

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

FORM 10-Q

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

For the quarterly period ended March 31, 2023

Or

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
(State or other jurisdiction of
incorporation or organization)

06-1245881
(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 No

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 No

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of May 22, 2023, 10,620,813 shares of the Company's common stock, \$0.01 par value, were outstanding.

DELCATH SYSTEMS, INC.

Table of Contents

	<u>Page</u>
<u>PART I—FINANCIAL INFORMATION</u>	
Item 1. <u>Financial Statements</u>	
Unaudited Condensed Consolidated Balance Sheets as of March 31, 2023 and December 31, 2022	3
Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2023 and 2022	4
Unaudited Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2023 and 2022	5
Unaudited Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2023 and 2022	6
Notes to the Condensed Consolidated Financial Statements	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	24
Item 4. <u>Controls and Procedures</u>	24
<u>PART II—OTHER INFORMATION</u>	25
Item 1. <u>Legal Proceedings</u>	25
Item 1A. <u>Risk Factors</u>	25
Item 6. <u>Exhibits</u>	26
<u>SIGNATURES</u>	27

[Table of Contents](#)

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

	March 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	\$ 24,222	\$ 7,671
Restricted cash	50	4,151
Accounts receivable, net	458	366
Inventories	2,337	1,998
Prepaid expenses and other current assets	1,955	1,969
Total current assets	29,022	16,155
Property, plant and equipment, net	1,392	1,422
Right-of-use assets	185	285
Total assets	<u>\$ 30,599</u>	<u>\$ 17,862</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 2,428	\$ 2,018
Accrued expenses	7,120	4,685
Lease liabilities, current	93	186
Loan payable, current	3,770	7,846
Total current liabilities	13,411	14,735
Warrant liability	4,940	—
Other liabilities, non-current	1,158	1,144
Loan payable, non-current	992	3,070
Convertible notes payable, non-current	4,806	4,772
Total liabilities	25,307	23,721
Commitments and contingencies	—	—
Mezzanine equity		
Preferred F-1 stock, \$0.01 par value; 24,900 shares designated; 24,900 shares and 0 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	18,368	—
Stockholders' equity (deficit)		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; 11,357 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	—	—
Common stock, \$0.01 par value; 40,000,000 shares authorized; 10,081,634 shares and 10,046,571 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	101	100
Additional paid-in capital	453,370	451,608
Accumulated deficit	(466,483)	(457,484)
Accumulated other comprehensive loss	(64)	(83)
Total stockholders' equity (deficit)	(13,076)	(5,859)
Total liabilities and stockholders' equity	<u>\$ 30,599</u>	<u>\$ 17,862</u>

See accompanying Notes to Condensed Consolidated Financial Statements.

[Table of Contents](#)

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

	Three months ended March 31,	
	2023	2022
Product revenue	\$ 597	\$ 207
Other revenue	—	171
Total revenues	597	378
Cost of goods sold	(181)	(33)
Gross profit	416	345
Operating expenses:		
Research and development expenses	4,576	4,481
Selling, general and administrative expenses	4,165	4,204
Total operating expenses	8,741	8,685
Operating loss	(8,325)	(8,340)
Interest expense, net	(688)	(645)
Other income (expense)	13	(15)
Net loss	(9,000)	(9,000)
Other comprehensive income:		
Foreign currency translation adjustments	19	2
Total other comprehensive loss	\$ (8,981)	\$ (8,998)
Common share data:		
Basic and diluted loss per common share	\$ (0.77)	\$ (1.10)
Weighted average number of basic and diluted shares outstanding	11,622,384	8,190,483

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three Months ended March 31, 2023							
	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	\$451,607	\$ (457,483)	\$ (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	<u>11,357</u>	<u>\$ —</u>	<u>10,081,634</u>	<u>\$ 101</u>	<u>\$453,370</u>	<u>\$ (466,483)</u>	<u>\$ (64)</u>	<u>\$ (13,076)</u>

	Three Months ended March 31, 2022							
	Preferred Stock \$0.01 Par Value		Common Stock \$0.01 Par Value		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	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	<u>11,357</u>	<u>\$ —</u>	<u>7,906,728</u>	<u>\$ 79</u>	<u>\$435,102</u>	<u>\$ (429,976)</u>	<u>\$ 20</u>	<u>\$ 5,225</u>

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	For Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (9,000)	\$ (9,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	1,661	2,271
Depreciation expense	30	31
Non-cash lease expense	100	97
Amortization of debt discount	194	194
Interest expense accrued related to convertible notes	27	40
Changes in assets and liabilities:		
Decrease in prepaid expenses and other assets	14	39
Increase in accounts receivable	(92)	(134)
Increase in inventories	(339)	(599)
Increase in accounts payable and accrued expenses	3,221	953
Decrease in other liabilities, non-current	(80)	(97)
Decrease in deferred revenue	—	(170)
Net cash used in operating activities	<u>(4,264)</u>	<u>(6,375)</u>
Cash flows from investing activities:		
Purchase of property, plant and equipment	—	(89)
Net cash used in investing activities	<u>—</u>	<u>(89)</u>
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)	—
Net cash provided by financing activities	<u>16,694</u>	<u>—</u>
Foreign currency effects on cash	20	2
Net increase (decrease) in total cash	<u>12,450</u>	<u>(6,462)</u>
Total Cash, Cash Equivalents and Restricted Cash:		
Beginning of period	11,822	26,953
End of period	<u>\$ 24,272</u>	<u>\$ 20,491</u>
Cash, Cash Equivalents and Restricted Cash consisted of the following:		
Cash	\$ 24,222	\$ 16,340
Restricted Cash	50	4,151
Total	<u>\$ 24,272</u>	<u>\$ 20,491</u>
For Three Months Ended March 31,		
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the periods for:		
Interest expense	<u>\$ 491</u>	<u>\$ 411</u>

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 months ended March 31, 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 resubmission was in response to a September 12, 2013 Complete Response Letter (“CRL”) from the FDA for the Company’s NDA 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 target action date of August 14, 2023. The Company continues to promote its early access programs 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 our early access program 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

While the long-term economic impact of either the COVID-19 pandemic or the conflict between Russia and Ukraine is difficult to assess or predict, each of these events has caused significant disruptions to the global financial markets and contributed to a general global economic slowdown. Furthermore, inflation rates, particularly in the United States and the United Kingdom, have increased recently to levels not seen in decades. In addition, 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. Recent bank failures, including Silicon Valley Bank (“SVB”), Signature Bank and First Republic Bank, may also have an impact on the Company’s liquidity and capital resources. If 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 ability to access our 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. See “Risk Factors” in “Part I – Item 1A – Risk Factors” in the Company’s Annual Report for additional risks associated with its substantial capital requirements.

Liquidity and Going Concern

At March 31, 2023, the Company had cash, cash equivalents and restricted cash totaling \$24.3 million, as compared to cash, cash equivalents and restricted cash totaling \$11.8 million at December 31, 2022. During the three months ended March 31, 2023, the Company used \$4.3 million of cash in our operating activities.

On March 10, 2023, the Company had a banking relationship with SVB. As of the closure of SVB on March 10, 2023, it held approximately \$1.1 million of unrestricted cash in deposits held in SVB, \$4.0 million held in a restricted SVB account as required per the Avenue Loan Agreement (as defined in “Note 8 – Loans and Convertible Notes Payable”) and approximately \$0.2 million of restricted cash held in SVB collateral accounts as required per the Company’s line of credit for the property in New York City and its credit card program with SVB. SVB was closed on March 10, 2023 by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. On March 12, 2023, the U.S. Treasury, Federal Reserve, and FDIC announced that SVB depositors would have access to all of their money starting March 13, 2023. On March 13, 2023, the Company was able to access all of its cash, cash equivalents and investments held at or through SVB. While the Company has not experienced any losses in such accounts, the recent failure of SVB exposed it to significant credit risk prior to the completion by the FDIC of the resolution of SVB in a manner that fully protected all depositors. The Company is evaluating alternative solutions which management believes does not expose us to significant credit risk or jeopardizes our liquidity.

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 has entered into a Controlled Equity OfferingSM 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 months ended March 31, 2023.

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. Subject to the approval by our stockholders of the private placement that we closed on March 29, 2023 at our upcoming annual general meeting of stockholders, the Tranche A and B warrants issued in such private placement will become exercisable. The exercise of all such warrants would generate approximately \$60.0 million in proceeds. We believe that this amount will be adequate to fund the commercialization of HEPZATO, if approved. 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, 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 curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash.

The Company’s capital commitments over the next twelve months include (a) \$9.6 million to satisfy accounts payable, accrued expenses and lease liabilities and (b) \$4.4 million of loan principal payments. Additional capital commitments beyond the next twelve months include (a) \$0.2 million of lease liabilities; (b) \$1.0 million for settlement of litigation with medac; (c) \$1.2 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.

The Company also expects to use cash and cash equivalents to fund its potential approval of HEPZATO from the FDA, commercialization of HEPZATO and CHEMOSAT and any future clinical research trials and operating activities. The Company’s 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.

On August 6, 2021, the Company 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 March 31, 2023 was 15.45%. The Avenue Loan is secured by all of the Company’s assets globally, including intellectual property. The Avenue Loan matures on August 1, 2024. On March 15, 2023, the Company returned to Avenue \$4.0 million held in restricted cash to paydown a portion of the outstanding Avenue Loan balance. On March 31, 2023, the Company reached an agreement to amend its existing loan agreement with Avenue 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, Delcath 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.

Table of Contents

On March 27, 2023, the Company entered into a securities purchase agreement with certain accredited investors (the “Preferred Purchase Agreement”). Pursuant to the Preferred Purchase Agreement, on March 29, 2023, the Company issued to purchasers an aggregate \$24.9 million in shares, consisting of 24,900 shares of the Company’s Series F-1 Convertible Preferred Stock, par value \$0.01 per share (the “Series F-1 Preferred Stock”), that are convertible into approximately 7.6 million shares of common stock at a conversion price of \$3.30 per share, and two tranches of warrants that are exercisable as follows:

- Tranche A warrants (the “Preferred Tranche A Warrants”) for an aggregate exercise price of approximately \$34.9 million are exercisable for an aggregate of up to 34,860 shares of Series F-3 Convertible Preferred Stock, par value \$0.01 per share (the “Series F-3 Preferred Stock”), at an exercise price of \$1,000 per share (and convertible into an aggregate of up to approximately 7.8 million shares of common stock at a conversion price of \$4.50 per share) until the earlier of 3/31/2026 or 21 days following the Company’s announcement of receipt of FDA approval for HEPZATO; and
- Tranche B warrants (the “Preferred Tranche B Warrants,” together with the Preferred Tranche A Warrant, the “Preferred Warrants”) for an aggregate exercise price of \$24.9 million are exercisable for an aggregate of up to 24,900 shares of Series F-4 Convertible Preferred Stock, par value \$0.01 per share (the “Series F-4 Preferred Stock” and, together with the Series F-3 Preferred Stock, the “Preferred Warrant Shares”), at an exercise price of \$1,000 per share, (and convertible into an aggregate of up to approximately 4.2 million shares of common stock at a conversion price of \$6.00 per share) until the earlier of 3/31/2026 or 21 days following disclosure of the Company’s public announcement of recording at least \$10 million in quarterly U.S. revenue from the commercialization of HEPZATO (collectively, the “Series F Preferred Offering”).

The shares of Series F-1 Convertible Preferred Stock, and accompanying warrants, were issued at a price of \$1,000 per share. Conversion of the Series F-1 Convertible Preferred Stock into shares of common stock of the Company, and the exercisability of the warrants, is subject to approval by the Company’s stockholders (the “Stockholder Approval”). The Company received gross proceeds of approximately \$24.9 million from the private placement, before deducting the fees paid to the placement agent and the financial advisors and other financing expenses payable by the Company.

See Note 9 – Preferred Purchase Agreement for additional details related to the Series F Preferred Offering.

Also on March 27, 2023, the Company entered into a securities purchase agreement with the Company’s Chief Executive Officer, Gerard Michel (the “Common Purchase Agreement”). Pursuant to the Common Purchase Agreement, on March 29, 2023, the Company issued to Mr. Michel 19,646 shares of common stock and two tranches of warrants that are exercisable as follows:

- A Preferred Tranche A Warrant (the “Common Tranche A Warrant”) for an aggregate exercise price of approximately \$0.1 million are exercisable for an aggregate of up to 31,110 shares of common stock until the earlier of 3/31/2026 or 21 days following the Company’s announcement of receipt of FDA approval for HEPZATO; and
- A Preferred Tranche B Warrant (the “Common Tranche B Warrant” and, together with the Common Tranche A Warrant, the “Common Warrants”) for an aggregate exercise price of \$0.1 million are exercisable for an aggregate of up to 16,666 shares of common stock until the earlier of 3/31/2026 or 21 days following disclosure of the Company’s public announcement of recording at least \$10 million in quarterly U.S. revenue from the commercialization of HEPZATO (collectively, the “Common Financing”). The shares of common stock issuable upon exercise of the Common Warrants collectively are referred to herein as the “Common Warrant Shares”.

See Note 10 – Stockholders’ Equity – Equity Offerings and Placements – Common Purchase Agreement for additional details related to the Common Offering.

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 March 31, 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 new 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. Management has determined that the Preferred Warrants issued in conjunction with the Preferred Purchase Agreement and the Common Warrants

issued in conjunction with the Common Purchase Agreement should be liability classified 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 preferred F-1 shares 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 preferred F-1 shares. The Company will adjust the fair value of the warranty liability at the end of each reporting period.

Mezzanine Equity

The Company accounts for its warrant liability 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. When ordinary or preferred shares are determined to be conditionally redeemable upon the occurrence of certain events that are not solely within the control of the issuer, and upon such event, the shares would become redeemable at the option of the holders, they are classified as ‘mezzanine equity’ (temporary equity). The purpose of this classification is to convey that such a security may not be permanently part of equity and could result in a demand for cash, securities or other assets of the entity in the future.

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.

[Table of Contents](#)

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 first quarter of 2022 is reflected in the following table:

	As previously report	Adjustment	As revised
Balance Sheet for March 31, 2022 (unaudited)			
Additional paid-in capital	\$ 434,305	\$ 797	\$ 435,102
Accumulated deficit	(429,179)	(797)	(429,976)
Consolidated Statement of Operations and Comprehensive Loss for the three months March 31, 2022 (unaudited)			
Research and development expenses	4,240	241	4,481
Selling, general and administrative expenses	3,648	556	4,204
Total operating expenses	7,888	797	8,685
Operating loss	(7,543)	(797)	(8,340)
Net loss	(8,203)	(797)	(9,000)
Total other comprehensive loss	(8,201)	(797)	(8,998)
Basic and diluted loss per common share	(1.00)	(0.10)	(1.10)
Consolidated statement of Stockholders' Equity (Deficit) for the three months ended March 31, 2022 (unaudited)			
Compensation expense for issuance of stock options	1,474	797	2,271
Net loss	(8,203)	(797)	(9,000)
Consolidated Statement of Cash Flows for the three months ended March 31, 2022 (unaudited)			
Net loss	(8,203)	(797)	(9,000)
Stock option compensation expense	1,474	797	2,271
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)

(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:

	March 31, 2023	December 31, 2022
Cash and cash equivalents	\$ 24,222	\$ 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	\$ 24,272	\$ 11,822

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

(3) Inventories

Inventories consist of the following:

	March 31, 2023	December 31, 2022
Raw materials	\$ 811	\$ 763
Work-in-process	1,410	1,102
Finished goods	116	133
Total inventories	\$ 2,337	\$ 1,998

[Table of Contents](#)**(4) Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consist of the following:

	March 31, 2023	December 31, 2022
Clinical trial expenses	\$ 1,630	\$ 1,630
Insurance premiums	109	123
Professional services	91	121
Other	125	95
Total prepaid expenses and other current assets	<u>\$ 1,955</u>	<u>\$ 1,969</u>

(5) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	March 31, 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	1,223	1,222	7 years
Furniture	201	201	5 years
Property, plant and equipment, gross	6,362	6,353	
Accumulated depreciation	<u>(4,970)</u>	<u>(4,931)</u>	
Property, plant and equipment, net	<u>\$ 1,392</u>	<u>\$ 1,422</u>	

Depreciation expenses for the three months ended March 31, 2023 and 2022 was \$30 and \$31 respectively.

(6) Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2023	December 31, 2022
Clinical expenses	\$ 2,398	\$ 1,470
Compensation, excluding taxes	1,559	1,040
Professional fees	2,189	1,087
Interest on convertible note	593	553
Other	381	535
Total accrued expenses	<u>\$ 7,120</u>	<u>\$ 4,685</u>

(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.

Table of Contents

The following table summarizes the Company's operating leases as of and for the three months ended March 31, 2023:

	U.S.	Ireland	Total
Lease cost			
Operating lease cost	\$ 97	\$ 9	\$ 106
Other information			
Operating cash flows out from operating leases	(97)	(9)	(106)
Weighted average remaining lease term	0.5	3.6	
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	58	28	86
Year ended December 31, 2024	—	37	37
Year ended December 31, 2025	—	37	37
Year ended December 31, 2026	—	22	22
Total	58	124	182
Less present value discount	(1)	(15)	(16)
Operating lease liabilities included in the condensed consolidated balance sheets at March 31, 2023	<u>\$ 57</u>	<u>\$ 109</u>	<u>\$ 166</u>

(8) Loans and Convertible Notes Payable

	March 31, 2023			December 31, 2022		
	Gross	Discount	Net	Gross	Discount	Net
Loan - Avenue ^[1]	5,610	(849)	4,762	11,923	(1,008)	10,916
Loan - Avenue ^[1] - Less Current Portion	(4,442)	672	(3,770)	(8,570)	724	(7,846)
Total - Loans Payable, Non-Current	<u>\$ 1,168</u>	<u>\$ (177)</u>	<u>\$ 992</u>	<u>\$ 3,353</u>	<u>\$ (284)</u>	<u>\$ 3,070</u>
Convertible Note Payable - Rosalind	2,000	—	2,000	2,000	—	2,000
Convertible Portion of Loan Payable - Avenue	3,000	(201)	2,799	3,000	(228)	2,772
Total - Convertible Notes Payable - Non-Current	<u>\$ 5,000</u>	<u>\$ (201)</u>	<u>\$ 4,799</u>	<u>\$ 5,000</u>	<u>\$ (228)</u>	<u>\$ 4,772</u>

^[1] The gross amount includes the 4.25% final payment of \$467.5.

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

	Loans	Convertible Notes	Total
Year ended December 31, 2023	\$4,442	\$ —	\$ 4,442
Year ended December 31, 2024	1,168	5,000	6,168
Total	<u>\$5,610</u>	<u>\$ 5,000</u>	<u>\$10,610</u>

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 for a term loan in an aggregate principal amount of up to \$20.0 million. 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 March 31, 2023 was 15.45%. 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 would be 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.

Table of Contents

The Company will make monthly interest-only payments during the first fifteen months of the term of the Avenue Loan, which could be increased to up to twenty-four months upon the achievement of specified performance milestones. Following the interest-only period, the Company will make equal monthly payments of principal plus interest until the maturity date, when all remaining principal outstanding and accrued interest must be paid. If the Company prepays the Avenue Loan, it will be required to pay (a) a prepayment fee of 3% if the Avenue Loan is prepaid during the interest-only period; and (b) a prepayment fee of 1% if the Avenue Loan is prepaid after the interest-only period. The Company must make an incremental final payment equal to 4.25% of the aggregate funding. On March 15, 2023, the Company returned to Avenue \$4.0 million held in the restricted cash to paydown a portion of the outstanding loan balance and reduce the monthly principal payments and an incremental 4.25% of the final payment totaling \$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 was not required to be bifurcated. The Company determined that the Avenue Warrant met the criteria to be equity-classified. The \$0.6 million value of the final payment was treated as original issue discount. The \$1.2 million relative fair value of the Avenue Warrant was credited to Additional Paid in Capital while it was debited as debt discount. Of the \$0.6 million of cash issuance costs, \$0.5 million was allocated to the Avenue Loan and was recorded as debit discount, while \$0.1 million was allocated to the Avenue Warrant and was debited to Additional Paid in Capital. Of the \$2.3 million of aggregate debt discount, \$1.9 million was allocated to the non-convertible portion of the Avenue Loan, while \$0.4 million was allocated to the convertible portion of the Avenue Loan. Aggregate debt discount amortization of \$0.2 million was recorded during the three months ended March 31, 2023, including \$0.2 million related to the non-convertible portion of the Avenue Loan and nominal amount to the convertible portion of the Avenue Loan. The Company also determined that the convertible portion of the Avenue Loan did not include a beneficial conversion feature, because the effective conversion price exceeded the commitment date market price of the Company's common stock. Interest expense incurred was \$0.5 million and \$0.4 million for the three months ended March 31, 2023 and 2022, respectively.

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 their 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 \$40 for the three months ended March 31, 2023 and 2022, respectively.

On August 6, 2021, the Company executed an agreement to amend the Rosalind Notes to (a) reduce the conversion price to \$1,198 per share of the Company's Series E Convertible Preferred Stock; and (b) extend the maturity date to October 30, 2024. In addition, in order to induce Avenue to provide the Avenue Loan described above, the holders of the Rosalind Notes agreed to subordinate all of the Company's indebtedness and obligations to the holders; and (b) 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. Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series F Convertible Voting Preferred Stock (the "Certificate of Designation"), each share of Series F-1 Preferred Stock is, subject to the Stockholder Approval, automatically convertible into shares of common stock and/or, if applicable, 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"), of the Company in lieu of common stock.

The aggregate exercise price of the Preferred Tranche A Warrants is approximately \$34.9 million, exercisable for an aggregate of 34,860 shares of Series F-3 Preferred Stock commencing on the Exercisability Date 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 is approximately \$24.9 million, exercisable for an aggregate of 24,900 shares of Series F-4 Preferred Stock commencing on the Exercisability Date 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.

Subject to the terms and limitations contained in the Certificate of Designation, the Series F-1 Preferred Stock issued in the Series F Preferred Offering will not become convertible until the Stockholder Approval. On the first (1st) Trading Day following the announcement of the Stockholder Approval, each share of Series F-1 Preferred Stock shall automatically convert into common stock, at the conversion price of \$3.30 per share, subject to the terms and limitations contained in the Certificate of Designation. Subject to the limitations set forth in the

[Table of Contents](#)

Certificate of Designation, at the option of the holder, each share of Series F-2 Preferred Stock, Series F-3 Preferred Stock or Series F-4 Preferred Stock shall be convertible into common stock, at the conversion price of \$3.30 per share, \$4.50 per share and \$6.00 per share, respectively, rounded down to the nearest whole share, and in each case subject to the terms and limitations contained in the Certificate of Designation.

If Stockholder Approval isn't received by the one-year anniversary of the March 2023 Securities Offering, then the Series F-1 Preferred becomes redeemable at the option of the Requisite Holders for the Liquidation Preference Amount at any time until the three-year anniversary of the March 31, 2023 Securities Offering. The Requisite Holders is a majority of the then Series F Stockholders. Series F Convertible Preferred Stock Liquidation Payments are triggered upon (a) any voluntary or involuntary liquidation, dissolution or winding up of the Company; (b) a change of control transaction; or (c) a Deemed Liquidation Event (collectively a "Liquidation"). Prior to Stockholder Approval, the Series F Convertible Preferred Stock has parity with the Series E and Series E-1 Convertible Preferred Stock and the Liquidation Payments would be three (3) times the original issuance price, plus declared but unpaid dividends, until Stockholder Approval is received. After Stockholder Approval, the Liquidation Payments would be distributed to both the Preferred and Common stockholders, on an "as converted basis".

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 but were not considered indexed to the Company's stock common 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.

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. Since the Series F-1 Preferred Stock is redeemable at the option of the holder beginning at the one-year anniversary of the March 2023 Securities Offering, until Stockholder Approval is received the Series F-1 Preferred Stock is initially classified as temporary (mezzanine) equity at allocated proceeds of \$20.0 million less issuance costs of the \$1.6 million. The Company expensed \$0.4 million of issuance costs that were allocated to the warranty liability during the three months ended March 31, 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 will be classified as permanent equity. After stockholder approval, the Series F-1 Preferred Stock automatically converts into common stock which is classified as permanent equity.

(10) Stockholders' Equity

Equity Offerings and Placements

Common Purchase Agreement

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

The aggregate exercise price of the Common Tranche A Warrants is approximately \$0.1 million, exercisable for an aggregate of 31,110 shares of Common Stock commencing on the Exercisability Date 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 is approximately \$0.1 million, exercisable for an aggregate of 16,666 shares of Common Stock commencing on the Exercisability Date 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 because they had the same features that resulted in the preferred warrants being liability-classified.

Registration Rights for Preferred and Common Offerings

Pursuant to the Preferred Purchase Agreement and the Common Purchase Agreement (collectively, the "Purchase Agreements"), as soon as practicable following the receipt of the Stockholder Approval, the Company shall file 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") and to use commercially reasonable efforts to have the registration statement declared effective within twenty-one (21) days following the filing date (or, in the event that the staff of the Securities and Exchange Commission reviews and has written comments to such registration statement, within forty-five (45) days following the filing date). The Company further agreed to take all steps necessary to keep such registration statement effective at all times until all Registrable Shares have been resold, or there remains no Registrable Shares.

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"), and until so registered the securities may not be offered or sold absent registration or availability of an applicable exemption from registration. There is no established public trading market for the Series F Preferred Stock, the Preferred Warrants, the Preferred Warrant Shares or the Common Warrants and the Company does not intend to list such securities on any national securities exchange or nationally recognized trading system.

The Company concluded that the common warrants were in the scope of Accounting Standards Codification (ASC) 480, Distinguishing Liabilities from Equity ASC 480,) since the common warrants are not mandatorily redeemable; and do not have obligations to issue a variable number of shares of common stock, The Company determined the common warrants met the definition of a derivative and were not considered indexed to the Company's stock common since the warrants require early settle by repurchasing the warrants for cash in an amount equal to the Black-Scholes Value in the event of a Fundamental Transaction at pre-specified volatility at 100% as an input to the Black-Scholes calculation. Since the common warrants uses a pre-specific volatility and needing stockholders' approval, the Company determined to record the common warrants at fair value and will be marked-to-market at subsequent reporting dates.

Table of Contents

Other Private Placements

On July 20, 2022, the Company closed a private placement for the issuance and sale of 690,954 shares of common stock and 566,751 pre-funded warrants to purchase common stock to certain investors. Each share of common stock was sold at a price per share of \$3.98 and the pre-funded warrants were sold at a price of \$3.97 per pre-funded warrant. The pre-funded warrants have an exercise price of \$0.01 per share of common stock and are immediately exercisable. The Company received gross proceeds from the private placement of approximately \$5.0 million before deducting offering expenses.

On December 13, 2022, the Company closed a private placement for the issuance and sale of 1,448,889 shares of common stock and 692,042 pre-funded warrants to purchase common stock to certain investors. Each share of common stock was sold at a price per share of \$2.90 and the pre-funded warrants were sold at a price of \$2.89 per pre-funded warrant. The pre-funded warrants have an exercise price of \$0.01 per share of common stock and are immediately exercisable. The Company received gross proceeds from the private placement of approximately \$6.2 million before deducting offering expenses.

At-the-Market Offering

The Company has entered into the ATM Sales Agreement, 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 months ended March 31, 2023.

The Company has no obligation to sell any shares of common stock under the Sales Agreement. Subject to the terms and conditions of the Sales Agreement, the Sales Agent is required to use commercially reasonable efforts, consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations and the rules of the Nasdaq Stock Market, to sell shares of common stock from time to time based upon the Company's instructions, including any price, time or size limits specified by the Company. The Company will pay the Sales Agent a commission of 3.0% of the aggregate gross proceeds from each such sale, reimburse the Sales Agent's legal fees and disbursements up to \$50 and provide the Sales Agent with customary indemnification and contribution rights. The Sales Agreement may be terminated by the Sales Agent or the Company upon notice to the other party as provided in the sales agreement, or the Sales Agent at any time in certain circumstances, including the occurrence of a material and adverse change in the Company's business or financial condition that makes it impractical or inadvisable to market common stock or to enforce contracts for the sale of common stock.

Authorized Shares

The Company is authorized to issue 40 million shares of common stock, \$0.01 par value, and 10 million shares of preferred stock, \$0.01 par value. To date, the Company has designated the following preferred stock: Series A (4,200 shares), Series B (2,360 shares), Series C (590 shares), Series D (10,000 shares), Series E (40,000 shares), Series E-1 (12,960 shares), Series F-1 (24,900 shares), Series F-2 (24,900 shares), Series F-3 (34,860 shares), and Series F-4 (24,900 shares).

Preferred Stock

As of March 31, 2023, there were an aggregate of 11,357 shares of Series E and Series E-1 Convertible Preferred Stock outstanding.

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. 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 March 31, 2023, there are 2,475,000 shares of common stock reserved under the 2020 Plan, of which 195,167 remained available to be issued.

Table of Contents

Stock Options

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

	Three Months Ended March 31,	
	2023	2022
Expected terms (years)	5.8%	5.5%-6.5%
Expected volatility	172.8%	174.8% -177.1%
Risk-free interest rate	4.08%	1.75% - 1.90%
Expected dividends	—	0.00%

The following is a summary of stock option activity for the three months ended March 31, 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	728,000	4.67		
Expired	(51,073)	10.54		
Cancelled/Forfeited	(17,586)	11.42		
Outstanding at March 31, 2023	2,894,393	\$ 8.87	8.4	\$ 935
Exercisable at March 31, 2023	1,505,927	\$ 10.81	7.7	\$ 44

The following table summarizes information for stock option shares outstanding and exercisable at March 31, 2023:

Range of Exercise Prices	Outstanding Number of Options	Options Exercisable	
		Weighted Average Remaining Option Term (in years)	Number of Options
\$2.83 - \$51.50	2,893,894	8.4	1,505,428
\$51.50+	499	5.8	499
	2,894,393	7.7	1,505,927

The following is a summary of share-based compensation expense in the statement of operations for the three months ended March 31, 2023 (in thousands):

	Three Months Ended March 31,	
	2023	2022
Selling, general and administrative	\$ 1,118	\$ 1,475
Research and development	417	744
Cost of goods sold	126	52
Total	\$ 1,661	\$ 2,271

At March 31, 2023, there was \$1.9 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 1.4 years.

Common Stock Warrants

The following is a summary of common stock warrant activity for the three months ended March 31, 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	
Outstanding at March 31, 2023	5,235,140	\$ 6.95	2.6
Exercisable at March 31, 2023	5,187,363	\$ 6.96	2.6

Table of Contents

The following table presents information related to common stock warrants at March 31, 2023:

Range of Exercise Prices	Outstanding Number of Warrants	Warrants Exercisable	
		Weighted Average Remaining Warrant Term (in years)	Number of Warrants
\$0.01	1,576,620	4.2	1,576,620
\$4.50-\$6.00	47,777		
\$10.00	3,610,743	1.9	3,610,743
	<u>5,235,140</u>	<u>2.6</u>	<u>5,187,363</u>

On April 18, 2023, there were 538,828 \$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.

(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 March 31, 2023 and 2022 because their effects would be anti-dilutive:

	March 31,	
	2023	2022
Common stock warrants	3,658,520	3,610,743
Assumed conversion of preferred stock warrants	11,896,667	—
Assumed conversion of preferred stock	8,681,176	1,135,721
Assumed conversion of convertible notes	488,031	488,031
Stock options	2,894,393	2,238,103
Total	<u>27,618,787</u>	<u>7,472,598</u>

At March 31, 2023, the Company had 1,576,620 pre-funded warrants outstanding. The following table provides a reconciliation of the weighted average shares outstanding calculation for the three months ended March 31, 2023 and 2022:

	Three months ended March 31,	
	2023	2022
Weighted average shares issued	10,081,634	7,906,728
Weighted average pre-funded warrants	1,540,750	283,755
Weighted average shares outstanding	<u>11,622,384</u>	<u>8,190,483</u>

(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 March 31, 2023, however the Company will continue to evaluate the effect on the tax provision each reporting period.

[Table of Contents](#)

(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 all member states of the European Union, Norway, Liechtenstein, Switzerland and the United Kingdom 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. medac disputed having an obligation to make the milestone payment and demanded withdrawal of the termination notice. In response to medac's continued failure to make the milestone payment and its demand for the Company to withdraw its termination notice, on December 16, 2021, the Company initiated an arbitration proceeding pursuant to the dispute resolution procedures of the medac Agreement. Thereafter, on December 30, 2021, the Company received a letter from medac stating that, due to the Company's failure to withdraw the termination notice, medac was terminating the medac Agreement with immediate effect. In a separate letter, medac agreed to orderly transition through February 28, 2022, in order to minimize the impact of any termination on patients and physicians. The Company agreed to purchase inventory held at medac in March 2022 for approximately \$0.2 million.

On December 30, 2022, the parties reached a final settlement of the matter and the Company agreed pay medac 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. The settlement terms also contain 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 March 31, 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 March 31, 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 lawsuit is Lachman Consultant Services, Inc. v. Delcath Systems, Inc., Index No. 650103-2023 (New York Supreme Court, New York County. The Company filed an answer to Lachman's Complaint on February 22, 2023. On March 17, 2023, Delcath responded to Lachman's March 3, 2023 Motion for Partial Summary Judgment. On March 20, 2023, the Court denied Lachman's request that the case be moved into the Commercial Division. The current return date of Lachman's motion for partial summary judgment is March 31, 2023. The dispute arises from a July 22, 2021 agreement between Lachman and Delcath under which Lachman was to provide assistance to the Company in regard to preparing for a FDA inspection and good manufacturing practices, training and support. In August 2022, the Company disputed \$0.3 million of charges from Lachman. As of March 31, 2023, the Company has accrued \$0.9 million as accrued liability on the Company's condensed consolidated balance sheet. The Company plans to vigorously defend this lawsuit and has reserved its rights to dispute all of Lachman charges as the litigation proceeds.

(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 year ended March 31, 2023:

	Contingent liabilities	Level 3 Warrants	Total
Balance at January 1, 2023	\$ 1,280	\$ —	\$1,280
Total change in foreign exchange	25		25
Fair value of the warrant liability issued		4,940	4,940
Balance at March 31, 2023	<u>\$ 1,305</u>	<u>\$ 4,940</u>	<u>\$6,245</u>

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 private placement of the Company's preferred F-1 shares to warrant liability issued in connection with the transaction. The valuations of the warrants 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. 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 and has accounted for them as derivative instruments in accordance with ASC 815, adjusting the fair value at the end of each reporting period.

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

	March 29, 2023
Risk free interest rate	3.80% - 4.80%
Expected term (years)	0.5 - 3.0
Expected volatility	70% - 75%
Expected dividends	0.00%

[Table of Contents](#)

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 Delcath 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 Delcath 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 March 31, 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:

<u>Description</u>	<u>Quoted Prices in Active Markets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Significant Unobservable Inputs (Level 3)</u>	<u>March 31, 2023</u>
Liabilities:				
Contingent liability	—	—	\$ 1,305	\$ 1,305
Warrant liability			4,940	4,940
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 6,245</u>	<u>\$ 6,245</u>

<u>Description</u>	<u>Quoted Prices in Active Markets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Significant Unobservable Inputs (Level 3)</u>	<u>December 31, 2022</u>
Liabilities:				
Contingent liability	—	—	\$ 1,280	\$ 1,280
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,280</u>	<u>\$ 1,280</u>

[Table of Contents](#)

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 our Annual Report in Part I, 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 FDA relating to our New Drug Application resubmission;
- the ability of the Company to respond to FDA queries related to our scheduled Prescription Drug User Fee Act target action dated of August 4, 2023;
- our successful inspections by the FDA or foreign regulatory agencies;
- 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 progress and results of our research and development programs;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of CHEMOSAT and HEPZATO and enter into supplier contracts;
- 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 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.

Table of Contents

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 a New Drug Application (“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 resubmission was in response to a September 12, 2013 Complete Response Letter (“CRL”), from the FDA for the Company’s NDA 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 Prescription Drug User Fee Act target action date of August 14, 2023. We continue to promote our early access programs 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 early access program 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, we have assumed direct responsibility for sales, marketing and distribution of CHEMOSAT in Europe.

Results of Operations for the three months ended March 31, 2023 (in thousands)

Three months ended March 31, 2023 Compared with Three months ended March 31, 2022

Revenue

We recorded approximately \$0.6 million in revenue for the three months ended March 31, 2023 compared to \$0.4 million for the three months ended March 31, 2022. The increase in product revenue was primarily due to the transition to direct sales in Europe beginning in March 2022.

Cost of Goods Sold

For the three months ended March 31, 2023, we recorded cost of goods sold of approximately \$0.2 million compared to a nominal amount for the three months ended March 31, 2022, which was primarily due to the transition of direct sales in Europe beginning in March 2022.

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. To date, these costs are related to generating pre-clinical data and the cost of manufacturing HEPZATO for clinical trials and conducting clinical trials. For the three months ended March 31, 2023, research and development expenses relatively flat at \$4.6 million and \$4.5 million for three months ended March 31, 2023 and March 31, 2022, respectively.

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 months ended March 31, 2023 and 2022, selling, general and administrative expenses also remained relatively flat at \$4.2 million, respectively.

Other Income/Expense

Other income (expense) is primarily related to income or expense associated with financial instruments. For the three months ended March 31, 2023 and 2022, other expenses were \$0.7 million.

Liquidity and Capital Resources

At March 31, 2023, we had cash, cash equivalents and restricted cash totaling \$24.3 million, as compared to cash, cash equivalents and restricted cash totaling \$11.8 million at December 31, 2022. During the three months ended March 31, 2023, we used \$4.3 million of cash for operating activities and \$6.3 million for principal payments.

[Table of Contents](#)

On March 27, 2023, we entered into a securities purchase agreement with certain accredited investors (the “Preferred Purchase Agreement”). Pursuant to the Preferred Purchase Agreement, on March 29, 2023, we issued to purchasers an aggregate \$24.9 million in shares, consisting of 24,900 shares of our Series F-1 Convertible Preferred Stock, par value \$0.01 per share (the “Series F-1 Preferred Stock”), that are convertible into approximately 7.6 million shares of common stock at a conversion price of \$3.30 per share, and two tranches of warrants that are exercisable as follows:

- Tranche A warrants (the “Preferred Tranche A Warrants”) for an aggregate exercise price of approximately \$34.9 million are exercisable for an aggregate of up to 34,860 shares of Series F-3 Convertible Preferred Stock, par value \$0.01 per share (the “Series F-3 Preferred Stock”), at an exercise price of \$1,000 per share (and convertible into an aggregate of up to approximately 7.8 million shares of common stock at a conversion price of \$4.50 per share) until the earlier of 3/31/2026 or 21 days following our announcement of receipt of FDA approval for HEPZATO; and
- Tranche B warrants (the “Preferred Tranche B Warrants,” together with the Preferred Tranche A Warrant, the “Preferred Warrants”) for an aggregate exercise price of \$24.9 million are exercisable for an aggregate of up to 24,900 shares of Series F-4 Convertible Preferred Stock, par value \$0.01 per share (the “Series F-4 Preferred Stock” and, together with the Series F-3 Preferred Stock, the “Preferred Warrant Shares”), at an exercise price of \$1,000 per share, (and convertible into an aggregate of up to approximately 4.2 million shares of common stock at a conversion price of \$6.00 per share) until the earlier of 3/31/2026 or 21 days following disclosure of our public announcement of recording at least \$10 million in quarterly U.S. revenue from the commercialization of HEPZATO (collectively, the “Series F Preferred Offering”).

The shares of Series F-1 Convertible Preferred Stock, and accompanying warrants, were issued at a price of \$1,000 per share. Conversion of the Series F-1 Convertible Preferred Stock into shares of our common stock, and the exercisability of the warrants, is subject to approval by our stockholders (the “Stockholder Approval”). We received gross proceeds of approximately \$25.0 million from private placement, 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 our Chief Executive Officer, Gerard Michel (the “Common Purchase Agreement”). Pursuant to the Common Purchase Agreement, on March 29, 2023, we issued to Mr. Michel 19,646 shares of common stock and two tranches of warrants that are exercisable as follows:

- A Preferred Tranche A Warrant (the “Common Tranche A Warrant”) for an aggregate exercise price of approximately \$0.1 million are exercisable for an aggregate of up to 31,110 shares of our common stock until the earlier of 3/31/2026 or 21 days following our announcement of receipt of FDA approval for HEPZATO; and
- A Preferred Tranche B Warrant (the “Common Tranche B Warrant” and, together with the Common Tranche A Warrant, the “Common Warrants”) for an aggregate exercise price of \$0.1 million are exercisable for an aggregate of up to 16,666 shares of common stock until the earlier of 3/31/2026 or 21 days following disclosure of our public announcement of recording at least \$10 million in quarterly U.S. revenue from the commercialization of HEPZATO (collectively, the “Common Financing”). The shares of common stock issuable upon exercise of the Common Warrants collectively are referred to herein as the “Common Warrant Shares”.

On March 10, 2023, we had a banking relationship with SVB. As of the closure of SVB on March 10, 2023, we held approximately \$1.1 million of unrestricted cash in deposits held in SVB, \$4.0 million held in a restricted SVB account as required per the Avenue Loan Agreement (as defined in “Note 8 – Loans and Convertible Notes Payable”) and approximately \$0.2 million of restricted cash held in SVB collateral accounts as required per our line of credit for the property in New York City and our credit card program with SVB. SVB was closed on March 10, 2023 by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. On March 12, 2023, the U.S. Treasury, Federal Reserve, and FDIC announced that SVB depositors will have access to all of their money starting March 13, 2023. On March 13, 2023, we were able to access all of our cash, cash equivalents and investments held at or through SVB. While we have not experienced any losses in such accounts, the recent failure of SVB exposed us to significant credit risk prior to the completion by the FDIC of the resolution of SVB in a manner that fully protected all depositors. We are evaluating alternative solutions which management believes does not expose us to significant credit risk or jeopardizes our liquidity.

Our future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history and there can be no assurance that we will ever achieve or maintain profitability. We have historically funded our operations primarily with proceeds from sales of common stock, warrants and prefunded warrants for the purchase of our common stock, sales of preferred stock, proceeds from the issuance of convertible debt and borrowings under loan and security agreements. We have entered into a Controlled Equity OfferingSM Sales Agreement (“ATM Sales Agreement”), with Cantor Fitzgerald & Co. (the “Sales Agent”), pursuant to which we may offer and sell, at our sole discretion through the Sales Agent, shares of our common stock having an aggregate offering price of up to \$17.0 million. To date, we have sold approximately \$4.0 million of our common stock, prior to issuance costs, under the ATM Sales Agreement. No sales were made during the three months ended March 31, 2023.

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. Subject to the approval by our stockholders of the private placement that we closed on March 29, 2023 at our upcoming annual general meeting of stockholders, the Tranche A and B warrants issued in such private placement will become exercisable. The exercise of all such warrants would generate approximately \$60.0 million in proceeds. We believe that this amount will be adequate to fund the commercialization of HEPZATO, if approved. 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, 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 curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash.

Our capital commitments over the next twelve months include (a) \$9.6 million to satisfy accounts payable, accrued expenses and lease liabilities and (b) \$4.4 million of loan principal payments. Additional capital commitments past the next twelve months include (a) \$0.2 million of lease liabilities; (b) \$1.0 million for settlement of litigation with medac; (c) \$1.2 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.

[Table of Contents](#)

The Company also expect to use cash and cash equivalents to fund our potential approval of HEPZATO from the FDA, commercialization of HEPZATO and CHEMOSAT and 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.

On August 6, 2021, the Company 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 7.70% plus the prime rate as reported in The Wall Street Journal and (b) 10.95%. The interest rate at March 31, 2023 was 15.45%. 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 the \$4.0 million held in the restricted cash to paydown a portion of the outstanding Avenue Loan balance. On March 31, 2023, we reached an agreement to amend its existing loan agreement with Avenue to defer the interest only 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 34,072 warrants to purchase shares of common stock. The exercise price of the warrants is \$0.01.

On July 20, 2022, we closed a private placement for the issuance and sale of 690,954 shares of common stock and 566,751 pre-funded warrants to purchase common stock to certain investors. Each share of common stock was sold at a price per share of \$3.98 and the pre-funded warrants were sold at a price of \$3.97 per pre-funded warrants. pre-funded warrants have an exercise price of \$0.01 per share of Common Stock and are immediately exercisable. We received gross proceeds from the private placement of approximately \$5.0 million before deducting offering expenses.

On December 13, 2022, we closed a private placement for the issuance and sale of 1,448,889 shares of common stock and 692,042 pre-funded warrants to purchase common stock to certain investors. Each share of common stock was sold at a price per share of \$2.90 and the pre-funded warrants were sold at a price of \$2.89 per pre-funded warrants. The pre-funded warrants have an exercise price of \$0.01 per share of Common Stock and are immediately exercisable. We received gross proceeds from the private placement of approximately \$6.2 million before deducting offering expenses.

Additionally, while the long-term economic impact of either the COVID-19 pandemic or the conflict between Russia and Ukraine is difficult to assess or predict, each of these events has caused significant disruptions to the global financial markets and contributed to a general global economic slowdown. Furthermore, inflation rates, particularly in the United States and the United Kingdom, have increased recently to levels not seen in decades. In addition, the U.S. Federal Reserve has raised, and is expected to further raise, 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. Recent bank failures, including Silicon Valley Bank (“SVB”), Signature Bank and First Republic Bank, may also have an impact on our liquidity and capital resources. If 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 ability to access our 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. See “Risk Factors” in “Part I – Item 1A – Risk Factors” in the Company’s Annual Report for additional risks associated with our substantial capital requirements.

[Table of Contents](#)

Critical Accounting Estimates

Other than the accounting for the valuation of warrant liability and preferred F-1 shares, during the three months ended March 31, 2023, there were no other material changes to critical accounting estimates as reported in our Annual Report.

The valuations of the warrant liability and preferred F-1 shares 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 preferred F-1 shares. 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 new policies described in our notes #1 of the Form 10Q for the three months ended March 31, 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 March 31, 2023, our management, under the supervision of our Chief Executive Officer and 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 March 31, 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 March 31, 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 all member states of the European Union, Norway, Liechtenstein, Switzerland and the United Kingdom 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. medac disputed having an obligation to make the milestone payment and demanded withdrawal of the termination notice. In response to medac's continued failure to make the milestone payment and its demand for the Company to withdraw its termination notice, on December 16, 2021, we initiated an arbitration proceeding pursuant to the dispute resolution procedures of the medac Agreement. Thereafter, on December 30, 2021, we received a letter from medac stating that, due to our failure to withdraw the termination notice, medac was terminating the medac Agreement with immediate effect. In a separate letter, medac agreed to orderly transition through February 28, 2022 in order to minimize the impact of any termination on patients and physicians. The Company agreed to purchase inventory held at medac in March 2022 for approximately \$0.2 million.

On December 30, 2022, the parties reached a final settlement of the matter and the Company agreed pay medac 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. The settlement terms also contain 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 March 31, 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 March 31, 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 lawsuit is Lachman Consultant Services, Inc. v. Delcath Systems, Inc., Index No. 650103-2023 (New York Supreme Court, New York County). The Company filed an answer to Lachman's Complaint on February 22, 2023. On March 17, 2023, Delcath responded to Lachman's March 3, 2023 Motion for Partial Summary Judgment. On March 20, 2023, the Court denied Lachman's request that the case be moved into the Commercial Division. The current return date of Lachman's motion for partial summary judgment is March 31, 2023. The dispute arises from a July 22, 2021 agreement between Lachman and Delcath under which Lachman was to provide assistance to the Company in regard to preparing for a FDA inspection and good manufacturing practices, training and support. In August 2022, the Company disputed \$0.3 million of charges from Lachman. As of March 31, 2023, the Company has accrued \$0.9 million as accrued liability on the Company's condensed consolidated balance sheet. The Company plans to vigorously defend this lawsuit and has reserved its rights to dispute all of Lachman charges as the litigation proceeds.

Item 1A. Risk Factors

You should carefully consider the risk factors discussed in "Part I – Item 1A – Risk Factors" to our Annual Report. There have been no material changes from the risk factors previously disclosed in our Annual Report.

Table of Contents

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	Amended and Restated By-Laws of the Company.
3.7	Certificate of Designation of Preferences, 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 filed on March 30, 2023)
4.1	Form of Preferred Tranche A Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on March 30, 2023)
4.2	Form of Preferred Tranche B Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on March 30, 2023)
4.3	Form of Common Tranche A Warrant (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on March 30, 2023)
4.4	Form of Common Tranche B Warrant (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed on March 30, 2023)
4.5	Warrant to Purchase Shares, dated March 31, 2023 issued by the Company to Avenue Venture Opportunities Fund, L.P.
10.1	Form of Securities Purchase Agreement, dated March 27, 2023, by and among Delcath Systems, Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 30, 2023)
10.2	Form of Securities Purchase Agreement, dated March 27, 2023, by and between Delcath Systems, Inc. and the purchaser named therein (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on March 30, 2023)
10.3	First Amendment to Loan Documents issued by the Company to Avenue Venture Opportunities Fund, L.P.
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.

May 22, 2023

/s/ Gerard Michel

Gerard Michel
Chief Executive Officer (Principal Executive Officer)

May 22, 2023

/s/ Anthony Dias

Anthony Dias
Principal Financial Officer

AMENDED AND RESTATED
BY-LAWS
OF
DELCATH SYSTEMS, INC.
A Delaware Corporation
ARTICLE I
MEETINGS OF STOCKHOLDERS

Section 1. Annual Meeting. A meeting of stockholders shall be held annually for the election of directors and the transaction of such other business as may properly come before the meeting. Such meeting shall be held at such time and at such place either within or without the State of Delaware as may be fixed from time to time by the board of directors.

Section 2. Special Meetings. Special meetings of the stockholders, for any purpose or purposes, unless otherwise prescribed by statute or by the certificate of incorporation, may be called by the Chief Executive Officer, the President or any three directors, and shall be called by the President or the Chief Executive Officer at the written request of the holders of at least twenty percent (20%) of the outstanding shares entitled to vote at such meeting. Special meetings of stockholders may be held at such place, within or without the State of Delaware, as shall be stated in the notice of the meeting.

Section 3. Notice of Meetings. Notice of each meeting shall be given in writing and state the place, date and hour of the meeting and in the case of special meetings, (i) the purpose or purposes for which the meeting is called, and (ii) at whose direction the notice is being issued. A copy of the notice of any meeting shall be delivered not less than ten nor more than fifty days before the date of the meeting, either personally or by mail, by or at the direction of the Chief Executive Officer, the President, the Secretary or the officer or persons calling the meeting, to each stockholder of record entitled to vote at such meeting.

When a meeting is adjourned to another time or place, it shall not be necessary to give any notice of the adjourned meeting if the time and place to which the meeting is adjourned are announced at the meeting at which the adjournment is taken, and at the adjourned meeting any business may be transacted that might have been transacted on the original date of the meeting. However, if after the adjournment the board of directors fixes a new record date for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record on the new record date entitled to notice.

Section 4. Quorum of Stockholders. The holders of a majority of the shares of stock issued and outstanding and entitled to vote, represented in person or by proxy, shall constitute a quorum at all meetings of the stockholders for the transaction of any business except as otherwise provided by statute or by the certificate of incorporation. Once a quorum is present to organize a meeting, it is not broken by the subsequent withdrawal of any stockholders. However, if a quorum shall not be present or

represented at any meeting of the stockholders, the stockholders present in person or represented by proxy shall have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present or represented. At such adjourned meeting at which a quorum shall be present or represented any business may be transacted which otherwise might have been transacted at the meeting as originally notified.

Section 5. Organization of Meeting. The Chief Executive Officer, or in his absence the President, shall call to order meetings of stockholders and shall act as chairman of such meetings. The board of directors, or, if the board of directors fails to act, the Stockholder, may appoint any Stockholder, director or officer of the corporation to act as chairman of any meeting in the absence of the Chief Executive Officer and the President.

The Secretary of the corporation shall act as secretary of all meetings of stockholders, but, in the absence of the Secretary, the chairman of the meeting may appoint any other person to act as secretary of any meeting.

Section 6. Voting. If a quorum is present, the vote of a majority of the shares of stock entitled to vote and represented at the meeting shall be the act of the stockholders, unless the vote of a greater or lesser number of shares of stock is required by law or the certificate of incorporation.

Section 7. Qualification of Voters and Proxies. Except as may be provided in the certificate of incorporation, each outstanding share of stock having voting power shall be entitled to one vote on each matter submitted to a vote at a meeting of stockholders. A stockholder may vote either in person or by written proxy executed by the stockholder or by his duly authorized attorney-in-fact.

Section 8. Inspectors. The board of directors in advance of any stockholders' meeting may appoint one or more inspectors to act at the meeting or any adjournment thereof. If inspectors are not so appointed, the person presiding at the stockholders' meeting may, and, on the request of any stockholder entitled to vote thereat, shall appoint one or more inspectors. In case any person appointed as inspector fails to appear or act, the vacancy may be filled by appointment made by the board of directors in advance of the meeting or at the meeting by the person presiding thereat. Each person appointed to serve as inspector, in advance of his duties, shall take and sign an oath faithfully to execute the duties of inspector at such meeting with strict impartiality and according to the best of his ability.

Section 9. Written Consent of Stockholders. Whenever stockholders are required or permitted to take any action by vote, such action may be taken without a meeting on written consent, setting forth the action so taken signed by the holders of outstanding shares having not less than the minimum number of votes necessary to take such action at a meeting at which all shares entitled to vote thereon were present.

ARTICLE II

DIRECTORS

Section 1. Qualification, Number, Election and Term of Directors. The board of directors shall consist of such number as shall be set by the board of directors, consistent with the corporation's certificate of incorporation, as amended from time to time. Directors shall be at least eighteen years of age and need not be stockholders of the corporation. The directors, other than the first board of

directors, shall be elected at the annual meeting of the stockholders, except as hereinafter provided, and each director elected shall serve until his successor shall have been elected and qualified. The class, the term of office and the class of stockholders entitled to elect such directors, shall be set forth in the corporation's certificate of incorporation, as amended from time to time.

Section 2. Removal of Directors. Any or all of the directors may be removed only as set forth in the corporation's certificate of incorporation, as amended from time to time.

Section 3. Resignation of Directors. Any director of the corporation may resign at any time by giving written notice to the board of directors, the Chief Executive Officer, the President, or the Secretary. Any such resignation shall take effect at the time specified therein or, if the time be not specified therein, then upon receipt thereof. The acceptance of such resignation shall not be necessary to make it effective, unless its effectiveness is made dependent upon acceptance.

Section 4. Newly Created Directorships and Vacancies. Newly created directorships resulting from an increase in the number of directors and vacancies occurring in the board for any reason may be filled only by vote of the board of directors then in office in the manner provided in the corporation's certificate of incorporation, as amended from time to time.

Section 5. Management of Business Affairs. The business affairs of the corporation shall be managed by its board of directors, which may exercise all such powers of the corporation and do all such lawful acts and things as are not by statute or by the certificate of incorporation or by these by-laws directed or required to be exercised or done by the stockholders.

Section 6. Books. The directors shall keep the books of the corporation at such place or places as they may from time to time determine, except as otherwise required by law.

Section 7. Compensation. The board of directors, by the vote of a majority of the directors then in office, and irrespective of any personal interest of any of its members, shall have authority to establish reasonable compensation of all directors for services to the corporation as directors, officers or otherwise.

ARTICLE III

MEETINGS OF THE BOARD OF DIRECTORS

Section 1. Number and Place of Meetings. The number of meetings of the board to be held each year shall be determined by the board from time to time at such location as the board shall determine. Board members will be reimbursed for all expenses incurred in attending board meetings and working on other special projects at the request of the corporation and shall receive such other compensation as may be established pursuant to Article II, Section 7.

Section 2. Annual Meetings. The annual meetings of each newly elected board of directors shall be held immediately after the annual meeting of stockholders and notice of such meeting need not be given to the newly elected directors to constitute such meeting as a meeting called in full compliance with the law, provided a quorum shall be present, or it may convene at such place and time as shall be fixed by and with the written consent of all the directors.

Section 3. Regular Meetings. Regular meetings of the board of directors may be held upon such notice, or without notice, and at such time and place as shall from time to time be determined by the board.

Section 4. Special Meetings. Special meetings of the board of directors may be called by the Chief Executive Officer, the President or any two directors on two days' notice to each director.

Section 5. Notice and Waiver Thereof. Notice of a meeting need not be given to any director who submits a signed waiver of notice whether before or after the meeting, or who attends the meeting without protesting, prior thereto or at its commencement, the lack of notice. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the board of directors need be specified in the notice of waiver or notice of such meeting.

Section 6. Quorum and Action by Board of Directors. A majority of the directors shall constitute a quorum for the transaction of business unless a greater or lesser number is required by law or by the certificate of incorporation. The vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the board of directors, unless the vote of a greater number is required by law or by the certificate of incorporation. If a quorum shall not be present at any meeting of directors, the majority of directors present may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present.

Section 7. Organization of Meeting. Meetings shall be presided over by such person as the directors may select. The Secretary of the corporation shall act as secretary of the meeting, but in his absence the chairperson of the meeting may appoint any person to act as secretary of the meeting.

Section 8. Consent of Directors in Lieu of Meeting. Any action required or permitted to be taken by the board of directors or any committee thereof may be taken without a meeting if all members of the board of directors or the committee consent in writing to the adoption of a resolution authorizing such action. The resolution and the written consents thereto by the members of the board of directors or the committee shall be filed with the minutes of the proceedings of the board of directors or the committee.

Section 9. Other Means of Participation in Meeting. Any one or more members of the board of directors or any committee thereof may participate in a meeting of such board of directors or committee by means of a conference telephone or similar communications equipment allowing all persons participating in the meeting to hear each other at the same time. Participation by such means shall constitute presence in person at a meeting.

ARTICLE IV

COMMITTEES OF THE BOARD OF DIRECTORS

Section 1. Executive Committee. The board of directors, by resolution adopted by a majority of the entire board of directors, may designate, from among its members, an executive committee, consisting of two or more directors, which, shall have the rights, power and authority of the board of directors as may from time to time be granted to it to the extent permitted by law.

Section 2. Audit Committee. The board of directors, by resolution adopted by a majority of the entire board of directors, shall designate, from among its members, an audit committee, consisting of two or more members, which shall have the authority to oversee and monitor management's and the corporation's independent auditors' participation in the financial reporting process as set forth in its charter or as otherwise required by law or the rules of the Securities and Exchange Commission, National Association of Securities Dealers, Inc., or any stock exchange on which the corporation's securities are listed.

Section 3. Compensation Committee. The board of directors, by resolution adopted by a majority of the entire board of directors, may designate from among its members, a compensation committee, consisting of two or more directors, which shall have the rights, power and authority of the board of directors in matters relating to compensation of employees, consultants and directors and administration of the corporation's stock option plans and other incentive plans and such other matters as may from time to time be granted to it to the extent permitted by law.

Section 4. Other Committees. The board of directors, by resolutions adopted by a majority of the entire board of directors, may appoint such other committee or committees as it shall deem advisable and with such rights, power and authority as it shall prescribe. Each such committee shall consist of one or more directors.

Section 5. Committee Changes. The board of directors shall have to power at any time to fill vacancies in, to change the membership of, and to discharge any committee.

Section 6. Procedure and Meetings. Each committee shall fix its own rules of procedure and shall meet at such times and at such place or places as may be provided by such rules or as the members of the committee shall fix. The committee shall keep regular minutes of its meetings, which it shall deliver to the board of directors from time to time. The chairman of a committee or, in his or her absence, a member of the committee chosen by a majority of the members present, shall preside at meetings of the committee; and a person chosen by the committee shall act as secretary of the committee and record the minutes.

Section 7. Quorum. A majority of the committee shall constitute a quorum for the transaction of business, and the affirmative vote of a majority of the members present at any meeting at which there is a quorum shall be required for any action of the committee; provided, however, that when a committee of one member is authorized under the provisions of this Article, that one member shall constitute a quorum.

Section 8. Resignation of Members of a Committee. Any member of any committee may resign at any time by giving written notice to the board of directors, the Chief Executive Officer, or the President or the Secretary. Any such resignation shall take effect at the time specified therein or, if the time be not specified therein, then upon receipt thereof. The acceptance of such resignation shall not be necessary to make it effective.

ARTICLE V

NOTICES

Section 1. Requirements of Notice. Whenever, under the provisions of the General Corporation Law of the State of Delaware or of the certificate of incorporation or of these by-laws, notice is required to be given to any director or stockholder, such notice may be given in writing, by mail, addressed to such director or stockholder, at his address as it appears on the records of the corporation, with postage thereon prepaid, and such notice shall be deemed to be given at the time when the same shall be deposited in the United States mail. Unless written notice by mail is required by law, written notice may also be given by telegram, messenger, electronic mail or teletype. Notice given other than by mail shall be deemed given upon receipt. Notice to directors may also be given by telephone.

Section 2. Waiver of Notice. Whenever any notice of a meeting is required to be given under the provisions of the General Corporation Law of the State of Delaware or under the provisions of the certificate of incorporation or these by-laws, a waiver thereof in writing signed by the person or persons entitled to such notice, whether before or after the time stated therein, shall be deemed equivalent to the giving of such notice.

ARTICLE VI

OFFICERS

Section 1. Executive Officers. The officers of the corporation shall be chosen by the board of directors and shall consist of a Chief Executive Officer, a President, a Secretary and a Treasurer. The board of directors may also choose one or more Vice Presidents, Assistant Secretaries and Assistant Treasurers. None of the officers of the corporation need be a member of the board of directors. Any number of offices may be held by the same person.

Section 2. Other Offices. The board of directors may appoint such other officers and agents as it shall deem necessary who shall hold their offices for such terms and shall exercise such powers and perform such duties as shall be determined from time to time by the board of directors.

Section 3. Election of Officers. The board of directors at its first meeting after each annual meeting of the stockholders shall choose a Chief Executive Officer, a President, a Secretary, a Treasurer and any other officers as the board of directors shall determine.

Section 4. Compensation of Officers. The compensation of all officers of the corporation shall be fixed by the board of directors.

Section 5. Term of Office, Removal of Officers, Vacancy. The officers of the corporation shall hold office for the term for which they are elected or appointed, and until their successors are chosen and qualified. Any officer elected or appointed by the board of directors may be removed at any time by vote of the board of directors. Removal from office, however, shall not prejudice the contract rights, if any, of the person removed. Any vacancy occurring in any office of the corporation shall be filled by the board of directors.

Section 6. Resignation of Officers. Any officer of the corporation may resign at any time by giving written notice to the board of directors, the Chief Executive Officer, the President, or the Secretary. Any such resignation shall take effect at the time specified therein, or, if the time be not specified therein, then upon receipt thereof. The acceptance of such resignation shall not be necessary to make it effective.

Section 7. Duties of the Officers. Officers shall perform their duties as officers in good faith and with the degree of care that an ordinarily prudent person in a like position would use under similar circumstances.

Section 8. Duties of the Chief Executive Officer. The Chief Executive Officer shall be the chief executive officer of the corporation, and shall have general management of the business of the corporation, subject to the control of the board of directors. He shall have and perform such powers and duties as the board of directors may from time to time prescribe.

Section 9. Duties of the President. The President shall be the chief operating officer of the corporation, shall have active management of the business of the corporation and shall see that all orders and resolutions of the board of directors are carried into effect. He shall have such other powers and duties as the board of directors or the Chief Executive Officer assigns to him.

Section 10. Duties of the Vice President. The Vice President or, if there shall be more than one, the Vice Presidents, in the order determined by the board of directors, shall, in the absence or disability of the President, perform the duties and exercise the powers of the President and shall perform such other duties and have such other powers as the board of directors may from time to time prescribe.

Section 11. Duties of the Secretary. The secretary shall attend all meetings of the board of directors and all meetings of the stockholders and record all the proceedings of the corporation and of the board of directors in a book to be kept for that purpose and shall perform like duties for the standing committee when required. He shall give, or cause to be given, notice of all meetings of the board of directors, and shall perform such other duties as may be prescribed by the board of directors. He shall have custody of the corporate seal of the corporation and he and/or any Assistant Secretary shall have authority to affix the same to any instrument requiring it and, when so affixed, it may be attested to by his signature or by the signature of such Assistant Secretary. The board of directors may give general authority to any other officer to affix the seal of the corporation and to attest to the affixing by his signature.

Section 12. Duties of the Assistant Secretary or Assistant Secretaries. The Assistant Secretary, if there be any, or, if there be more than one, the Assistant Secretaries in the order determined by the board of directors, shall, in the absence or disability of the Secretary, perform the duties and exercise the powers of the Secretary and shall perform such other duties and have such other powers as the board of directors may from time to time prescribe.

Section 13. Duties of the Treasurer. The Treasurer shall have the custody of the corporation funds and securities and shall keep full and accurate accounts of receipts and disbursements in books belonging to the corporation and shall deposit all moneys and other valuable effects in the name and to the credit of the corporation in such depositories as may be designated by the board of directors. He shall perform all other duties incident to the office of Treasurer and shall have such other powers and duties as the board of directors assigns to him.

Section 14. Duties of the Assistant Treasurer or Assistant Treasurers. The Assistant Treasurer, if there be any, or, if there shall be more than one, the Assistant Treasurers in the order determined by the board of directors, shall, in the absence or disability of the Treasurer, perform the duties and exercise the powers of the Treasurer and shall perform such other duties and have such other powers as the board of directors may from time to time prescribe.

ARTICLE VII

CERTIFICATE FOR SHARES

Section 1. General Requirements. The shares of the corporation shall be represented by certificates signed by the President or the Vice President and by the Secretary or an Assistant Secretary or the Treasurer or an Assistant Treasurer of the corporation and may be sealed with the seal of the corporation or a facsimile thereof. In addition, the board of directors may provide by resolution that some or all of any or all classes and series of its shares be uncertificated shares, provided that such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the corporation.

When the corporation is authorized to issue shares of more than one class there shall be set forth upon the face or back of the certificate (or the certificate shall have a statement that the corporation will furnish to any stockholder upon request and without charge) a full statement of the designation, relative rights, preferences, and limitations of the shares of each class authorized to be issued.

When the corporation is authorized to issue any class of preferred shares in series, there shall be set forth upon the face or back of the certificate (or the certificate shall have a statement that the corporation will furnish to any stockholder upon request and without charge) a full statement of the designation, relative rights, preferences and limitations of each such series, so far as the same have been fixed, and the authority of the board to designate and fix the relative rights, preferences and limitations of other series.

Section 2. Facsimile Signatures. The signatures of the officers of the corporation upon a certificate may be facsimiles if the certificate is countersigned by a transfer agent or registered by a registrar other than the corporation itself or an employee of the corporation. In case any officer who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer before such certificate is issued, it may be issued by the corporation with the same effect as if he were such officer at the date of issue.

Section 3. Lost Certificate. The board of directors may direct a new certificate to be issued in place of any certificate theretofore issued by the corporation which is alleged to have been lost, stolen or destroyed. When authorizing such issue of a new certificate, the board of directors, in its discretion and as a condition precedent to the issuance thereof, may prescribe such terms and conditions as it deems expedient, and may require such indemnities as it deems adequate, to protect the corporation from any claim that may be made against it with respect to any such certificate alleged to have been lost or destroyed.

Section 4. Transfer of Shares. Upon surrender to the corporation or the transfer agent of the corporation of a certificate representing shares duly endorsed or accompanied by proper evidence of succession, assignment or authority to transfer, a new certificate shall be issued to the person entitled thereto and the old certificate cancelled and the transaction recorded upon the books of the corporation.

Section 5. Fixing Record Date. For the purpose of determining stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, or to express consent to or dissent from any proposal without a meeting, or for the purpose of determining stockholders entitled to receive payments of any dividend or the allotment of any rights, or for the purpose of any other action, the board of directors may fix, in advance, a date as the record date for any such determination of stockholders. Such date shall not be more than sixty nor less than ten days before the date of such meeting nor more than sixty days prior to any other action. When a determination of stockholders of record entitled to notice of or to vote at any meeting of stockholders has been made as provided in this section, such determination shall apply to any adjournment thereof, unless the board of directors fixes a new record date for the adjourned meeting.

Section 6. Registered Stockholders. The corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends, and to vote as such owner, and to hold liable for calls and assessments a person registered on its books as the owner of shares, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of the State of Delaware.

Section 7. List of Stockholders. A list of stockholders as of the record date, certified by the corporate officer responsible for its preparation or by a transfer agent, shall be produced at any meeting upon the request thereat or prior thereto of any stockholder. If the right to vote at any meeting is challenged, the inspector(s) or person presiding thereat, shall require such list of stockholders to be produced as evidence of the right of the persons challenged to vote at such meeting and all persons who appear from such list to be stockholders entitled to vote thereat may vote at such meeting.

ARTICLE VIII

GENERAL PROVISIONS

Section 1. Dividends - General Requirements. Subject to the provisions of the certificate of incorporation relating thereto, if any, dividends may be declared by the board of directors at any regular or special meeting, pursuant to any provisions of law. Dividends may be paid in cash, in shares of the capital stock or bonds of the corporation or its property, including the shares or bonds of other corporations subject to any provisions of law and of the certificate of incorporation.

Section 2. Dividends - Reserve Fund. Before payment of any dividend, there may be set aside out of any funds of the corporation available for dividends such sum or sums as the directors from time to time, in their absolute discretion, think proper as a reserve fund to meet contingencies, or for equalizing dividends, or for repairing or maintaining any property of the corporation, or for such other purpose as the directors shall think conducive to the interest of the corporation and the directors may modify or abolish any such reserve in the manner in which it was created.

Section 3. Checks. All checks or demands for money and notes of the corporation shall be signed by such officer or officers or such other person or persons as the board of directors may from time to time designate.

Section 4. Fiscal Year. The fiscal year of the corporation shall be initially fixed by resolution of the board of directors and may thereafter be amended from time to time by the directors.

Section 5. Seal. The corporation's seal shall have inscribed thereon the name of the corporation, the year of its organization and the words "Corporate Seal, Delaware." The seal may be used by causing it or a facsimile thereof to be impressed or affixed or in any manner reproduced.

Section 6. Pronouns. Any masculine personal pronoun shall be considered to mean the corresponding feminine or neuter personal pronoun, as the context requires.

Section 7. Publications. Except with respect to publications in scientific journals, the corporation shall not make, or authorize or permit to be made, any press release or other public announcement, whether written, oral, electronic or other, without the prior written consent of the board of directors. As to scientific journals or other such publications, the corporation shall not submit for publication any articles or data unless it shall have, at least 15 days prior to such submission, presented such articles or data to the members of the board.

ARTICLE IX

AMENDMENTS

By-laws may be adopted, amended or repealed by the affirmative vote of a majority of the entire board of directors at any regular or special meeting thereof or by written consent in lieu of such meeting. These by-laws may also be amended or repealed by the stockholders; except that Articles II, III, IV, V, VI and IX of these By-Laws shall not be altered, amended or repealed by the stockholders and no provisions inconsistent therewith shall be adopted by the stockholders without the affirmative vote of eighty percent (80%) of the outstanding stock of the corporation entitled to vote. If any by-law regulating an impending election of directors is adopted, amended or repealed by the board of directors, there shall be set forth in the notice of the next meeting of stockholders for the election of directors the by-law so adopted, amended or repealed, together with a concise statement of the changes made. By-laws adopted by the board of directors are subject to being amended or repealed by the stockholders entitled to vote thereon, in accordance with the required vote as set forth above.

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE AND DISTRIBUTION THEREOF, AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”) OR ANY STATE SECURITIES LAWS. SUCH SECURITIES MAY NOT BE SOLD OR TRANSFERRED IN THE ABSENCE OF (A) SUCH REGISTRATION, (B) AN OPINION OF COUNSEL IN A FORM REASONABLY ACCEPTABLE TO COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED DUE TO AN EXEMPTION THEREFROM UNDER SAID ACT AND ANY APPLICABLE STATE SECURITIES LAWS OR (C) DELCATH SYSTEMS, INC. OTHERWISE SATISFIES ITSELF THAT SUCH TRANSACTION IS COMPLIANT WITH SUCH LAWS.

Date of Issuance: March 31, 2023

WARRANT TO PURCHASE

SHARES OF STOCK OF

DELCATH SYSTEMS, INC.

(Void after March 31, 2028)

This certifies that AVENUE VENTURE OPPORTUNITIES FUND, LP, a Delaware limited partnership, or permitted assigns (“Holder”), for value received, is entitled to purchase from DELCATH SYSTEMS, INC., a Delaware corporation (“Company”), the Applicable Number (hereinafter defined) of fully paid and nonassessable shares of the Company’s Common Stock (the “Common Stock”), for cash, at a purchase price per share equal to the Stock Purchase Price (hereinafter defined). Holder may also exercise this Warrant on a cashless or “net issuance” basis as described in Section 1(b) below, and this Warrant shall be deemed to have been exercised in full on such basis on the Expiration Date (hereinafter defined), to the extent not fully exercised prior to such date. This Warrant is issued in connection with that certain Loan and Security Agreement and Supplement thereto, both of even date herewith (as amended, restated and supplemented from time to time, the “Loan Agreement” and the “Supplement”, respectively), between Company, as borrower, and Holder, as lender (“Lender”). Capitalized terms used herein and not otherwise defined in this Warrant shall have the meaning(s) ascribed to them in the Loan Agreement and the Supplement, unless the context would otherwise require.

“Applicable Number” means 34,072 shares of Common Stock.

“Market Price” means \$5.87.

“Stock Purchase Price” means \$0.01.

Subject to Sections 4.3 and 4.8, this Warrant may be exercised at any time or from time to time up to and including 5:00 p.m. (Pacific time) on March 31, 2028 (the “Expiration Date”), upon surrender to Company at its principal office at 1633 Broadway, Suite 22C, New York, NY 10019 (or at such other location as Company may advise Holder in writing) of this Warrant properly endorsed with the Form of Subscription attached hereto duly completed and signed and upon payment in cash or by check of the aggregate Stock Purchase Price for the number of shares for which this Warrant is being exercised determined in accordance with the provisions hereof. The Stock Purchase Price and the number of shares purchasable hereunder are subject to further adjustment as provided in Section 4 of this Warrant.

This Warrant is subject to the following terms and conditions:

1. Exercise; Issuance of Certificates; Payment for Shares.

(a) Unless an election is made pursuant to clause (b) of this Section 1, this Warrant shall be exercisable at the option of Holder, at any time or from time to time, on or before the Expiration Date for all or any portion of the shares of Common Stock (but not for a fraction of a share) which may be purchased hereunder for the Stock Purchase Price multiplied by the number of shares to be purchased. Company agrees that the shares of Common Stock purchased under this Warrant shall be and are deemed to be issued to Holder as the record owner of such shares as of the close of business on the date on which the form of subscription shall have been delivered and payment made for such shares. Subject to the provisions of Section 2, certificates for the shares of Common Stock so purchased, together with any other securities or property to which Holder is entitled upon such exercise, shall be delivered to Holder by Company at Company's expense within a reasonable time after the rights represented by this Warrant have been so exercised. Except as provided in clause (b) of this Section 1, in case of a purchase of less than all the shares which may be purchased under this Warrant, Company shall cancel this Warrant and execute and deliver a new Warrant or Warrants of like tenor for the balance of the shares purchasable under this Warrant surrendered upon such purchase to Holder within a reasonable time. Each stock certificate so delivered shall be in such denominations of Common Stock as may be requested by Holder and shall be registered in the name of such Holder or such other name as shall be designated by such Holder, subject to the limitations contained in Section 2.

(b) Holder, in lieu of exercising this Warrant by the cash payment of the Stock Purchase Price pursuant to clause (a) of this Section 1, may elect, at any time on or before the Expiration Date, to surrender this Warrant and receive that number of shares of Common Stock computed using the following formula:

$$X = \frac{Y(A-B)}{A}$$

- Where:
- X = the number of shares of Common Stock to be issued to Holder.
 - Y = the number of shares of Common Stock that Holder would otherwise have been entitled to purchase hereunder pursuant to Section 1(a) (or such lesser number of shares as Holder may designate in the case of a partial exercise of this Warrant).
 - A = the Closing Price.
 - B = the Stock Purchase Price then in effect.

Election to exercise under this Section 1(b) may be made by delivering a signed form of subscription to Company via facsimile, to be followed by delivery of this Warrant. Notwithstanding anything to the contrary contained in this Warrant, if as of the close of business on the last business day preceding the Expiration Date this Warrant remains unexercised as to all or a portion of the shares of Common Stock purchasable hereunder, then effective as 9:00 a.m. (Pacific time) on the Expiration Date, Holder shall be deemed, automatically and without need for notice to Company, to have elected to exercise this Warrant in full pursuant to the provisions of this Section 1(b), and upon surrender of this Warrant shall be entitled to receive that number of shares of Common Stock computed using the above formula, provided that the application of such formula as of the Expiration Date yields a positive number for "X".

2. Limitation on Transfer.

(a) This Warrant and the Common Stock shall not be transferable except upon the conditions specified in this Section 2, which conditions are intended to ensure compliance with the provisions of the Securities Act of 1933, as amended (the "Securities Act"). Each holder of this Warrant or the Common Stock issuable hereunder will cause any proposed transferee of the Warrant or Common Stock to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Section 2. Notwithstanding the

foregoing and any other provision of this Section 2 but subject to the last sentence of Section 2(c), Holder may freely transfer all or part of this Warrant or the shares issuable upon exercise of this Warrant (or the securities issuable, directly or indirectly, upon conversion of the shares, if any) at any time to any affiliate of Lender under the Loan Agreement, by giving Company notice of the portion of the Warrant being transferred setting forth the name, address and taxpayer identification number of the transferee and surrendering this Warrant to Company for reissuance to the transferees(s) (and Holder, if applicable).

(b) Each certificate representing (i) this Warrant, (ii) the Common Stock, and (iii) any other securities issued in respect to the Common Stock issued upon any stock split, stock dividend, recapitalization, merger, consolidation or similar event, shall (unless otherwise permitted by the provisions of this Section 2 or unless such securities have been registered under the Securities Act or sold under Rule 144) be stamped or otherwise imprinted with a legend substantially in the following form (in addition to any legend required under applicable state securities laws):

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE AND DISTRIBUTION THEREOF, AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OR ANY STATE SECURITIES LAWS. SUCH SECURITIES MAY NOT BE SOLD OR TRANSFERRED IN THE ABSENCE OF (A) SUCH REGISTRATION, (B) AN OPINION OF COUNSEL IN A FORM REASONABLY ACCEPTABLE TO COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED DUE TO AN EXEMPTION THEREFROM UNDER SAID ACT AND ANY APPLICABLE STATE SECURITIES LAWS OR (C) DELCATH SYSTEMS, INC. OTHERWISE SATISFIES ITSELF THAT SUCH TRANSACTION IS COMPLIANT WITH SUCH LAWS.

(c) Holder of this Warrant and each person to whom this Warrant is subsequently transferred represents and warrants to Company and agrees (by acceptance of such transfer) that it will not transfer this Warrant (or securities issuable upon exercise hereof unless a registration statement under the Securities Act was in effect with respect to such securities at the time of issuance thereof) unless (i) there is an effective registration statement under the Securities Act and applicable state securities laws covering any such transaction, (ii) pursuant to Rule 144 under the Securities Act (or any other rule under the Securities Act relating to the disposition of securities), (iii) Company receives an opinion of counsel, reasonably satisfactory to Company, that an exemption from such registration is available or (iv) the Company otherwise satisfies itself that such transaction is exempt from registration. Notwithstanding the foregoing or any other provision of this Section 2, Holder shall not transfer this Warrant (or securities issuable upon exercise hereof, or securities issuable, directly or indirectly, upon conversion of such securities, if any) to any competitor of Company, as determined in good faith by the Board of Directors of Company (the "Board"), without the prior written consent of Company.

3. Shares to be Fully Paid; Reservation of Shares. Company covenants and agrees that all shares of Common Stock which may be issued upon the exercise of the rights represented by this Warrant will, upon issuance, be duly authorized, validly issued, fully paid and nonassessable and free from all preemptive rights of any stockholder and free of all taxes, liens and charges with respect to the issue thereof. Company further covenants and agrees that during the period within which the rights represented by this Warrant may be exercised, Company will at all times have authorized and reserved, for the purpose of issue or transfer upon exercise of the subscription rights evidenced by this Warrant, a sufficient number of shares of authorized but unissued Common Stock, or other securities and property, when and as required to provide for the exercise of the rights represented by this Warrant. Company will take all such action as may be necessary to assure that such shares of Common Stock may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of any domestic securities exchange upon which the Common Stock may be listed. Company will not take any action which would result in any adjustment of the Stock Purchase Price (as described in Section 4 hereof) (i) if the total number of shares of Common Stock issuable after such action upon exercise of all outstanding warrants, together with all shares of Common Stock then outstanding and all shares of Common Stock then issuable upon exercise of all options and upon the conversion of all convertible securities then outstanding, would exceed the total number of shares of Common Stock then authorized by Company's Certificate of Incorporation, as amended and restated from time to time (the "Charter") or (ii) if the par value per share of the Common Stock would exceed the Stock Purchase Price.

4. Adjustment of Stock Purchase Price and Number of Shares. The Stock Purchase Price and the number of shares purchasable upon the exercise of this Warrant shall be subject to adjustment from time to time upon the occurrence of certain events described in this Section 4. Upon each adjustment of the Stock Purchase Price, Holder of this Warrant shall thereafter be entitled to purchase, at the Stock Purchase Price resulting from such adjustment, the number of shares obtained by multiplying the Stock Purchase Price in effect immediately prior to such adjustment by the number of shares purchasable pursuant hereto immediately prior to such adjustment, and dividing the product thereof by the Stock Purchase Price resulting from such adjustment.

4.1 Subdivision or Combination of Stock. In case Company shall at any time subdivide its outstanding shares of Common Stock into a greater number of shares, the Stock Purchase Price in effect immediately prior to such subdivision shall be proportionately reduced, and conversely, in case the outstanding shares of Common Stock of Company shall be combined into a smaller number of shares, the Stock Purchase Price in effect immediately prior to such combination shall be proportionately increased.

4.2 Dividends. If at any time or from time to time the holders of Common Stock (or any shares of stock or other securities at the time receivable upon the exercise of this Warrant) shall have received or become entitled to receive,

(a) Common Stock, or any shares of stock or other securities whether or not such securities are at any time directly or indirectly convertible into or exchangeable for Common Stock, or any rights or options to subscribe for, purchase or otherwise acquire any of the foregoing by way of dividend or other distribution,

(b) any cash paid or payable including as a cash dividend, or

(c) Common Stock or other or additional stock or other securities or property (including cash) by way of spin off, split-up, reclassification, combination of shares or similar corporate rearrangement, (other than shares of Common Stock issued as a stock split, adjustments in respect of which shall be covered by the terms of Section 4.1 above),

then and in each such case, Holder hereof shall, upon the exercise of this Warrant, be entitled to receive, in addition to the number of shares of Common Stock receivable thereupon, and without payment of any additional consideration therefor, the amount of stock and other securities and property (including cash in the cases referred to in clauses (b) and (c) above) which such Holder would hold on the date of such exercise had it been the holder of record of such Common Stock as of the date on which holders of Common Stock received or became entitled to receive such shares and/or all other additional stock and other securities and property.

4.3 Change of Control. In the event of a Change of Control (as hereinafter defined), this Warrant shall be automatically exchanged for a number of shares of Company's securities, such number of shares being equal to the maximum number of shares issuable pursuant to the terms hereof (after taking into account all adjustments described herein) had Holder elected to exercise this Warrant immediately prior to the closing of such Change of Control and purchased all such shares pursuant to the cash exercise provision set forth in Section 1(a) hereof (as opposed to the cashless exercise provision set forth in Section 1(b)). Company acknowledges and agrees that Holder shall not be required to make any payment (cash or otherwise) for such shares as further consideration for their issuance pursuant to the terms of the preceding sentence. "Change of Control" shall mean any sale, license, or other disposition of all or substantially all of the assets of Company, any reorganization, consolidation, merger or other transaction involving Company where the holders of Company's securities before the transaction beneficially own less than 50% of the outstanding voting securities of the surviving entity after the transaction; provided that an issuance of equity securities for the primary purpose of raising capital shall not be considered a Change of Control under this Warrant. This Warrant shall terminate upon Holder's receipt of the number of shares of Company's equity securities described in this Section 4.3.

4.4 Reserved.

4.5 Notice of Adjustment. Upon any adjustment of the Stock Purchase Price, and/or any increase or decrease in the number of shares purchasable upon the exercise of this Warrant, Company shall give written notice thereof to Holder pursuant to Section 12. The notice, which may be substantially in the form of Exhibit "A" attached hereto, shall be signed by Company's chief financial officer and shall state the Stock Purchase Price resulting from such adjustment and the increase or decrease, if any, in the number of shares purchasable at such price upon the exercise of this Warrant, setting forth in reasonable detail the method of calculation and the facts upon which such calculation is based.

4.6 Other Notices. If at any time:

(a) Company shall declare any cash dividend upon its Common Stock;

(b) Company shall declare any dividend upon its Common Stock payable in stock or make any special dividend or other distribution to the holders of its Common Stock;

(c) Company shall offer for subscription pro rata to the holders of its Common Stock any additional shares of stock of any class or other rights;

(d) there shall be any capital reorganization or reclassification of the capital stock of Company, or consolidation or merger of Company with, or sale of all or substantially all of its assets to, another entity;

(e) there shall be a voluntary or involuntary dissolution, liquidation or winding-up of Company; or

(f) Company shall take or propose to take any other action, notice of which is actually provided to holders of the Common Stock;

then, in any one or more of said cases, Company shall give Holder, pursuant to Section 12, (i) at least 20 days' prior written notice of the date on which the books of Company shall close or a record shall be taken for such dividend, distribution or subscription rights or for determining rights to vote in respect of any such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding-up, or other action and (ii) in the case of any such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding-up, or other action, at least 20 days' written notice of the date when the same shall take place. Any notice given in accordance with the foregoing clause (i) shall also specify, in the case of any such dividend, distribution or subscription rights, the date on which the holders of Common Stock shall be entitled thereto. Any notice given in accordance with the foregoing clause (ii) shall also specify the date on which the holders of Common Stock shall be entitled to exchange their Common Stock for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding-up, or other action as the case may be.

4.7 Certain Events. If any change in the outstanding Common Stock of Company or any other event occurs as to which the other provisions of this Section 4 are not strictly applicable or if strictly applicable would not fairly effect the adjustments to this Warrant in accordance with the essential intent and principles of such provisions, then the Board shall make in good faith an adjustment in the number and class of shares issuable under this Warrant, the Stock Purchase Price and/or the application of such provisions, in accordance with such essential intent and principles, so as to protect such purchase rights as aforesaid. The adjustment shall be such as will give Holder of this Warrant upon exercise for the same aggregate Stock Purchase Price the total number, class and kind of shares as Holder would have owned had this Warrant been exercised prior to the event and had Holder continued to hold such shares until after the event requiring adjustment.

4.8 Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 1 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable notice of exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, the Conversion Option set forth in the Supplement) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 4.8, beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 4.8 applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a notice of exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 4.8, in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the SEC, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the transfer agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one trading day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon written election by Holder which is delivered to the Company prior to the issuance of any Warrant Shares to such Holder, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 4.8, provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 4.8 shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 4.8 to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

5. Issue Tax. The issuance of certificates for shares of Common Stock upon the exercise of this Warrant shall be made without charge to Holder of this Warrant for any issue tax in respect thereof; provided, however, that Company shall not be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of any certificate in a name other than that of the then Holder of this Warrant being exercised.

6. Closing of Books. Company will at no time close its transfer books against the transfer of this Warrant or of any shares of Warrant Stock issued or issuable upon the exercise of this Warrant in any manner which interferes with the timely exercise of this Warrant.

7. No Voting Rights; Limitation of Liability. Nothing contained in this Warrant shall be construed as conferring upon Holder hereof the right to vote or to consent as a stockholder in respect of meetings of stockholders for the election of directors of Company or any other matters or any rights whatsoever as a stockholder of Company. No dividends or interest shall be payable in respect of this Warrant or the interest represented hereby or the shares purchasable hereunder until, and only to the extent that, this Warrant shall have been exercised; provided, however, that if any dividends are due or paid at any time on the underlying securities for which this Warrant is exercisable, then upon exercise, the securities issued to Holder shall be deemed to have accrued dividends and be paid identical dividends from the same time as the outstanding shares for which this Warrant is exercisable were first issued (or, if later, the date of this Warrant). No provisions hereof, in the absence of affirmative action by Holder to purchase shares of Common Stock, and no mere enumeration herein of the rights or privileges of Holder hereof, shall give rise to any liability of such Holder for the Stock Purchase Price or as a stockholder of Company, whether such liability is asserted by Company or by its creditors.

8. Amendment of Charter. Unless Holder consents thereto in writing, Company shall not amend its Charter prior to the exercise of this Warrant if the Common Stock would be adversely affected by such amendment in a manner that would be more adverse to Holder with respect to the shares of Common Stock issuable upon the exercise of this Warrant than, and substantially dissimilar to, such amendment's effect on the other holders of Common Stock.

9. Registration Rights. Holder shall be entitled, with respect to the shares of Common Stock issued upon exercise hereof, to the registration rights set forth in Section 3(c) of the Supplement.

10. Rights and Obligations Survive Exercise of Warrant. The rights and obligations of Company, of Holder of this Warrant and of the holder of shares of Common Stock issued upon exercise of this Warrant, contained in Sections 6, 8, 9 and 18 shall survive the exercise of this Warrant.

11. Modification and Waiver. This Warrant and any provision hereof may be changed, waived, discharged or terminated only by an instrument in writing signed by the party against which enforcement of the same is sought.

12. Notices. Any notice, request or other document required or permitted to be given or delivered to Holder or Company shall be deemed to have been given (i) upon receipt if delivered personally or by courier (ii) upon confirmation of receipt if by telecopy or (iii) three business days after deposit in the US mail, with postage prepaid and certified or registered, to each such Holder at its address as shown on the books of Company or to Company at the address indicated therefor in the opening paragraphs of this Warrant (or at such other location as Company may advise Holder in writing).

13. Survival of Certain Obligations. All of the obligations of Company relating to the Common Stock issuable upon the exercise of this Warrant shall survive the exercise and termination of this Warrant. All of the covenants and agreements of Company shall inure to the benefit of and be binding upon the successors and permitted assigns of Holder. Company will, at the time of the exercise of this Warrant, in whole or in part, upon request of Holder but at Company's expense, acknowledge in writing its continuing obligation to Holder in respect of any rights (including, without limitation, any right to registration of the shares of Common Stock) to which Holder shall continue to be entitled after such exercise in accordance with this Warrant; provided, that the failure of Holder to make any such request shall not affect the continuing obligation of Company to Holder in respect of such rights.

14. Descriptive Headings and Governing Law. The descriptive headings of the several sections and paragraphs of this Warrant are inserted for convenience only and do not constitute a part of this Warrant. This Warrant shall be construed and enforced in accordance with, and the rights of the parties shall be governed by, the laws of the State of Delaware.

15. Lost Warrants or Stock Certificates. Company agrees that upon receipt of evidence reasonably satisfactory to Company of the loss, theft, destruction, or mutilation of any Warrant or stock certificate and, in the case of any such loss, theft or destruction, upon receipt of an indemnity reasonably satisfactory to Company, or in the case of any such mutilation upon surrender and cancellation of such Warrant or stock certificate, Company at its expense will make and deliver a new Warrant or stock certificate, of like tenor, in lieu of the lost, stolen, destroyed or mutilated Warrant or stock certificate.

16. Fractional Shares. No fractional shares shall be issued upon exercise of this Warrant. Company shall, in lieu of issuing any fractional share, pay the holder entitled to such fraction a sum in cash equal to such fraction multiplied by the then effective Stock Purchase Price.

17. Representations of Holder. With respect to this Warrant, Holder represents and warrants to Company as follows:

17.1 Experience. It is experienced in evaluating and investing in companies engaged in businesses similar to that of Company; it understands that investment in this Warrant involves substantial risks; it has made detailed inquiries concerning Company, its business and services, its officers and its personnel; the officers of Company have made available to Holder any and all written information it has requested; the officers of Company have answered to Holder's satisfaction all inquiries made by it; in making this investment it has relied upon information made available to it by Company; and it has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of investment in Company and it is able to bear the economic risk of that investment.

17.2 Investment. It is acquiring this Warrant for investment for its own account and not with a view to, or for resale in connection with, any distribution thereof. It understands that this Warrant and the shares of Common Stock issuable upon exercise of this Warrant, have not been registered under the Securities Act, nor qualified under applicable state securities laws.

17.3 Rule 144. It acknowledges that this Warrant and the Common Stock issuable upon exercise of this Warrant must be held indefinitely unless they are subsequently registered under the Securities Act or an exemption from such registration is available. It has been advised or is aware of the provisions of Rule 144 promulgated under the Securities Act.

17.4 Access to Data. It has had an opportunity to discuss Company's business, management and financial affairs with Company's management and has had the opportunity to inspect Company's facilities.

17.5 Accredited Investor. It is an "accredited investor" within the meaning of Regulation D promulgated under the Securities Act.

18. Additional Representations and Covenants of Company. Company hereby represents, warrants and agrees as follows:

18.1 Corporate Power. Company has all requisite corporate power and corporate authority to issue this Warrant and to carry out and perform its obligations hereunder.

18.2 Authorization. All corporate action on the part of Company, its directors and stockholders necessary for the authorization, execution, delivery and performance by Company of this Warrant has been taken. This Warrant is a valid and binding obligation of Company, enforceable in accordance with its terms.

18.3 Offering. Subject in part to the truth and accuracy of Holder's representations set forth in Section 17 hereof, the offer, issuance and sale of this Warrant is, and the Common Stock issuable upon exercise of this Warrant will be, exempt from the registration requirements of the Securities Act, and are exempt from the qualification requirements of any applicable state securities laws; and neither Company nor anyone acting on its behalf will take any action hereafter that would cause the loss of such exemptions.

18.4 Listing; Stock Issuance. Company shall use its best efforts to secure and maintain the listing of the Common Stock or other securities issuable upon exercise of this Warrant, upon each securities exchange or over-the-counter market upon which securities of the same class or series issued by Company are listed, if any. Upon exercise of this Warrant, Company will use commercially reasonable efforts to cause the issuance of the shares of Common Stock purchased pursuant to the exercise to be issued in book-entry form in the names of Holder, its nominees or assignees, as appropriate at the time of such exercise.

18.5 Charter Documents. Company has provided Holder with true and complete copies of Company's Charter, By-Laws, and each Certificate of Designation or other charter document setting forth any rights, preferences and privileges of Company's capital stock, each as amended and in effect on the date of issuance of this Warrant.

18.6 Reserved.

18.7 Financial and Other Reports. Until the earlier of (a) the Expiration Date, and (b) the termination of this Warrant pursuant to Section 4.3, Company agrees to provide Holder at any time and from time to time with such information as Holder may reasonably request for purposes of Holder's compliance (as determined by Holder in its reasonable discretion) with regulatory, accounting and reporting requirements applicable to Holder (e.g., Fair Value Accounting Standard 157), including any 409A valuation reports (or equivalent reports) and budgets. Notwithstanding the foregoing, Company shall not be required to furnish to Holder the financial information described in this Section 18.7 in the event such financial information has been previously delivered to Lender pursuant to the Loan Agreement.

19. Counterparts; Facsimile. Holder's execution and delivery of Holder's counterpart signature page to this Warrant via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) shall constitute Holder's effective execution and delivery of this Warrant and agreement to and acceptance of the terms hereof for all purposes.

[Remainder of this page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, Company has caused this Warrant to be duly executed by its officer, thereunto duly authorized as of the date of issuance set forth on the first page hereof.

DELCATH SYSTEMS, INC.

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

AGREED AND ACCEPTED:

HOLDER:

AVENUE VENTURE OPPORTUNITIES FUND, LP

By: Avenue Venture Opportunities Partners, LLC
Its: General Partner

By: /s/ Sonia Gardner
Name: Sonia Gardner
Title: Authorized Signatory

FORM OF SUBSCRIPTION

(To be signed only upon exercise of Warrant)

To: _____

- The undersigned, the holder of the within Warrant, hereby irrevocably elects to exercise the purchase right represented by such Warrant for, and to purchase thereunder, (1) _____ (____) shares¹ (the "Shares") of Stock of _____ and herewith makes payment of _____ Dollars (\$_____) therefor, and requests that the certificates for such shares be issued in the name of, and delivered to, _____, whose address is _____.
- The undersigned hereby elects to convert _____ percent (__%) of the value of the Warrant pursuant to the provisions of Section 1(b) of the Warrant.

The undersigned acknowledges that it has reviewed the representations and warranties contained in Section 17 of this Warrant and by its signature below hereby makes such representations and warranties to Company.

Dated _____

Holder: _____

By: _____

Its: _____

(Address)

¹ Insert here the number of shares called for on the face of the Warrant (or, in the case of a partial exercise, the portion thereof as to which the Warrant is being exercised), in either case without making any adjustment for additional Warrant Stock or any other stock or other securities or property or cash which, pursuant to the adjustment provisions of the Warrant, may be issuable upon exercise.

ASSIGNMENT

FOR VALUE RECEIVED, the undersigned, the holder of the within Warrant, hereby sells, assigns and transfers all of the rights of the undersigned under the within Warrant, with respect to the number of shares of Common Stock covered thereby set forth herein below, unto:

Name of Assignee

Address

No. of Shares

Dated _____

Holder: _____

By: _____

Its: _____

EXHIBIT "A"

[On letterhead of Company]

Reference is hereby made to that certain Warrant dated August 6, 2021 issued by DELCATH SYSTEMS, INC., a Delaware corporation (the "Company"), to AVENUE VENTURE OPPORTUNITIES FUND, LP, a Delaware limited partnership (the "Holder").

[IF APPLICABLE] The Warrant provides that the actual number and type of shares of Company's capital stock issuable upon exercise of the Warrant and the initial exercise price per share are to be determined by reference to one or more events or conditions subsequent to the issuance of the Warrant. Such events or conditions have now occurred or lapsed, and Company wishes to confirm the actual number of shares issuable and the initial exercise price. The provisions of this Supplement to Warrant are incorporated into the Warrant by this reference, and shall control the interpretation and exercise of the Warrant.

[IF APPLICABLE] Notice is hereby given pursuant to Section 4.5 of the Warrant that the following adjustment(s) have been made to the Warrant: [describe adjustments, setting forth details regarding method of calculation and facts upon which calculation is based].

This certifies that Holder is entitled to purchase from Company _____, at the Holder's option, either (i) (_____) fully paid and nonassessable shares of Company's _____ Stock at a price of _____ Dollars (\$_____) per share or (ii) (_____) fully paid and nonassessable shares of Company's _____ Stock at a price of _____ Dollars (\$_____) per share. The applicable Stock Purchase Price and the number of shares purchasable under the Warrant remain subject to adjustment as provided in Section 4 of the Warrant.

Executed this _____ day of _____, 20_____.

DELCATH SYSTEMS, INC.

By: _____
Name: _____
Title: _____

FIRST AMENDMENT TO LOAN DOCUMENTS

This First Amendment to Loan Documents (this “**Amendment**”) is entered into as of March 31, 2023, by and among AVENUE VENTURE OPPORTUNITIES FUND, L.P., a Delaware limited partnership (“**Lender**”) and DELCATH SYSTEMS, INC., a Delaware corporation (“**Borrower**”).

RECITALS

Borrower, Agent and Lender are parties to those certain Loan Documents, dated as of August 6, 2021, including the Loan and Security Agreement (as amended from time to time, the “**Agreement**”) and the Supplement to Loan and Security Agreement (as amended from time to time, the “**Supplement**”). The parties desire to amend the Agreement and the Supplement in accordance with the terms of this Amendment.

NOW, THEREFORE, the parties agree as follows:

1. **Consent.** Notwithstanding anything in the Loan Documents to the contrary and subject to the terms and conditions of this Amendment, Lender hereby consents to Borrower’s prepayment of the full amount of Tranche 1(b) on the First Amendment Effective Date and agrees to waive the Prepayment Fee that otherwise would have been due with respect to Tranche 1(b); provided, however, that such waiver is applicable only to the Prepayment Fee with respect to the full amount of Tranche 1(b) and Lender does not waive Borrower’s obligations under any other Sections or under such Section for any other time periods, and Lender does not waive any other failure by Borrower to perform the Obligations under the Loan Documents.

2. The following terms and their respective definitions hereby are either amended and restated in, or, if applicable, added in their entirety to, Part 1 of the Supplement as follows:

“**Amortization Period**” means (i) the period commencing on the first day of the first full calendar month following the Initial Interest-only Period and continuing until December 1, 2022 and (ii) the period commencing on the first day of the first full calendar month following the First Amendment Interest-only Period and continuing until the Maturity Date.

“**First Amendment Effective Date**” means March 31, 2023.

“**First Amendment Interest-only Period**” means the period commencing on the First Amendment Effective Date and continuing until the September 30, 2023; *provided*, however, that such period shall be extended to December 31, 2023 (the “**First Amendment Interest-only Period Extension**”) if as of the last day of the Interest-only Period then in effect Borrower has (a) received FDA approval for HEPZATO KIT and (b) received net proceeds of at least Ten Million Dollars (\$10,000,000.00) from the sale and issuance of Borrower’s equity securities after the First Amendment Effective Date; in each case of subject to written evidence of the same, in form and content reasonably acceptable to Lender.

“**Initial Interest-only Period**” means the period commencing on the Closing Date and continuing until November 30, 2022.

“**Final Payment**” means a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) equal to four and one-quarter percent (4.25%) of the funded amount of Tranche 1 and Tranche 2; provided, however, that the Final Payment with respect to Tranche 1(b) in the amount of One Hundred Seventy Thousand Dollars (\$170,000.00) shall be paid to Lender on or before March 31, 2023.

3. Section 3(a) of the Supplement hereby is amended and restated in its entirety to read as follows:

“(a) **Warrant.** As additional consideration for the making of its Commitment, Lender has earned and is entitled to receive (a) immediately upon the execution of the Loan and Security Agreement and this Supplement, a warrant instrument issued by Borrower (the “**Warrant**”) and (b) immediately upon the execution of the First Amendment to Loan Documents, an additional warrant instrument issued by Borrower (the “**First Amendment Warrant**”; and together with the Warrant, the “**Warrants**”).

4. No course of dealing on the part of Lender, nor any failure or delay in the exercise of any right by Lender, shall operate as a waiver thereof, and any single or partial exercise of any such right shall not preclude any later exercise of any such right. Lender's failure at any time to require strict performance by Borrower of any provision shall not affect any right of Lender thereafter to demand strict compliance and performance. Any suspension or waiver of a right must be in writing signed by an officer of Lender.

5. Unless otherwise defined, all initially capitalized terms in this Amendment shall be as defined in the Loan Documents (as defined in the Agreement). The Loan Documents, as amended hereby, shall be and remain in full force and effect in accordance with their respective terms and hereby are ratified and confirmed in all respects. Except as expressly set forth herein, the execution, delivery, and performance of this Amendment shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of Lender under the Loan Documents, as in effect prior to the date hereof.

6. Borrower hereby represents that Borrower has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Documents, as amended by this Amendment and the organizational documents of Borrower delivered to Lender on the Closing Date, and updated pursuant to subsequent deliveries by the Borrower to the Lender, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect.

7. As a condition to the effectiveness of this Amendment, Lender shall have received, in form and substance reasonably satisfactory to Lender, the following:

(a) this Amendment, duly executed by Borrower;

(b) the First Amendment Warrant, duly executed by Borrower;

(c) evidence of receipt of net proceeds of at least Twenty Million Dollars (\$20,000,000.00) from the sale and issuance of Borrower's equity securities, in form and substance reasonably acceptable to Lender;

(d) evidence of the repayment in full in cash of Tranche 1(b), in form and substance reasonably acceptable to Lender;

(e) the Final Payment with respect to Tranche 1(b), which may be ACH'd from any of Borrower's accounts on or before March 31, 2023;

(f) all reasonable Lender expenses incurred through the date of this Amendment, which Borrower shall remit via wire transfer on the date of execution of this Amendment per the instructions set forth on Annex A hereto; and

(g) such other documents, and completion of such other matters, as Lender may reasonably deem necessary or appropriate.

8. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first above written.

BORROWER:

DELCATH SYSTEMS, INC.

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

Address for Notices:

1633 Broadway, Suite 22C
New York, NY 10019
Attn: Gerard Michel, CEO
Email: gmichel@delcath.com

LENDER:

AVENUE VENTURE OPPORTUNITIES FUND, L.P.

By: Avenue Venture Opportunities Partners, LLC
Its: General Partner

By: /s/ Sonia Gardner
Name: Sonia Gardner
Title: Authorized Signatory

Address for Notices:

11 West 42nd Street, 9th Floor
New York, New York 10036
Attn: Todd Greenberg, Senior Managing Director
Email: tgreenberg@avenuecapital.com
Phone # 212-878-3523

[Signature Page to First Amendment to Loan Documents]

ANNEX A

(Barnes & Thornburg Wire Instructions)

Lender's legal fees and expenses: \$3,237.30

Account Name: Barnes & Thornburg LLP Attorney Operating Account
Bank Name: Fifth Third Bank
251 North Illinois Ave
Indianapolis, IN 46204
Account Number: 7653510706
ABA Number: 042000314 for wires
ABA Number: 074908594 for ACHs
SWIFT CODE: FTBCUS3C
Reference: 82485-9
Please send remittance information to: wireconfirmations@btlaw.com; troy.zander@btlaw.com

DEL CATH 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.

May 22, 2023

/s/ Gerard Michel

Gerard Michel

Chief Executive Officer (Principal Executive Officer)

DEL CATH 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.

May 22, 2023

/s/ Anthony Dias

Anthony Dias

Principal Financial Officer

DEL CATH 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 March 31, 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.

May 22, 2023

/s/ Gerard Michel
Gerard Michel
Chief Executive Officer (Principal Executive Officer)

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 March 31, 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.

May 22, 2023

/s/ Anthony Dias

Anthony Dias

Principal Financial Officer