest, costs and attorneys' fees. The dispute arose from a July 22, 2021 agreement between Lachman and Delcath under which Lachman provided assistance to the Company in regard to preparing for a FDA inspection and good manufacturing practices, training and support. As of June 30, 2023, the Company recorded $0.9 million as an accrued liability on the Company's condensed consolidated balance sheet. A settlement was reached on July 5, 2023, under which the Company paid Lachman $0.9 million.

Item 1A. Risk Factors

Our business is subject to various risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. You should carefully consider the risks and uncertainties described below, together with all of the other information included in this Quarterly Report on Form 10-Q and in the Annual Report on Form 10-K. Our business faces significant risks and uncertainties, and those described below may not be the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also significantly impair our business, financial condition or results of operations. If any of these risks or uncertainties occur, our business, financial condition or results of operations could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock.

Risk Factor Summary

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider this summary to be a complete discussion of all potential risks or uncertainties that may substantially impact our business. An additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, are described below, and this summary is qualified in its entirety by that description. Moreover, we operate in a competitive and rapidly changing environment. New factors emerge from time to time, and it is not possible to predict the impact of all of these factors on our business, financial condition or results of operations. You should carefully consider the risks and uncertainties described below as part of your evaluation of an investment in our common stock.

- Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern. If there is a delay in the potential commercialization of HEPZATO, including a delay in the approval of HEPZATO or lower than anticipated revenue from any HEPZATO commercialization, we will be unable to continue to operate for the foreseeable future without additional capital;

- If there is a delay in the potential commercialization of HEPZATO, including a delay in the approval of HEPZATO or lower than anticipated revenue from any HEPZATO commercialization, we will need additional capital to maintain our operations. If we cannot raise additional capital, our potential to generate future revenues will be significantly limited since we may not be able to further commercialize CHEMOSAT and HEPZATO, complete our clinical trials or conduct future product development and clinical trials;

- The Company does not expect to generate significant revenue for the foreseeable future;

- Continuing losses may exhaust our capital resources;

- If we cannot raise additional capital, our potential to generate future revenues will be significantly limited since we may not be able to further commercialize CHEMOSAT and HEPZATO, or conduct future product development and clinical trials;

- Our failure to obtain, or delays in obtaining, regulatory approvals may have a material adverse effect on our business, financial condition and results of operations;

- We have obtained the right to affix the CE Mark for the CHEMOSAT Hepatic Delivery System as a medical device for the delivery of melphalan. Since we may only promote the device within this specific indication, if physicians are unwilling to obtain melphalan separately for use with CHEMOSAT, our ability to commercialize CHEMOSAT in the EU will be significantly limited;

- We are subject to significant ongoing regulatory obligations and oversight in the EU and will be subject to such obligations in any other country where we receive marketing authorization or approval;

- The development and approval process in the United States is time consuming, requires substantial resources and may never lead to the approval of HEPZATO by the FDA for use in the United States. The FDA may reject our New Drug Application resubmission or refuse to approve the New Drug Application for HEPZATO;

- If future clinical trials are unsuccessful, significantly delayed or not completed, we may not be able to market HEPZATO for other indications;
- We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates;
- We rely on third parties to conduct certain elements of the clinical trials for CHEMOSAT and HEPZATO, and if these third parties do not perform their obligations to us, we may not be able to obtain regulatory approvals for our system;
- Purchasers of CHEMOSAT in the EU may not receive third-party reimbursement or such reimbursement may be inadequate. Without adequate reimbursement, commercialization of CHEMOSAT in the EU may not be successful. The success of any of our products may be harmed if the government, private health insurers or other third-party payers do not provide sufficient coverage or reimbursement;
- CHEMOSAT and HEPZATO may not achieve sufficient acceptance by the medical community to sustain our business;
- We may be subject, directly or indirectly, to federal and state health care fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties;
- Compliance with laws and regulations pertaining to the privacy and security of health information may be time consuming, difficult and costly for us, particularly in light of increased focus on privacy issues in countries around the world, including the U.S. and in the EU;
- Changes in health care law and governmental policies and initiatives with respect to health care, including government restrictions on pricing and reimbursement and other health care payor cost-containment initiatives, may have a material adverse effect on us;
- Changes in general market, economic, and political conditions, as well as uncertainty resulting from geopolitical tensions, and other macroeconomic conditions;
- Consolidation in the healthcare industry could lead to demands for price concessions;
- We may not be able to enter into or maintain acceptable arrangements for the supply of components and/or raw materials needed for the manufacture of HEPZATO and/or CHEMOSAT;
- The FDA may determine that our NDA Resubmission is not approvable due to cGMP deficiencies;
- We must maintain or enter into acceptable arrangements for the production of melphalan and other critical components of HEPZATO, we may not be able to ensure adequate supply impacting our ability to successfully commercialize HEPZATO in the United States or complete any future clinical trials;
- If we cannot successfully manufacture CHEMOSAT and HEPZATO, our ability to develop and commercialize the system would be impaired;
- Even if we receive FDA or other foreign regulatory approvals, we may be unsuccessful in commercializing our product in markets outside the EU, because of inadequate infrastructure or an ineffective commercialization strategy; and
- Any plan by the Company to use collaborative arrangements with third parties to help finance and to market and sell CHEMOSAT and HEPZATO may not be successful.

Risks Related to Our Business and Financial Condition

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern as of December 31, 2022. If there is a delay in the potential commercialization of HEPZATO, including a delay in the approval of HEPZATO or lower than anticipated revenue from any HEPZATO commercialization, we will be unable to continue to operate for the foreseeable future without additional capital.

Our independent registered public accounting firm issued a report dated March 27, 2023 in connection with the audit of our financial statements as of December 31, 2022, which included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern including our significant working capital deficiency, significant losses and need to raise additional funds to meet our obligations and sustain our operations. In addition, the notes to our financial statements for the year ended December 31, 2022 and quarter ended June 30, 2023, included in our Annual Report on Form 10-K and Quarterly Report on Form 10-Q, respectively, contain disclosures describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern was dependent upon our ability to obtain substantial additional funding in connection with our continuing operations. We anticipate that our existing cash and cash equivalents will enable us to maintain our current operations past our anticipated PDUFA date of August 14, 2023 for HEPZATO. If there is a substantial delay in the approval of HEPZATO, in the absence of potential proceeds from cash exercises of currently outstanding warrants and/or substantial modifications to the Company's current preparations for the potential commercialization of HEPZATO, our ability to continue as a going concern depends on our ability to raise additional funding. If we are not able to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements and/or seek protection under federal bankruptcy law or enter into a receivership, and it is likely that holders of our common stock and holders of securities convertible into our common stock will lose all of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

As such, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern.

If there is a delay in the potential commercialization of HEPZATO, including a delay in the approval of HEPZATO or lower than anticipated revenue from any HEPZATO commercialization, we will need additional capital to maintain our operations. If we cannot raise additional capital, our potential to generate future revenues will be significantly limited since we will not be able to further commercialize CHEMOSAT and HEPZATO, complete our clinical trials or conduct future product development and clinical trials.

Preclinical testing and clinical trials are long, expensive, and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. Drug development is very risky, and it takes several years to complete clinical trials. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability, or prevalence of use of a comparator treatment or required prior therapy, clinical outcomes including insufficient efficacy, safety concerns, or our own financial constraints.

We will require additional substantial financing to complete our clinical trial program or seek other approvals, to conduct future development and clinical trials and to further commercialize our product in the EU and any other markets where we may receive approval for our products. We anticipate that our existing cash and cash equivalents will enable us to maintain our current operations past our anticipated PDUFA date of August 14, 2023 for HEPZATO. If there is a substantial delay in the approval of HEPZATO, in the absence of potential proceeds from cash exercises of currently outstanding warrants, we will require substantial additional funding to complete product development projects or clinical trials. If we are unable to raise additional capital, our ability to complete product development projects or clinical trials will be impaired. We do not know if additional financing will be available on commercially reasonable terms or at all. In addition, we may not be able to access a portion of our existing cash, cash equivalents and investments due to market conditions.

If we require additional financing in the near-term due to any change to our anticipated PDUFA date, we will not be able to further commercialize CHEMOSAT and HEPZATO, obtain regulatory approvals or complete our development projects or clinical trials, which could result in a complete loss of an investment in our securities.

Our liquidity and capital requirements will depend on numerous factors, including:

- the outcome of clinical studies;

- the timing and costs of our various United States and foreign regulatory filings, obtaining approvals and complying with regulations;
- our ability to secure the continuous supply of melphalan and other critical components of HEPZATO and CHEMOSAT from facilities in compliance with applicable manufacturing regulations;
- our ability to secure commercially reasonable terms for the supply of melphalan and other critical components of HEPZATO and CHEMOSAT;
- the timing, costs and regulatory approval processes associated with developing our and/or our partners' manufacturing operations;
- the timing of product commercialization activities, including marketing and distribution arrangements;
- market acceptance of any approved product candidates, including product pricing and product reimbursement by third-party payors;
- executive compensation, including the cost of attracting senior executives;
- the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and
- the impact of competing technological and market developments.

Insufficient capital may require us to curtail or stop our commercialization activities, regulatory submissions or ongoing activities for regulatory approval, research and development and clinical trials, which will significantly limit our potential to generate future revenues. If we are not able to raise additional capital in the near term, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements and/or seek protection under federal bankruptcy law or enter into a receivership, and it is likely that holders of our common stock and holders of securities convertible into our common stock will lose all of their investment.

If we do not receive FDA Approval before September 30, 2023, we may be unable to comply with the terms and conditions of our Loan and Security Agreement (the "Avenue Loan Agreement") with Avenue Venture Opportunities Fund, L.P. (the "Lender," or "Avenue"). If we breach the Avenue Loan Agreement, this may adversely impact our business and financial condition.

On August 6, 2021, we entered into the Avenue Loan Agreement, pursuant to which, we have borrowed $15 million as of the date hereof. Pursuant to the Avenue Loan Agreement, we made monthly interest-only payments during the first fifteen months of the term of the Avenue Loan Agreement and began principal payments in December 2022. On March 31, 2023, the Company reached an agreement to amend the Avenue Loan Agreement to defer the interest only to September 30, 2023. The interest only period may be extended at the Company's option to December 31, 2023 if, by September 30, 2023, the Company has (a) received FDA approval for the HEPZATO KIT and (b) received net proceeds of at least $10 million from the sale and issuance of equity securities or exercise of existing warrants.

The Avenue Loan Agreement bears interest at an annual rate equal to the greater of (a) the sum of 7.7% plus the prime rate as reported in The Wall Street Journal and (b) 10.95%. The interest rate at June 30, 2023 was 15.95%. The Avenue Loan Agreement is secured by all of the Company's assets globally, including intellectual property. The amount borrowed pursuant to the Avenue Loan Agreement matures on August 1, 2024.

The Avenue Loan Agreement contains customary events of default, including, among other things, our failure to fulfill certain of our obligations under the Avenue Loan Agreement and the occurrence of a material adverse change in our business, operations or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan, the failure to deliver an unqualified audit report and board approved financial projections within time periods set forth in the Avenue Loan Agreement, or a material impairment in the perfection or priority of lender's lien in the collateral or in the value of such collateral. In the event of default by us under the Avenue Loan Agreement, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Avenue Loan Agreement, which could harm our business, operations and financial condition.

We anticipate that our existing cash and cash equivalents will enable us to maintain our current operations through past our anticipated PDUFA date of August 14, 2023. If we do not make our required monthly repayment on October 1, 2023, in accordance with the March 2023 amendment to the Avenue Loan Agreement, we would be in default of the Avenue Loan Agreement. If we were to be in default of the Avenue Loan Agreement, our business and financial condition may be adversely impacted and result in us losing rights to certain or our assets, including intellectual property that is secured by the Avenue Loan Agreement. Furthermore, if we default on any installment under the Avenue Loan Agreement, we will not be eligible to use Form S-3 registration statements for an extended period of time, which could further adversely impact our ability to raise additional financing.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. In 2013, we received a complete response letter from the FDA declining to approve our NDA in its then current form. There can be no assurance that our recent resubmission will be accepted by FDA or will not result in another Complete Response Letter.

Preclinical testing and clinical trials are long, expensive, and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. Drug development is very risky, and it takes several years to complete clinical trials. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability, or prevalence of use of a comparator treatment or required prior therapy, clinical outcomes including insufficient efficacy, safety concerns, or our own financial constraints.

In response to our NDA, which we submitted to the FDA in August 2012 seeking approval for use of our HEPZATO for the treatment of patients with ocular melanoma of the liver, in September 2013, the FDA denied approval of the NDA in its then current form and issued a complete response letter, or CRL. A CRL is issued by the FDA when the review of an NDA is completed, and deficiencies remain that preclude approval of the NDA in its current form. The deficiencies in the CRL included, but were not limited to, a statement that we must perform additional "well-controlled randomized trial(s) to establish the safety and efficacy of HEPZATO using overall survival as the primary efficacy outcome measure" and which "demonstrates that the clinical benefits of HEPZATO outweigh its risks." The FDA also required that the additional clinical trial(s) be conducted using the product we intend to market. Prior to conducting additional clinical trials, we were required to satisfy certain other requirements of the CRL, including, but not limited to, product quality testing, pre-clinical studies and human factors validation information.

We have completed a pivotal Phase 3 trial in ocular melanoma liver metastases. We will need to justify how the results of the study support a favorable risk-benefit assessment, particularly whether the response rate is sufficient to overcome the toxicity of HEPZATO. The FDA may review and issue another CRL if it does not conclude that the clinical benefits outweigh the risks and that HEPZATO is safe and effective for use in the intended population.

In addition, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations and trial endpoints to support additional indications for HEPZATO with other drug therapies. In 2014, we initiated a Phase 2 clinical trial with HEPZATO for hepatocellular carcinoma, or HCC, in both the United States and Europe. In 2015, the Phase 2 clinical trial for HCC was expanded to include a cohort of patients with intrahepatic cholangiocarcinoma, a type of primary liver cancer, or ICC. The trial for this cohort was conducted at the same centers participating in the Phase 2 HCC trial. Unfavorable or inconsistent clinical data from clinical trials, including the Phase 2 clinical trial for HCC, the market's perception of these clinical data or FDA's perception of this clinical data, may adversely impact our ability to obtain approval, and our financial condition. We have paused our work on this trial while we reevaluated the trial design. Additionally, even if the results of our Phase 2 clinical trial for HCC are positive, there is a substantial risk that it will fail to have positive results in Phase 3 clinical trials with regard to efficacy, safety or other clinical outcomes and may never obtain regulatory approval.

Raising additional capital, or the exercise or conversion of securities exercisable or convertible into shares of common stock, may cause dilution to our existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require it to relinquish proprietary rights.

Significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, exercise of our outstanding warrants and conversion of outstanding preferred stock, strategic alliances and license and development agreements in connection with any collaborations. We do not currently have any committed external source of funds and we anticipate that our existing cash and cash equivalents will enable us to maintain our current operations past our anticipated PDUFA date of August 14, 2023. To the extent that we raise additional capital by issuing equity securities, existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of a common stockholder. In addition, the exercise of outstanding warrants and options will also cause dilution. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, creating liens, redeeming its stock or making investments.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, or through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties on acceptable terms, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market.

Continuing losses may exhaust our capital resources.

As of June 30, 2023, we had $14.6 million in cash and cash equivalents. We have had minimal revenue to date, and have a substantial accumulated deficit, recurring operating losses and negative cash flow. We are not profitable and have incurred losses in each year since commencing operations. For the six months ended June 30, 2023 and years ended December 31, 2022 and 2021, we incurred net losses of approximately $16.2 million, $36.5 million and $25.6 million, respectively, and expect to continue to incur losses in 2023. To date, we have funded operations through a combination of private placements and public offerings of our securities, debt financing including convertible notes. If we continue to incur losses, we may exhaust our capital resources, and as a result may be unable to complete our clinical trials, engage in product development and the regulatory approval process and commercialization of CHEMOSAT and HEPZATO or any other versions of these products. If we are unable to raise capital or generate sufficient revenue, we may not be able to pay our debts when they become due and may have to seek protection under federal bankruptcy law or enter into a receivership.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. In addition, we will not be able to generate product revenue unless and until one of our product candidates successfully completes clinical trials, receives regulatory approval and is successfully commercialized. In addition, we will not be able to generate product revenue unless and until one of our product candidates successfully completes clinical trials, receives regulatory approval and is successfully commercialized. Our ability to generate any product revenue from our current or future product candidates also depends on a number of additional factors, including our ability to:

- successfully complete research and clinical development of current and future product candidates and obtain regulatory approval for those product candidates;
- establish and maintain supply and manufacturing relationships, under commercially reasonable terms, with third parties, and ensure adequate, scaled up and legally compliant manufacturing of necessary components, including melphalan, bulk drug substances and drug products to maintain sufficient supply;
- launch and commercialize any product candidates for which marketing approval is obtained, if any, and, if launched independently by us without a partner, successfully establish a sales force and marketing and distribution infrastructure;
- demonstrate the necessary safety data (and, if accelerated approval is obtained, verify the clinical benefit) post-approval to ensure continued regulatory approval;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors, for any approved products;
- achieve market acceptance for any approved products;
- establish, maintain, protect and enforce our intellectual property rights; and
- attract, hire and retain qualified personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, including that our product candidates may not advance through development or be approved for commercial sale, we are unable to predict if or when we will generate product revenue or achieve or maintain profitability. Even if we successfully complete development and regulatory processes for any product candidates that we take forward, we anticipate incurring significant costs associated with launching and commercializing any products. If we fail to become profitable or do not sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or cease our operations.

We have in the past, and may in the future, become subject to litigation or claims arising in or outside the ordinary course of business that could negatively affect our business operations and financial condition.

We have in the past, and may in the future, become subject to litigation or claims arising in or outside the ordinary course of business (other than intellectual property infringement actions) that could negatively affect our business operations and financial condition, including securities class actions and shareholder derivative actions, both of which are typically expensive to defend. Such claims and litigation proceedings may be brought by third parties, including our competitors, advisors, service providers, partners or collaborators, employees, and governmental or regulatory bodies. For information on past legal proceedings, please see "Part I - Item 1. Legal Proceedings." Any claims and lawsuits, and the disposition of such claims and lawsuits, could be time-consuming and expensive to resolve, divert management attention and resources, and lead to attempts on the part of other parties to pursue similar claims. We may not be able to determine the amount of any potential losses and other costs we may incur due to the inherent uncertainties of litigation and settlement negotiations. In the event we are required or decide to pay amounts in connection with any claims or lawsuits, such amounts could be significant and could have a material adverse impact on our liquidity, business, financial condition and results of operations. In addition, depending on the nature and timing of any such dispute, a resolution of a legal matter could materially affect our future operating results, our cash flows or both. Additionally, we

may be unable to maintain our existing directors' and officers' liability insurance in the future at satisfactory rates or adequate coverage amounts and may incur significant increases in insurance costs.

The Company does not expect to generate significant revenue for the foreseeable future.

Our entire focus has been on developing, commercializing, and obtaining regulatory authorizations and approvals of CHEMOSAT and HEPZATO and we have only developed these products for the treatment of cancers in the liver. If CHEMOSAT and HEPZATO for the treatment of cancers in the liver fail as commercial products, we have no other products to sell. In addition, since CHEMOSAT currently is approved for commercialization solely in the European Union, or the EU, and limited other jurisdictions (including the United Kingdom), if we are unsuccessful in commercializing the product in the EU and/or if HEPZATO is not approved in the United States and elsewhere, we will have no means of generating revenue. Accordingly, we may not generate material revenues from product sales in the United States in the next year, if at all. As a result, our revenue sources are, and will remain, extremely limited unless and until our product candidates are approved by the FDA or other additional foreign regulatory agencies and successfully marketed. CHEMOSAT and HEPZATO may not be approved by the FDA or other additional foreign regulatory agency or marketed at any time in the foreseeable future or at all.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, geopolitical events, such as the crisis in Ukraine, or other macroeconomic conditions, which have in the past and may in the future negatively impact our business and financial performance.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in economic growth, supply chain shortages and disruptions, increases in inflation rates, higher interest rates and uncertainty about economic stability.

The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Similarly, public health crises and the ongoing military conflict between Russia and Ukraine has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, or do not improve, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive.

Further downgrades of the U.S. credit rating, automatic spending cuts, or a government shutdown could negatively impact our liquidity, financial condition and earnings.

The U.S. debt ceiling and budget deficit concerns have increased the possibility of credit-rating downgrades and economic slowdowns, or a recession in the United States. Although U.S. lawmakers have previously passed legislation to raise the federal debt ceiling on multiple occasions, there is a history of ratings agencies lowering or threatening to lower the long-term sovereign credit rating on the United States given such uncertainty. On August 1, 2023, Fitch Ratings downgraded the United States' long-term foreign currency issuer default rating to AA+ from AAA as a result of these repeated debt ceiling and budget deficit concerns. The impact of this or any further downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness could adversely affect the U.S. and global financial markets and economic conditions. Moreover, these developments could cause interest rates and borrowing costs to rise, which may negatively impact our ability to access the debt markets on favorable terms. In addition, disagreement over the federal budget has caused the U.S. federal government to shut down for periods of time. Continued adverse political and economic conditions could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to FDA and Foreign Regulatory Approvals and Regulatory Matters

The development and approval process in the United States could take many years, require substantial resources and may never lead to the approval of HEPZATO by the FDA for use in the United States.

We cannot sell or market HEPZATO with melphalan or other chemotherapeutic agents in the United States without prior FDA approval of the NDA for HEPZATO. Although melphalan and other drugs have been approved by the FDA for use as chemotherapeutic agents, regulatory approval is required in the United States for the combined medical device component and drug component and the specific indication, dose and route of administration of melphalan or other chemotherapeutic agents or compounds used in our system. We are seeking approval of HEPZATO for a substantially higher dose of melphalan than prior approved doses of melphalan and such other chemotherapeutic agents or other compounds. We must obtain separate regulatory approvals for HEPZATO with melphalan, and every other chemotherapeutic agent or other compound used with the system that we intend to market, and all the manufacturing facilities used to manufacture components or assemble our system must be

inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish to the FDA's satisfaction the product's safety, efficacy, potency and purity for each intended use. The pre-clinical testing and clinical trials of HEPZATO with melphalan or any other chemotherapeutic agent or compound we use in its system must comply with the regulations of the FDA and other federal, state and local government authorities in the United States. Clinical development is a long, expensive and uncertain process and is subject to delays. We may encounter delays or rejections for various reasons. Moreover, approval policies or regulations may change. If we do not obtain and maintain regulatory approval for HEPZATO and the use of melphalan or other chemotherapeutic agents, our business, results of operations, financial condition and prospects would be materially and adversely affected.

In August 2012, we submitted an NDA seeking an indication for ocular melanoma liver metastases for HEPZATO. In September 2013, the FDA issued a complete response letter or CRL indicating that we must perform additional well-controlled randomized trial(s) to establish the safety and efficacy of HEPZATO using overall survival as the primary efficacy outcome measure and which demonstrates that the clinical benefits of HEPZATO outweigh its risks. Our Phase 3 trial in ocular melanoma liver metastases, the FOCUS Trial, was not randomized and used a different primary efficacy outcome measure. Failure to obtain FDA approval for HEPZATO will have a material adverse effect on our business, financial condition, and results of operations and prospects.

On February 14, 2023, the Company completed a NDA resubmission to the FDA for the HEPZATO KIT (melphalan hydrochloride for Injection/Hepatic Delivery System) seeking approval for the treatment of patients with unresectable hepatic-dominant metastatic ocular melanoma (mOM). On March 20, 2023, the FDA determined the resubmission constituted a complete response and set a PDUFA target action date of August 14, 2023.

The resubmission is in response to the September 12, 2013 CRL from the FDA. The NDA resubmission contains comprehensive data and information relating to the matters identified in the CRL. FDA may find our attempt to address the issues in the 2013 CRL insufficient to support approval and we may receive another CRL, which would have significant adverse effects on our business operations.

In addition to specific issues raised in the September 12, 2013 CRL, we must demonstrate to FDA that our manufacturing operations, including those of third party suppliers, are compliant with all applicable requirements, including current good manufacturing practices. As a result of an inspection unrelated to the HEPZATO NDA resubmission, FDA issued the melphalan supplier listed in our NDA resubmission 483 observations, regarding the manufacturer's operations, and that the manufacturer is working to address these observations. In addition, we are aware that our current melphalan manufacturer is planning to suspend its operations beginning in December 2023 for several months to perform facility maintenance. Although we believe that we have adequate melphalan supply to meet internal projections through the shutdown and there are multiple sources of generic melphalan available in the event of FDA approval of the HEPZATO NDA, we cannot be certain that our efforts to avoid a supply interruption will be successful. If the FDA approves HEPZATO, we also must be able to enter into long-term supply agreements for critical components, including melphalan, under commercially reasonable terms.

Even if we obtain regulatory approval for HEPZATO in the United States, our ability to market HEPZATO would be limited to those uses that are approved.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. If the FDA approves the NDA for HEPZATO, our ability to market and promote HEPZATO would be limited to the approved indication, so even with FDA approval, HEPZATO may only be promoted in this limited market. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use, and FDA approval may otherwise limit our sales practices and our ability to promote, sell and distribute the product. Thus, we may only market HEPZATO, if approved by the FDA, for its approved indication and could be subject to enforcement action for off-label marketing. Further, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, FDA warning letters, corrective advertising and potential civil and criminal penalties.

If future clinical trials are unsuccessful, significantly delayed or not completed, we may not be able to market HEPZATO for other indications.

The clinical trial data on our product was limited to specific types of liver cancer. In 2010, we concluded a Phase 3 clinical trial of HEPZATO with a prior version of the medical device and procedure in patients with metastatic ocular and cutaneous melanoma to the liver and also completed a multi-arm Phase 2 clinical trial of that same version of HEPZATO in patients with primary and metastatic melanoma stratified into four arms.

We have completed the dosing phase and analysis of the primary endpoint of an open-label Phase 3 clinical trial in ocular melanoma liver metastases called the FOCUS Trial.

It may take several years if the FDA or foreign regulatory authorities requests additional clinical trials of HEPZATO relating to our NDA submission, and failure can occur at any stage of development, for many reasons, including:

- any pre-clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities;
- establish and maintain the supply of necessary components, including melphalan, bulk drug substances and drug products to maintain sufficient supply to conduct such clinical studies;
- pre-clinical or clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;
- the FDA or foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- we may encounter delays or rejections based on changes in regulatory agency policies during the period in which we are developing a system, or the period required for review of any application for regulatory agency approval;
- enrollment in any additional clinical trials may proceed more slowly than expected;
- any other clinical trials may not demonstrate the safety and efficacy of any system or result in marketable products;
- the FDA or a foreign regulatory authority may change its approval policies or adopt new regulations that may negatively affect or delay our ability to bring a system to market or require additional clinical trials; and
- a system may not be approved for all the requested indications.

The failure or delay of clinical trials could cause an increase in the cost of product development, delay filing of a NDA for marketing approval or cause us to cease the development of HEPZATO for other indications. If we are unable to develop HEPZATO for other indications, the future growth of our business could be negatively impacted. In addition, we have limited clinical data relating to the effectiveness of HEPZATO in certain types of cancer. Such limited data could slow the adoption of CHEMOSAT and HEPZATO and significantly reduce our ability to commercialize CHEMOSAT and HEPZATO.

We have obtained the right to affix the CE Mark for the CHEMOSAT Hepatic Delivery System as a medical device for the delivery of melphalan. Since we may only promote the device within this specific indication, if physicians are unwilling to obtain melphalan separately for use with CHEMOSAT, our ability to commercialize CHEMOSAT in the EU will be significantly limited.

In the EU, CHEMOSAT is regulated as a Class III medical device indicated for the intra-arterial administration of a chemotherapeutic agent, melphalan hydrochloride, to the liver with additional extracorporeal filtration of the venous blood return. Our ability to market and promote CHEMOSAT is limited to this approved indication. To the extent that our promotion of CHEMOSAT is found to be outside the scope of its approved indication, we may be subject to fines or other regulatory action, limiting our ability to commercialize CHEMOSAT in the EU.

We are limited to marketing CHEMOSAT in the EU as a medical device for the delivery of melphalan. If physicians are unwilling to obtain melphalan separately for use with CHEMOSAT, our ability to commercialize CHEMOSAT in the EU will be significantly limited. Our product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the EU reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. As a result, the delivery of melphalan with our device may not be within the applicable label with respect to some indications in some Member States of the EU where the drugs are authorized for marketing. Physicians intending to use CHEMOSAT must obtain melphalan separately for use with CHEMOSAT and must use melphalan independently at their discretion. If physicians are unwilling to obtain melphalan separately from CHEMOSAT and/or to prescribe the use of melphalan independently, our sales opportunities in the EU will be significantly limited.

We are subject to significant ongoing regulatory obligations and oversight in the EU and will be subject to such obligations in the United States and any other country where we receive marketing authorization or approval.

In April 2012, we obtained the required certification from a designated EU Notified Body, enabling us to complete an EC Declaration of Conformity with the essential requirements of the EU Medical Device Directive and affix the CE Mark to the Generation Two version of CHEMOSAT. More recently, on February 28, 2022, we obtained Medical Device Regulation certification under the new European Medical Devices Regulation [2017/745/EU]. In order to maintain the right to affix the CE Mark in the EU, we are subject to compliance obligations, and any material changes to the approved product, such as manufacturing changes, product improvements or revised labeling, may require further regulatory review. Additionally, we are subject to ongoing audits by the European Notified Body, and the right to affix the CE Mark to the Generation Two version of CHEMOSAT may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product.

To the extent that HEPZATO is approved by the FDA or CHEMOSAT by any other regulatory agency, we will be subject to similar ongoing regulatory obligations and oversight in those countries where approval is obtained. For example, we may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice, or cGMPs, good clinical practices, or GCPs, and good laboratory practices, which are regulations and guidelines enforced by the FDA for all products in clinical development, for any pre-clinical or clinical trials that we conduct post-approval. In addition, post-marketing requirements for HEPZATO may include implementation of a risk evaluation and mitigation strategies, or REMS, program to ensure that the benefits of the product outweigh its risks. A typical REMS may include a medication guide, a patient package insert, a communication plan to healthcare professionals, restrictions on distribution or use and/or other elements to assure safe use of the product. However, our discussions with the FDA have indicated that a medication guide or communication plan will not be required.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- refusals or delays in the approval of NDAs or supplements to approved NDAs;
- refusal of a regulatory authority to review pending market approval applications or supplements to approved NDAs;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;
- fines, FDA warning letters or untitled letters, or holds on clinical trials;
- import or export restrictions;
- injunctions or the imposition of civil or criminal penalties;
- restrictions on product administration, requirements for additional clinical trials or changes to product labeling or REMS programs; or
- recommendations by regulatory authorities against entering into governmental contracts with us.

If we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and may not achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

The FDA has granted us six orphan drug designations and we may seek additional orphan drug designations in the future.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the European Medicines Agency, or EMA, from approving another marketing application for the same indication for that drug during that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently

profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We cannot assure you that any future application for orphan drug designation with respect to any product candidate will be granted. If we are unable to obtain orphan drug designation in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

We rely on third parties to conduct certain elements of the clinical trials for CHEMOSAT and HEPZATO, and if they do not perform their obligations to us, we may not be able to obtain regulatory approvals for our system.

We design the clinical trials for our products, but rely on academic institutions, corporate partners, contract research organizations and other third parties to assist in managing, monitoring and otherwise carrying out these trials. We rely heavily on these parties for the execution of our clinical studies and control only certain aspects of their activities. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. We rely on third parties to conduct monitoring and data collection of our future clinical trials. Although we rely on these third parties to manage the data from these clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with our general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. Our reliance on third parties does not relieve us of these responsibilities and requirements and if we or the third parties upon whom we rely for our clinical trials fail to comply with the applicable GCPs, the data generated in our clinical trials may be deemed unreliable and the FDA or other foreign regulatory agencies may require us to perform additional trials before approving our marketing application. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with GCPs. In addition, our clinical trials must be conducted with product that complies with the FDA's cGMP requirements and we are dependent on third-party manufacturing and supply of critical components necessary for such clinical trial supply. To the extent a critical component relies on a single-sourced manufacture/supplier our ability to mitigate this risk decreases. Our failure, or any failure by such third party partners, to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, and may result in a failure to obtain regulatory approval for HEPZATO if these requirements are not met.

Purchasers of CHEMOSAT in Europe may not receive third-party reimbursement or such reimbursement may be inadequate. Without adequate reimbursement, commercialization of CHEMOSAT in Europe may not be successful.

We have obtained the right to affix the CE Mark for CHEMOSAT, and we intend to seek third-party or government reimbursement within those countries in Europe where we expect to market and sell CHEMOSAT. In Germany, we had received a ZE diagnostic-related group code, or ZE Code, which, beginning in 2016, permits hospitals in Germany to obtain reimbursement for CHEMOSAT procedures. Negotiations on the amount of reimbursement to be received under the ZE Code were concluded in 2016 and the procedure was reimbursed under the ZE Code in 2017. Reimbursement negotiations under the ZE system are conducted annually. Consequently, reimbursement obtained may not be for the full amount sought. In countries where we are able to obtain reimbursement, local policy could limit our ability to obtain adequate and consistent reimbursement and limit other sales opportunities in those countries.

In other countries, until we obtain government reimbursement, we will rely on private payors or local pre-approved funds where available. There are also no assurances that third-party payors or government health agencies in Europe will reimburse use of CHEMOSAT in the long term or at all. Further, each country has its own protocols regarding reimbursement, so successfully obtaining third party or government health agency reimbursement in one country does not necessarily translate to similar reimbursement in another European country. Physicians, hospitals and other health care providers may be reluctant to purchase CHEMOSAT if they do not receive substantial reimbursement for the cost of using the product from third-party payors or government entities. The lack of adequate reimbursement may significantly limit sales opportunities in Europe.

The success of our products may be harmed if the government, private health insurers or other third-party payers do not provide sufficient coverage or reimbursement.

Our ability to commercialize CHEMOSAT and HEPZATO successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. We will seek reimbursement by third-party payors of the cost of HEPZATO after its use is approved, but there are no assurances that adequate third-party coverage will be available to establish and maintain price

levels sufficient for us to realize an appropriate return on our investment in developing new therapies. Government, private health insurers and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing. Accordingly, even if coverage and reimbursement are provided by government, private health insurers and third-party payors for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for healthcare providers.

Further implementation of healthcare reforms in the United States and in significant overseas markets may limit the ability to commercialize CHEMOSAT and HEPZATO and the demand for CHEMOSAT and HEPZATO.

Healthcare providers may respond to such cost-containment pressures by choosing lower cost products or other therapies.

CHEMOSAT and HEPZATO may not achieve sufficient acceptance by the medical community to sustain our business.

The commercial success of CHEMOSAT and HEPZATO, if approved, will depend upon their acceptance by the medical community and third-party payers as clinically useful, cost effective and safe. Acceptance by the medical community may depend on the extent to which leaders in the scientific and medical communities publish scientific papers in reputable academic journals. If testing and clinical practice do not confirm the safety and efficacy of CHEMOSAT and HEPZATO or even if further testing and clinical practice produce positive results but the medical community does not view these favorably, our efforts to market CHEMOSAT and HEPZATO may fail, which would cause us to cease operation.

We may be subject, directly or indirectly, to federal and state health care fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our drug candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws. These laws may affect, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal health care program, such as Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010, which requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to certain payments and other transfers of value provided to physicians, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members; and
- state law and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. If our operations are found to be in violation of any of the laws described above or any other governmental

regulations that apply to us, we may be subject to penalties, including exclusion from payment by federal health care programs, civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Compliance with laws and regulations pertaining to the privacy and security of health information may be time consuming, difficult and costly, particularly in light of increased focus on privacy issues in countries around the world, including the United States and the European Union.

We are subject to various domestic and international privacy and security regulations. The confidentiality, collection, use and disclosure of personal data, including clinical trial patient-specific information, are subject to governmental regulation generally in the country where the personal data were collected or used. In the United States we are subject to various state and federal privacy and data security regulations, including but not limited to, HIPAA as amended by HITECH. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In the European Union, personal data includes any information that relates to an identified or identifiable natural person with health information carrying additional obligations, including obtaining the explicit consent from the individual for collection, use or disclosure of the information. In addition, we are subject to EU regulation with respect to protection of and cross-border transfers of such data out of the European Union, and this regulation became more stringent in May 2018 when the EU's General Data Protection Regulation (GDPR) came into effect. Furthermore, the legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues. The United States and the European Union and its member states continue to issue new privacy and data protection rules and regulations that relate to personal data and health information.

Compliance with these laws may be time consuming, difficult and costly. If we fail to comply with applicable laws, regulations or duties relating to the use, privacy or security of personal data we could be subject to the imposition of significant civil and criminal penalties, be forced to alter our business practices and suffer reputational harm.

Changes in health care law and implementing regulations, including government restrictions on pricing and reimbursement, as well as health care policy and other health care payor cost-containment initiatives, may have a material adverse effect on us.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system and efforts to control health care costs, including drug prices, that could have a significant negative impact on our business, including preventing, limiting or delaying regulatory approval of our drug candidates and reducing the sales and profits derived from our products once they are approved.

For example, in the United States, the Patient Protection and Affordable Care Act of 2010, or ACA, substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. The ACA, among other things, subjected manufacturers to new annual fees and taxes for specified branded prescription drugs, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, expanded health care fraud and abuse laws, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, imposed an additional rebate similar to an inflation penalty on new formulations of drugs, extended the Medicaid Drug Rebate Program to Medicaid managed care organizations, expanded the 340B program, which caps the price at which manufacturers can sell covered outpatient pharmaceuticals to specified hospitals, clinics and community health centers, and provided incentives to programs that increase the federal government's comparative effectiveness research. Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Congressional actions to repeal and replace provisions of the law and litigation and legislation over the ACA is likely to continue with unpredictable and uncertain results.

More recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare

(beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Consolidation in the healthcare industry could lead to demands for price concessions.

The cost of healthcare has risen significantly over the past decade and numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the medical device industry. Group purchasing organizations, independent delivery networks and large single accounts in the United States and foreign markets may result in a consolidation of purchasing decisions for potential healthcare provider customers. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances which may exert further downward pressure on the price of CHEMOSAT and HEPZATO and adversely impact our business, financial condition and results of operations.

Risks Related to Manufacturing, Commercialization and Market Acceptance of CHEMOSAT and HEPZATO

Manufacturers of melphalan may be unable to provide adequate supplies of melphalan.

Under the current regulatory scheme in the European Union, CHEMOSAT is approved for marketing as a device only, and doctors will separately obtain melphalan for use with CHEMOSAT. Although melphalan has been approved in the European Union for over a decade, we are aware that there are currently three approved manufacturers of melphalan in certain countries of the European Union. If any of these manufacturers fails to provide end-users with adequate supplies of melphalan or fails to comply with the requirements of regulatory authorities, we may be unable to successfully commercialize our product in the European Union. Additionally, melphalan is not available in certain foreign countries outside the European Union where we may seek to market CHEMOSAT. If supply of melphalan remains limited or unavailable, we will be unable to commercialize CHEMOSAT in these markets, thereby limiting future sales opportunities.

The FDA may determine that our NDA Resubmission is not approvable due to cGMP deficiencies.

We must demonstrate to FDA that our manufacturing operations, including those of third party suppliers, are compliant with all applicable requirements, including cGMPs in order for FDA to approve our HEPZATO NDA resubmission. If FDA determines that our facility or any of supplier/manufacturer listed in our NDA resubmission is not in compliance with cGMPs, it could result in the FDA issuing a CRL regarding the NDA resubmission. Such a conclusion could be unrelated to the manufacturing of a component for us, but still impact our NDA resubmission.

We must maintain or enter into acceptable arrangements for the production of melphalan and other critical components of HEPZATO and we may not be able to ensure adequate supply impacting our ability to successfully commercialize HEPZATO in the United States or complete any future clinical trials.

Each manufacturer/supplier of components for the production of HEPZATO and CHEMOSAT must be in compliance with cGMPs. Our supply of critical components of HEPZATO and CHEMOSAT includes the use of one contracted supplier. If the FDA approves HEPZATO, we also must be able to enter into long-term supply agreements for critical components, including melphalan, under commercially reasonable terms.

In addition, FDA inspections of our suppliers/manufacturers, even for products other than those supplied to us, may result in the supplier/manufacturer being shut down or unable to deliver critical components to us in a timely manner. Such risks are increased for those components for which we have one contractual supplier.

We currently have an agreement with one supplier of melphalan and, with the goal of minimizing the risk of a supply interruption, are in discussions with several melphalan ANDA holders who have indicated interest in supplying melphalan to us. We are aware that FDA issued our current melphalan manufacturer 483 observations as a result of an inspection unrelated to the HEPZATO

NDA resubmission and the manufacturer is working to address these observations. The manufacturer is planning to suspend its operations beginning in December 2023 for several months to perform facility maintenance. The Company believes it has sufficient quantities of melphalan to meet its forecasted HEPZATO KIT demand through this shutdown period. The Company believes it has sufficient stock for the device components of the HEPZATO KIT to meet the first year of its forecasted demand and intends to manage supply chain risk through stockpiled inventory and contracting with multiple suppliers for critical components.

Although we are pursuing a variety of strategies to mitigate the risk of a supply interruption as we prepare to obtain commercial supply for our product, if approved by FDA, we cannot assure you that such shutdown and related matters will not result in a loss of supply in the event the shutdown is longer than anticipated or in the event regulatory action is taken against the supplier.

We may pursue agreements with additional contract manufacturers to produce melphalan and other critical components for use in any future clinical trial programs and for the production of CHEMOSAT and HEPZATO, as well as for labeling and finishing services. We may not be able to enter into such arrangements on commercially reasonable terms or at all. To manufacture melphalan or other chemotherapeutic agents on our own, we would have to develop a manufacturing facility that complies with FDA regulations for the production of melphalan and each other chemotherapeutic agent we choose to manufacture for use with our system. Developing these resources would be an expensive and lengthy process and would have a material adverse effect on our revenues and profitability. If we are unable to obtain sufficient melphalan and labeling services on acceptable terms or encounter delays or difficulties in our relationships with current and future suppliers or if current and future suppliers of melphalan do not comply with applicable regulations for the manufacturing and production of melphalan, our business, financial condition and results of operations may be materially harmed.

If we cannot successfully manufacture CHEMOSAT and HEPZATO, our ability to develop and commercialize the system would be impaired.

We manufacture certain components of our products, including our proprietary filter media, and assemble and package CHEMOSAT and HEPZATO at our facility in Queensbury, New York. We have established our European headquarters in Galway, Ireland and conduct finishing operations, assembly, packaging, labeling and distribution at this facility. We currently utilize third parties to manufacture some components of CHEMOSAT and HEPZATO. We may have difficulty obtaining components for our products from our third-party suppliers in a timely manner or at all, which may adversely affect our ability to deliver CHEMOSAT and HEPZATO to purchasers.

In addition to limiting sales opportunities, delays in manufacturing CHEMOSAT and HEPZATO may adversely affect our ability to obtain regulatory approval in the United States and other jurisdictions. Our ability to conduct timely clinical trials in the United States and abroad depends on our ability to manufacture the system, including sourcing the chemotherapeutic agents or other compounds through third parties in accordance with FDA and other regulatory requirements. If we are unable to manufacture CHEMOSAT and HEPZATO in a timely manner, we may not be able to conduct the clinical trials required to obtain regulatory approval and commercialize our product.

We have implemented quality systems throughout our organization designed to enable us to satisfy the various international quality system regulations, including those of the FDA with respect to products sold in the United States and those established by the International Standards Organization, or ISO, with respect to products sold in the European Union. We are required to maintain ISO 13485 certification for medical devices to be sold in the European Union, which requires, among other items, an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations. All of our facilities are presently ISO 13485:2016 certified. If our Queensbury, New York facility fails to maintain compliance with ISO 13485 and FDA cGMP or fails to pass facility inspection or audits, our ability to manufacture at the facility could be limited or terminated. In the future, we may manufacture and assemble CHEMOSAT and HEPZATO in our Galway, Ireland facility or elsewhere in the European Union, and any facilities in the European Union would have to obtain and maintain similar approvals or certifications of compliance.

Although Delcath is not aware of any direct impacts of the war between the Ukraine and the Russian Federation on its supply chain, the war could adversely impact our ability to obtain components and/or significantly increase the cost of obtaining such components for the Company’s products from its third-party suppliers in a timely manner or at all. In addition, at this time, although the Company is not aware of any direct impacts, any increase in COVID cases and associated restrictions could adversely impact the Company’s ability to obtain components and/or significantly increase the cost of obtaining such components for the Company’s products from its third-party suppliers in a timely manner or at all. A rise in COVID cases and the associated absences from work of internal and external resources may also impact the Company’s ability to meet anticipated timelines.

We do not have written contracts with all of our suppliers for the manufacture of components for CHEMOSAT and HEPZATO.

While we have written contracts and supply agreements for key components for CHEMOSAT and HEPZATO, we do not have written contracts with all suppliers for the manufacture of components for CHEMOSAT and HEPZATO. If we are unable to obtain an adequate supply of the necessary components or negotiate acceptable terms, we may not be able to manufacture CHEMOSAT and HEPZATO in commercial quantities or in a cost-effective manner, and commercialization of CHEMOSAT and HEPZATO in the United States, the European Union and elsewhere may be delayed. In addition, certain components are available from only a limited number of sources. Components of CHEMOSAT and HEPZATO are currently manufactured for us in small quantities. We may require significantly greater quantities to further commercialize the product. We may not be able to find alternate sources of comparable components. If we are unable to obtain adequate supplies of components from existing suppliers or need to switch to an alternate supplier and obtain FDA or other regulatory agency approval of that supplier, commercialization of CHEMOSAT and HEPZATO may be delayed.

Even if we receive FDA or other foreign regulatory approvals, we may be unsuccessful in commercializing CHEMOSAT and HEPZATO in markets outside the European Union, because of inadequate infrastructure or an ineffective commercialization strategy.

Even if we obtain regulatory approval from the FDA or other foreign regulatory agencies, our ability to commercialize CHEMOSAT and HEPZATO may be limited due to our inexperience in developing a sales, marketing and distribution infrastructure. If we are unable to develop this infrastructure in the United States or elsewhere or to collaborate with an alliance partner to market our products in the United States or foreign countries, particularly in Asia, our efforts to commercialize CHEMOSAT and HEPZATO or any other product outside of the European Union may be less successful.

We may not be successful in our efforts to expand the commercialization of CHEMOSAT in the European Union, and we may not be successful in commercializing HEPZATO in the United States and CHEMOSAT or HEPZATO in other foreign countries. Each country requires a different commercialization strategy, so our European Union marketing strategy may not translate to other markets. Without a successful commercialization strategy tailored for each market, our efforts to promote and market CHEMOSAT and HEPZATO in each of our target markets may fail in any or all of those markets. If we are unsuccessful in accomplishing our objectives, or if our commercialization efforts do not develop as planned, we may not be able to successfully commercialize HEPZATO or any future approved products, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We may use collaborative arrangements with third parties to help finance and to market and sell CHEMOSAT and HEPZATO, but it may not be successful.

We may be unable to enter into collaborative agreements without additional clinical data or unable to continue a collaborative agreement as a result of unsuccessful future clinical trials. Additionally, we may face competition in the search for alliances. As a result, we may not be able to enter into alliances on acceptable terms, if at all. Our collaborative relationships may never result in the successful development or commercialization of CHEMOSAT and HEPZATO or any other product. The success of any collaboration will depend upon our ability to perform our obligations under any agreements as well as factors beyond our control, such as the commitment of our collaborators and the timely performance of their obligations. The terms of any such collaboration may permit our collaborators to abandon the alliance at any time for any reason or prevent us from terminating arrangements with collaborators who do not perform in accordance with our expectations, or our collaborators may breach their agreements with us. In addition, any third parties with whom we collaborate may have significant control over important aspects of the development and commercialization of our products, including research and development, market identification, marketing methods, pricing, composition of sales force and promotional activities. We will not control the amount and timing of resources that any collaborator may devote to our research and development programs or the commercialization, marketing or distribution of our products. We may not be able to prevent any collaborators from pursuing alternative technologies or products that could result in the development of products that compete with CHEMOSAT and HEPZATO or the withdrawal of their support for our products. The failure of any such collaboration could have a material adverse effect on our business.

If we fail to overcome the challenges inherent in international operations, our business and results of operations may be materially adversely affected.

Currently we have only received authorization to market CHEMOSAT in the European Union and intend to seek similar authorization or approvals in other foreign countries. To accommodate our international sales, we will need to further invest financial and management resources to develop an international infrastructure that will meet the needs of our customers. Accordingly, we will face additional risks resulting from our international operations including:

- difficulties in enforcing agreements and collecting receivables in a timely manner through the legal systems of many countries outside the United States;
- the failure to satisfy foreign regulatory requirements to market our products on a timely basis or at all;
- availability of, and changes in, reimbursement within prevailing foreign healthcare payment systems;
- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign sales or marketing employees and agents;
- limited protection for intellectual property rights in some countries;
- fluctuations in currency exchange rates;
- the possibility that foreign countries may impose additional withholding taxes or otherwise tax our foreign income, impose tariffs or adopt other restrictions on foreign trade;
- the possibility of any material shipping delays;
- significant changes in the political, regulatory, safety or economic conditions in a country or region;
- protectionist laws and business practices that favor local competitors; and
- trade restrictions, including the imposition of, or significant changes to, the level of tariffs, customs duties and export quotas.

If we fail to overcome the challenges inherent in international operations, our business and results of operations may be materially adversely affected.

Rapid technological developments in treatment methods for liver cancer and competition with other forms of liver cancer treatments could affect our ability to achieve meaningful revenues or profit.

Competition in the cancer treatment industry is intense. CHEMOSAT and HEPZATO compete with all forms of liver cancer treatments that are alternatives to surgical resection. Many of our competitors have substantially greater resources and considerable experience in conducting clinical trials and obtaining regulatory approvals. If these competitors develop more effective or more affordable products or treatment methods, or achieve earlier product development, our revenues or profitability will be substantially reduced.

If another company has orphan drug designations for the same drug and indication as us and receives marketing approval before we do, then we will be blocked from marketing approval for seven years from the date of its approval for the same indication of use unless we can make a showing of the clinical superiority of our drug.

Risks Related to our Intellectual Property

Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.

Our success depends significantly on our ability to maintain and protect our proprietary rights in the technologies and inventions used in or embodied by our products. To protect our proprietary technology, we rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, as well as nondisclosure, confidentiality, license and other contractual restrictions in our employment, manufacturing, consulting and other third-party agreements. These legal means may afford only limited protection, however, and may not adequately protect our rights or permit us to gain or keep any competitive advantage.

We have not and may not be able to adequately protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our products and technologies in all countries throughout the world could be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from copying our inventions in foreign countries to the extent we can in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection that covers the commercial products to develop their own competing products that are the same or substantially the same as our commercial product and, further, may export otherwise infringing products to territories where we have patent protection, but judicial systems do not adequately enforce patents to cause infringing activities to be ceased.

We do not have patent rights in certain foreign countries in which a market for our product and technologies exists or may exist in the future. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. The complexity and uncertainty of European patent laws have increased in recent years. In Europe, a new

unitary patent system will likely be introduced by the end of 2023, which would significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our product and technologies.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The United States Patent and Trademark Office (USPTO), and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our product and technologies.

Our success depends in part on our ability to obtain patents, which can be an expensive, time consuming, and uncertain process, and the value of the patents is dependent in part on the breadth of coverage and the relationship between the coverage and the commercial product.

The patent position of medical drug and device companies is generally highly uncertain. The degree of patent protection we require may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us sufficient exclusivity, or to gain or keep our competitive advantage. For example:

- we might not have been the first to invent or the first to file patent applications on the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or license from others in the future may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties; and
- any patents we obtain or license from others in the future may not be valid or enforceable.

The process of applying for patent protection itself is time consuming and expensive and we cannot assure you that we have prepared or will be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is possible that innovation over the course of development and commercialization may lead to changes in CHEMOSAT and HEPZATO methods and/or devices that cause such methods and/or devices to fall outside the scope of the patent protection we have obtained and the patent protection we have obtained may become less valuable. It is also possible that we will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. In addition, our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. Moreover, we cannot assure you that all of our pending patent applications will issue as patents or that, if issued, they will issue in a form that will be advantageous to us.

Our success depends in part on our ability to commercialize CHEMOSAT and HEPZATO prior to the expiration of our patent protection.

Our patent protection for CHEMOSAT and HEPZATO is primarily in the United States and the EU. We currently have patents in the United States and the EU directed to our product, system, components, procedure, and method of treatment, with additional design patent protection in Argentina, Canada, Europe, the UK, and Japan. Our patents provide patent protection for our CHEMOSAT hepatic delivery system, HEPZATO, hemofiltration cartridge apparatus, hemofiltration cartridge design, methods of treatment of a subject with cancer in accordance with various embodiments of our system, embodiments of our system for delivering a high concentration of a small molecule chemotherapeutic agent to a subject while minimizing systemic exposure to the small molecule chemotherapeutic agent, and methods of setting up a filter apparatus for hemofiltration in accordance with our procedures using our proprietary hepatic deliver system. However, patents have a limited lifespan. In the United States and the EU, the ordinary statutory natural expiration of a utility patent is generally 20 years from its filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited.

We may in the future become involved in lawsuits to protect or enforce our intellectual property, or to defend our products against assertion of intellectual property rights by a third party, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To stop any such infringement or unauthorized use, litigation may be necessary. Our intellectual property has not been tested in litigation. There is no assurance that any of our issued patents will be upheld if later challenged or will provide significant protection or commercial advantage. A court may declare our patents invalid or unenforceable, may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question, or may interpret the claims of our patents narrowly, thereby substantially narrowing the scope of patent protection they afford. Because of the length of time and expense associated with bringing new medical drugs and devices to the market, the healthcare industry has traditionally placed considerable emphasis on patent and trade secret protection for significant new technologies. Other parties may challenge patents, patent claims or patent applications licensed or issued to us, or may design around technologies we have patented, licensed or developed.

In addition, third parties may initiate legal or administrative proceedings against us to challenge the validity or scope of our intellectual property rights, such as inter partes review, post-grant review, re-examination or opposition proceedings before the USPTO, the European Patent Office or other foreign counterparts. Third parties may also allege an ownership right in our patents, as a result of their past employment or consultancy with us. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor’s patents, we could be prevented from marketing our product in one or more foreign countries.

Our competitors or other patent holders may assert that our products and the methods employed in our products are covered by their patents. Although we have performed a search for third-party patents and believe we have adequate defenses available if faced with any allegations that we infringe these third-party patents, it is possible that CHEMOSAT and HEPZATO could be found to infringe these patents. It is also possible that our competitors or potential competitors may have patents, or have applied for, will apply for, or will obtain patents that will prevent, limit or interfere with our ability to make, have made, use, sell, offer for sale, import or export our product. If our products or methods are found to infringe, we could be prevented from manufacturing or marketing our product.

Companies in the medical drug/device industry may use intellectual property infringement litigation to gain a competitive advantage. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, there may be some uncertainties associated with avoiding patent infringement. Litigation may be necessary to enforce any patents issued or assigned to us or to determine the scope and validity of third-party proprietary rights. Litigation could be costly and could divert our attention from our business. There are no guarantees that we will receive a favorable outcome in any such litigation. If a third-party claims that we infringed its patents, any of the following may occur:

- we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a competitor’s patent;
- we may become prohibited from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and

- we may have to redesign our product so that it does not infringe upon others' patent rights, which may not be possible or could require substantial funds or time.

Litigation related to infringement and other intellectual property claims such as trade secrets, with or without merit, is unpredictable, can be expensive and time-consuming, and can divert management's attention from our core business. If we lose this kind of litigation, a court could require us to pay substantial damages, treble damages, and attorneys' fees, and could prohibit us from using technologies essential to our product, any of which would have a material adverse effect on our business, results of operations, and financial condition. If relevant third-party patents are upheld as valid and enforceable and we are found to infringe, we could be prevented from selling our product unless we can obtain licenses to use technology covered by such patents. We do not know whether any necessary licenses would be available to us on satisfactory terms, if at all. If we cannot obtain these licenses, we could be forced to design around those patents at additional cost or abandon the product altogether. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could cause the price of our common stock to decline.

If others have filed patent applications with respect to inventions for which we already have patents issued to us or have patent applications pending, we may be forced to participate in interference or derivation proceedings declared by the USPTO to determine priority of invention, which could also be costly and could divert our attention from our business. If the USPTO declares an interference and determines that our patent or application is not entitled to a priority date earlier than that of the other patent application, our ability to maintain or obtain those patent rights will be curtailed. Similarly, if the USPTO declares a derivation proceeding and determines that the invention covered by our patent application was derived from another, we will not be able to obtain patent coverage of that invention.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before CHEMOSAT and HEPZATO or any other product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Not all of our United States patent rights have corresponding patent rights effective in European or other foreign jurisdictions. Similar considerations apply in any other country where we are prosecuting patent applications, have been issued patents, or have decided not to pursue patent protection relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product and our technologies.

Patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications. Furthermore, the United States Supreme Court and the United States Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain and enforce or defend additional patent protection in the future.

Our trademarks may be infringed or successfully challenged, resulting in harm to our business.

We rely on our trademarks as one means to distinguish for our customers our products from the products of our competitors, and we have registered or applied to register many of these trademarks. The USPTO or foreign trademark offices may deny our trademark applications, however, and even if published or registered, these trademarks may be ineffective in protecting our brand and goodwill and may be successfully opposed or challenged. Third parties may oppose our trademark applications, or otherwise challenge our use of our trademarks. For example, even if FDA approves our NDA resubmission, it may not approve use of the proprietary name HEPZATO, in which case any goodwill we have built up with that tradename in the U.S. would be extinguished. In addition, third parties may use marks that are confusingly similar to our own, which could result in confusion or a likelihood of confusion among our customers, thereby weakening the strength of our brand or allowing such third parties to capitalize on our goodwill. In such an event, or if our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademark rights in the face of any such infringement.

We may rely primarily on trade secret protection for important proprietary technologies.

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain our competitive position. Unlike patents, trade secrets are only recognized under applicable law if they are kept secret by restricting their disclosure to third parties. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. However, certain consultants and third parties with whom we have business relationships, and to whom in some cases we have disclosed trade secrets and other proprietary knowledge, may also provide services to other parties in the medical device industry, including companies, universities and research organizations that are developing competing products. In addition, some of our former employees who were exposed to certain of our trade secrets and other proprietary knowledge in the course of their employment may seek employment with, and become employed by, our competitors. We cannot be assured that consultants, employees and other third parties with whom we have entered into confidentiality agreements will not breach the terms of such agreements by improperly using or disclosing our trade secrets or other proprietary knowledge. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Trade secret protection does not prevent independent discovery of the technology or proprietary information or use of the same. Competitors may independently duplicate or exceed our technology in whole or in part. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us in countries where we do not have patent protection.

Similar considerations apply in foreign countries where we receive approval and do not have issued patents for the current version of CHEMOSAT and HEPZATO. In these countries, our ability to successfully commercialize CHEMOSAT and HEPZATO will depend on our ability to maintain trade secret protection in these markets.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers, competitors, or other third parties. Although we endeavor to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our product, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers or other third parties. An inability to incorporate technologies or features that are important or essential to our product may prevent us from selling our product. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product.

Risks Related to Our Common Stock

The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors.

The trading price of our common stock has been, and we expect it to continue to be, volatile. For example, the trading price of our common stock has varied between a high of $7.99 on May 31, 2023 and a low of $3.44 on January 4, 2023. The price at which our common stock trades depends upon a number of factors, including historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or our competitors, our ability or inability to raise the additional capital needed and the terms on which it may be raised, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading, regardless of our financial condition, results of operations, business or prospects. Among the factors that may cause the market price of our common stock to fluctuate are the risks described elsewhere in this “Risk Factors” section and other factors, including:

- fluctuations in our quarterly operating results or the operating results of competitors;
- variance in financial performance from the expectations of investors;
- changes in the estimation of the future size and growth rate of our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect financial results;
- conditions and trends in the markets served;
- changes in general economic, industry and market conditions;
- success of competitive products and services;
- changes in market valuations or earnings of competitors;
- changes in pricing policies or the pricing policies of competitors;
- announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;
- potentially negative announcements, such as a review of any of our filings by the SEC, changes in accounting treatment or restatements of previously reported financial results or delays in our filings with the SEC;
- the commencement or outcome of litigation involving us, our general industry or both;
- our filing for protection under federal bankruptcy laws;
- changes in capital structure, such as future issuances of securities or the incurrence of additional debt;
- actual or expected sales of common stock by stockholders; and
- the trading volume of our common stock.

In addition, the stock markets and the market for pharmaceutical companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose the Company to securities class action litigation. Such litigation, even if unsuccessful, could be costly to defend and divert management’s attention and resources, which could further materially harm our financial condition and results of operations.

Because of volatility in our trading price and trading volume, we may incur significant costs from class action securities litigation.

Holders of stock in companies that have a volatile stock price frequently bring securities class action litigation against the company that issued the stock. We may be the target of this type of litigation in the future. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit and the time and attention of our management could be diverted from other business concerns, either of which could seriously harm our business.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock and could impair our ability to raise additional equity capital.

As of June 30, 2023, 15,250,469 shares of common stock are issued and outstanding, and we had reserved 27,383,009 shares of our common stock for future issuance pursuant to our stock option and equity incentive plans, outstanding warrants and preferred stock.

Future sales of a substantial number of shares of our common stock in the public market or the perception that such sales may occur, or the issuance of our common stock pursuant to outstanding warrants or convertible preferred stock, could cause immediate dilution and adversely affect the market price of our common stock. The sale or issuance of our common stock, as well as the existence of outstanding stock options and shares of common stock reserved for issuance under our equity incentive plans and outstanding warrants and convertible preferred stock, could cause the market price of our common stock to decline and could impair our ability to raise capital through the sale of additional equity securities. We cannot predict the effect that future sales of shares of our common stock or other equity-related securities would have on the market price of our common stock.

We have a history of reverse splits, which have severely impacted our common stock price.

Since our initial public offering in 2000, we have effected five reverse stock splits, for a cumulative ratio since our IPO of 1:31,360,000,000. Each such reverse split has resulted in an effective decline in the price of our common stock. There can be no assurance that we will not be required to effect one or more additional reverse stock splits which could further impact the market price and liquidity of our common stock.

Anti-takeover provisions in our Amended and Restated Certificate of Incorporation and By-laws may reduce the likelihood of a potential change of control or make it more difficult for our stockholders to replace management.

Certain provisions of our Amended and Restated Certificate of Incorporation and By-laws could have the effect of making it more difficult for our stockholders to replace management at a time when a substantial number of stockholders might favor a change in management. These provisions include providing for a staggered board of directors and authorizing the board of directors to fill vacant directorships or increase the size of the board of directors.

Furthermore, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval. Any series of preferred stock is likely to be senior to the common stock with respect to dividends, liquidation rights and, possibly, voting rights. The board’s ability to issue preferred stock may have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock.

We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future.

We intend to retain all earnings for use in connection with the expansion of our business and for general corporate purposes. The board of directors will have the sole discretion in determining whether to declare and pay dividends in the future. The declaration of dividends will depend on profitability, financial condition, cash requirements, future prospects and other factors deemed relevant by our board of directors. Our ability to pay cash dividends in the future could be limited or prohibited by the terms of financing agreements that we may enter into or by the terms of any preferred stock that may be authorized and issued. For example, the terms of the Avenue Loan Agreement contains negative covenants prohibiting us from issuing cash dividends. We do not expect to pay dividends in the foreseeable future. As a result, holders of our common stock must rely on stock appreciation for any return on their investment.

If we engage in acquisitions, reorganizations or business combinations, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time, we may consider strategic alternatives, such as acquiring businesses, technologies or products or entering into a business combination with another company. If we do pursue such a strategy, we could, among other things:

- issue equity securities that would dilute current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources in integrating new businesses, personnel, intellectual property, technologies and products;
- assume substantial actual or contingent liabilities;
- reprioritize our programs and even cease development and commercialization of CHEMOSAT and HEPZATO;
- suffer the loss of key personnel, or
- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company or a combination of both on terms that certain of our stockholders may not deem desirable.

Although we intend to evaluate and consider different strategic alternatives, we have no agreements or understandings with respect to any acquisition, reorganization, or business combination at this time.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding our securities adversely, the price and trading volume of our securities could decline.

The trading market for our securities will be influenced by the research and reports that industry or securities analysts may publish about us, our business, market or competitors. Securities and industry analysts do not currently, and may never, publish research on us. If no securities or industry analysts commence coverage of us, the price and trading volume of our securities would likely be negatively impacted. If any of the analysts who may cover us change their recommendation regarding our shares of Common Stock adversely, or provide more favorable relative recommendations about our competitors, the price of our shares of Common Stock would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

We have identified material weaknesses in our internal control over financial reporting. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements would not be prevented or detected on a timely basis. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Management determined there was material weaknesses that existed at December 31, 2022. The material weaknesses relate to detection and application of the Company's expense policy on its share-based compensation under the accelerated method. We have commenced measures to remediate this material weaknesses and will design additional key controls in order to ensure the Company's share-based compensation is calculated under the accelerated method. We will continue to assess our finance and accounting staffing needs to ensure remediation of this material weakness. The material weakness will not be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. If not remediated, this material weakness could result in further material misstatements to our annual or interim consolidated financial statements that might not be prevented or detected on a timely basis, or in delayed filing of required periodic reports. If we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of the stock could be adversely affected, and we could become subject to litigation or investigations by Nasdaq, the SEC, or other regulatory authorities, which could require additional financial and management resources.

Management will be required to assess the effectiveness of our internal controls annually. However, for as long as we are a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements requiring us to incur the expense of remediation and could also result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

General Risk Factors

The loss of key personnel could adversely affect our business.

Our success depends upon the efforts of our employees. The loss of any of our senior executives or other key employees could harm its business. Competition for experienced personnel is intense and, if key individuals leave us, we could be adversely affected if suitable replacement personnel are not quickly identified and hired. Competition for qualified individuals exists in all functional areas, which makes it difficult to attract and retain the qualified employees we need to operate our business. Our success also depends in part on our ability to attract and retain highly qualified scientific, technical, commercial and administrative personnel. If we are unable to attract new employees and retain our current key employees, our ability to compete could be adversely affected and the development and commercialization of our products could be delayed or negatively impacted.

We rely on the proper function, availability and security of information technology systems to operate our business and a cyber-attack or other breach of these systems could have a material adverse effect on our business, financial condition or results of operations.

We rely on information technology systems to process, transmit, and store electronic information in our day-to-day operations. Similar to other companies, the size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards. Any failure by us to maintain or protect our information technology systems and data integrity, including from cyber-attacks, intrusions or other breaches, could result in the unauthorized access to personally identifiable information, theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Any of these events may cause us to have difficulty preventing, detecting, and controlling fraud, be subject to legal claims and liability, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach or theft of intellectual property, or suffer other adverse consequences, any of which could have a material adverse effect on our business, financial condition or results of operations.

We may be the subject of product liability claims or product recalls, and we may be unable to maintain insurance adequate to cover potential liabilities.

Our business exposes us to potential liability risks that may arise from clinical trials and the testing, manufacture, marketing, sale and use of CHEMOSAT and HEPZATO. In addition, because CHEMOSAT and HEPZATO are intended for use in patients with cancer, there is an increased risk of death among the patients treated with our system, which may increase the risk of product liability lawsuits related to clinical trials or commercial sales. We may be subject to claims against us even if the injury is due to the actions of others. For example, if the medical personnel that use our system on patients are not properly trained or are negligent in the use of the system, the patient may be injured, which may subject us to claims. Were such a claim asserted, we would likely incur substantial legal and related expenses even if we prevail on the merits. Claims for damages, whether or not successful, could cause delays in clinical trials and result in the loss of physician endorsement, adverse publicity and/or limit our ability to market and sell the system, resulting in loss of revenue. In addition, it may be necessary for us to recall products that do not meet approved specifications, which would also result in adverse publicity and costs connected to the recall and loss of revenue. A successful products liability claim or product recall would have a material adverse effect on our business, financial condition, and results of operations. While we currently carry product liability and clinical trial insurance coverage, it may be insufficient to cover one or more large claims.

We will continue to incur significant costs as a result of operating as a public company, and our management will continue to devote substantial time to compliance initiatives.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel need to continue to devote a substantial amount of time to comply with these requirements. Moreover, these rules

and regulations have increased, and will continue to increase, our legal and financial compliance costs and make some activities more time- consuming and costly. The increased costs may increase our net loss. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be forced to accept reduced policy limits or incur substantially higher costs to maintain the same or similar coverage as we did prior to becoming a public company. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in future uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board, our board committees or as our executive officers.

We are a "smaller reporting company" and have elected to comply with reduced public company reporting requirements, which could make our Common Stock less attractive to investors.

Because our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our voting and non-voting Common Stock held by non-affiliates was less than $560.0 million measured on the last business day of our second fiscal quarter, we qualify again as a "smaller reporting company" as defined in the Exchange Act. Accordingly, we may provide less public disclosure than larger public companies, including, the inclusion of only two years of audited financial statements and only two years of related selected financial data and management's discussion and analysis of financial condition and results of operations disclosure. We are also no longer required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests. We cannot predict if investors will find our Common Stock less attractive as a result of our reliance on these exemptions. If some investors find our Common Stock less attractive as a result of any choice we make to reduce disclosure, there may be a less active trading market for our Common Stock and the market price for our Common Stock may be more volatile.

Item 6. Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1/A filed September 25, 2019).
3.2	Amendment to the Amended and Restated Certificate of Incorporation of the Company dated October 17, 2019 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 23, 2019).
3.3	Certificate of Correction to Amendment to the Amended and Restated Certificate of Incorporation of the Company dated October 22, 2019 (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on October 23, 2019).
3.4	Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective December 24, 2019 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 30, 2019).
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, dated November 23, 2020 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on November 24, 2020).
3.6	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, dated June 12, 2023 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 13, 2023).
3.7	Certificate of Designation of Preference, Rights and Limitations of the Series F Convertible Voting Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K on March 30, 2023).
3.8	Amended and Restated By-Laws of the Company.
31.1*	Certification by Chief Executive Officer Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2*	Certification by Principal Accounting Officer Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1*+	Certification by Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2*+	Certification by Principal Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

*+ This exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any filing, except to the extent the Company specifically incorporates it by reference.

DELCATH SYSTEMS, INC.

SIGNATURES

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.

August 9, 2023 /s/ Gerard Michel

Gerard Michel

Chief Executive Officer (Principal Executive Officer)

August 9, 2023 /s/ Sandra Pennell

Sandra Pennell

Principal Financial Officer

Exhibit 31.1

DELCATH SYSTEMS, INC.

CERTIFICATION
PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gerard Michel, certify that:

1) I have reviewed this Quarterly Report on Form 10-Q of Delcath Systems, Inc.;

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 9, 2023

/s/ Gerard Michel

Gerard Michel

Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

DELCATH SYSTEMS, INC.

CERTIFICATION
PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Anthony Dias, certify that:

1) I have reviewed this Quarterly Report on Form 10-Q of Delcath Systems, Inc.;

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 9, 2023

/s/ Anthony Dias

Anthony Dias

Principal Financial Officer

Exhibit 32.1

DELCATH SYSTEMS, INC.

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of DELCATH SYSTEMS, INC. (the "Company") on Form 10-Q for the period ended June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gerard Michel, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 9, 2023

/s/ Gerard Michel

Gerard Michel

Chief Executive Officer (Principal Executive Officer)

Exhibit 32.2

DELCATH SYSTEMS, INC.

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of DELCATH SYSTEMS, INC. (the "Company") on Form 10-Q for the period ended June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Anthony Dias, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 9, 2023

/s/ Anthony Dias
Anthony Dias
Principal Financial Officer