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

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2022

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

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**DELCATH SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

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**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)

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**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

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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   
Non-accelerated filer

Accelerated filer   
Smaller reporting company   
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the 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 November 2, 2022, 8,597,682 shares of the Company's common stock, \$0.01 par value, were outstanding.

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DELCATH SYSTEMS, INC.

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

	September 30, 2022	December 31, 2021
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 9,831	\$ 22,802
Restricted cash	4,151	4,151
Accounts receivable, net	537	44
Inventories	1,926	1,412
Prepaid expenses and other current assets	2,035	2,743
Total current assets	18,480	31,152
Property, plant and equipment, net	1,452	1,348
Right-of-use assets	294	624
Total assets	<u>\$ 20,226</u>	<u>\$ 33,124</u>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
Current liabilities		
Accounts payable	\$ 2,632	\$ 638
Accrued expenses	5,137	4,109
Deferred revenue	—	170
Lease liabilities, current	196	416
Loan payable, current	6,481	621
Total current liabilities	14,446	5,954
Other liabilities, non-current	1,299	207
Loan payable, non-current	4,990	10,372
Convertible notes payable, non-current	4,737	4,639
Total liabilities	25,472	21,172
Commitments and contingencies		
Stockholders' equity (deficit)		
Preferred stock, \$.01 par value; 10,000,000 shares authorized; 11,357 shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, \$.01 par value; 40,000,000 shares authorized; 8,597,682 shares and 7,906,728 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	86	79
Additional paid-in capital	442,066	432,831
Accumulated deficit	(447,341)	(420,976)
Accumulated other comprehensive (loss) income	(57)	18
Total stockholders' equity (deficit)	(5,246)	11,952
Total liabilities and stockholders' equity (deficit)	<u>\$ 20,226</u>	<u>\$ 33,124</u>

*See accompanying Notes to Condensed Consolidated Financial Statements.*

**DELCATH SYSTEMS, INC.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
**(Unaudited)**

*(in thousands, except share and per share data)*

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	2022	2021	2022	2021
Product revenue	\$ 906	\$ 395	\$ 1,909	\$ 1,054
Other revenue	—	127	171	393
Cost of goods sold	(235)	(227)	(449)	(541)
Gross profit	671	295	1,631	906
Operating expenses:				
Research and development expenses	3,953	2,955	13,649	10,159
Selling, general and administrative expenses	4,519	4,036	12,309	10,621
Total operating expenses	8,472	6,991	25,958	20,780
Operating loss	(7,801)	(6,696)	(24,327)	(19,874)
Interest expense, net	(730)	(420)	(2,040)	(501)
Other income (expense)	26	(9)	2	73
Net loss	(8,505)	(7,125)	(26,365)	(20,302)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(46)	51	(82)	84
Total other comprehensive loss	\$ (8,551)	\$ (7,074)	\$ (26,447)	\$ (20,218)
Common share data:				
Basic and diluted loss per common share	\$ (0.92)	\$ (0.94)	\$ (3.09)	\$ (2.93)
Weighted average number of basic and diluted shares outstanding	9,215,786	7,587,643	8,536,006	6,923,541

*See accompanying Notes to Condensed Consolidated Financial Statements.*

**DEL CATH SYSTEMS, INC.**  
**Condensed Consolidated Statements of Stockholders' Equity (Deficit)**  
**(Unaudited)**

*(in thousands, except share and per share data)*

	Three and nine months ended September 30, 2022							
	Preferred Stock \$0.01 Par Value		Common Stock \$0.01 Par Value		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	No. of Shares	Amount	No. of Shares	Amount				
Balance at January 1, 2022	11,357	\$ —	7,906,728	\$ 79	\$432,831	\$ (420,976)	\$ 18	\$11,952
Compensation expense for issuance of stock options	—	—	—	—	1,474	—	—	1,474
Net loss	—	—	—	—	—	(8,203)	—	(8,203)
Total comprehensive income	—	—	—	—	—	—	2	2
Balance at March 31, 2022	11,357	—	7,906,728	79	434,305	(429,179)	20	5,225
Compensation expense for issuance of stock options	—	—	—	—	1,617	—	—	1,617
Net loss	—	—	—	—	—	(9,657)	—	(9,657)
Total comprehensive loss	—	—	—	—	—	—	(31)	(31)
Balance at June 30, 2022	11,357	—	7,906,728	79	435,922	(438,836)	(11)	(2,846)
Compensation expense for issuance of stock options	—	—	—	—	1,255	—	—	1,255
Private placement -issuance of common shares and prefunded warrants, net of expenses	—	—	690,954	7	4,889	—	—	4,896
Net loss	—	—	—	—	—	(8,505)	—	(8,505)
Total comprehensive loss	—	—	—	—	—	—	(46)	(46)
Balance at September 30, 2022	<u>11,357</u>	<u>\$ —</u>	<u>8,597,682</u>	<u>\$ 86</u>	<u>\$442,066</u>	<u>\$ (447,341)</u>	<u>\$ (57)</u>	<u>\$ (5,246)</u>
	Three and nine months ended September 30, 2021							
	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, 2021	20,631	\$ —	5,996,101	\$ 60	\$417,449	\$ (395,327)	\$ (104)	\$22,078
Compensation expense for issuance of stock options	—	—	—	—	2,148	—	—	2,148
Shares settled for services	—	—	2,636	—	57	—	—	57
Conversion of Preferred stock into common stock	(150)	—	15,000	—	—	—	—	—
Exercise of warrants into common stock	—	—	237,520	3	2,373	—	—	2,376
Net loss	—	—	—	—	—	(6,747)	—	(6,747)
Total comprehensive income	—	—	—	—	—	—	94	94
Balance at March 31, 2021	20,481	—	6,251,257	63	422,027	(402,074)	(10)	20,006
Compensation expense for issuance of stock options	—	—	—	—	1,626	—	—	1,626
Conversion of Preferred stock into common stock	(8,774)	—	877,379	9	(8)	—	—	1
Exercise of warrants into common stock	—	—	221,141	2	15	—	—	17
Net loss	—	—	—	—	—	(6,430)	—	(6,430)
Total comprehensive loss	—	—	—	—	—	—	(61)	(61)
Balance at June 30, 2021	11,707	—	7,349,777	74	423,660	(408,504)	(71)	15,159
Compensation expense for issuance of stock options	—	—	—	—	2,449	—	—	2,449
Proceeds allocated to warrant	—	—	—	—	1,171	—	—	1,171
Cash issuance costs of warrant	—	—	—	—	(44)	—	—	(44)
Exercise of warrants into common stock	—	—	6,512	—	65	—	—	65
Net loss	—	—	—	—	—	(7,125)	—	(7,125)
Total comprehensive income	—	—	—	—	—	—	51	51
Balance at September 30, 2021	<u>11,707</u>	<u>\$ —</u>	<u>7,356,289</u>	<u>\$ 74</u>	<u>\$427,301</u>	<u>\$ (415,629)</u>	<u>\$ (20)</u>	<u>\$11,726</u>

*See accompanying Notes to Condensed Consolidated Financial Statements.*

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

	<u>Nine months ended September 30,</u>	
	<u>2022</u>	<u>2021</u>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (26,365)	\$ (20,302)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	4,345	6,224
Depreciation expense	98	115
Non-cash lease expense	339	—
Amortization of debt discount	574	127
Interest expense accrued related to convertible notes	120	119
Changes in assets and liabilities:		
Decrease in prepaid expenses and other assets	708	676
Increase in accounts receivable	(493)	(12)
Increase in inventories	(515)	(383)
Increase (decrease) in accounts payable and accrued expenses	2,907	(2,622)
Increase in other liabilities, non-current	861	—
Decrease in deferred revenue	(170)	(517)
Net cash used in operating activities	<u>(17,591)</u>	<u>(16,575)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property, plant and equipment	(209)	(144)
Net cash used in investing activities	<u>(209)</u>	<u>(144)</u>
<b>Cash flows from financing activities:</b>		
Net proceeds from private placement	4,896	—
Net proceeds from debt financing	—	14,437
Net proceeds from the exercise of warrants	—	2,458
Net cash provided by financing activities	<u>4,896</u>	<u>16,895</u>
Foreign currency effects on cash	(67)	84
Net (decrease) increase in total cash	<u>(12,971)</u>	<u>260</u>
<b>Total Cash, Cash Equivalents and Restricted Cash:</b>		
Beginning of period	26,953	28,756
End of period	<u>\$ 13,982</u>	<u>\$ 29,016</u>
<b>Cash, Cash Equivalents and Restricted Cash consisted of the following:</b>		
Cash	\$ 9,831	\$ 24,865
Restricted Cash	4,151	4,151
Total	<u>\$ 13,982</u>	<u>\$ 29,016</u>
	<u>Nine months ended September 30,</u>	
	<u>2022</u>	<u>2021</u>
<b>Supplemental Disclosure of Cash Flow Information:</b>		
Cash paid during the periods for:		
Interest expense	\$ 1,337	\$ 260
<b>Supplemental Disclosure of Non-Cash Investing and Financing Activities:</b>		
Conversions of preferred stock into common stock	\$ —	\$ 9
Issuance of restricted stock for accrued fees due to a former board member	\$ —	\$ 57
Right of use assets obtained in exchange for lease obligations	\$ —	\$ 192

*See accompanying Notes to Condensed Consolidated Financial Statements.*

**DELCATH SYSTEMS, INC.**  
**Notes to the Condensed Consolidated Financial Statements**  
**(Unaudited)**

**(1) General**

The unaudited condensed consolidated financial statements of Delcath Systems, Inc. (“Delcath” or the “Company”) as of September 30, 2022 and the three and nine months ended September 30, 2022 and 2021 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, 2021 (the “Annual Report”), which was filed with the Securities and Exchange Commission (the “SEC”) on March 30, 2022 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<sup>®</sup> 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. HEPZATO has not been approved for sale in the United States. 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<sup>®</sup> 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.

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, or 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 which will maximize the value of the HEPZATO platform.

In the United States, HEPZATO is considered a combination drug and device product regulated by the Food and Drug Administration (“FDA”). Primary jurisdiction for regulation of HEPZATO has been assigned to the FDA’s Center for Drug Evaluation and Research. The FDA has granted the Company six orphan drug designations (five for melphalan in ocular melanoma, cutaneous melanoma, cholangiocarcinoma, hepatocellular carcinoma, and neuroendocrine tumor indications and one for doxorubicin in the hepatocellular carcinoma indication).

In December 2021, the Company announced that the FOCUS Trial of HEPZATO met its pre-specified endpoint. Based on the FOCUS Trial results, the Company is preparing to submit a new drug application, or NDA, to the FDA for HEPZATO. The Company held a pre-NDA meeting with the FDA in April 2022. Based on the feedback from the FDA, the Company does not believe any additional pre-clinical or clinical studies are required to re-file the NDA. Due to vendor delays in delivering certain reports, the Company plans to submit an NDA to the FDA by the end of the year. The Company has opened two Expanded Access Program sites to provide access to patients who meet the inclusion criteria during the pendency of FDA’s review of HEPZATO.

On February 28, 2022, CHEMOSAT received Medical Device Regulation 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***

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



### ***Liquidity and Going Concern***

The accompanying interim condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred significant losses and has an accumulated deficit of \$447.3 million as of September 30, 2022. These losses, among other factors, raise substantial doubt about the Company's ability to continue as a going concern.

On July 20, 2022, the Company closed a private placement for the issuance and sale of 690,954 shares of common stock (the "Common Stock") and 566,751 pre-funded warrants to purchase common stock (the "Pre-Funded Warrants") 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. The Company intends to use the net proceeds from the private placement for working capital purposes and other general corporate purposes.

On October 26, 2022, the Company received a letter from the Nasdaq indicating that, for the last thirty consecutive business days, the Market Value of Listed Securities, as defined by Nasdaq ("MVLS") had been below the \$35 million minimum requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company has been provided an initial period of 180 calendar days, or until April 24, 2023, to regain compliance. The letter states that the Nasdaq staff will provide written notification that the Company has achieved compliance with Rule 5550(b)(2) if at any time before April 24, 2023, the Company maintains its MVLS at \$35 million or more for a minimum of ten consecutive business days (or such longer period of time as the Nasdaq staff may require in some circumstances, but generally not more than 20 consecutive business days). The Nasdaq deficiency letter has no immediate effect on the listing or trading of the Company's common stock. If compliance is not achieved by April 24, 2023, the Company may be eligible for an additional 180 calendar day compliance period to demonstrate compliance with the minimum MVLS requirement. To qualify for the additional 180-day period, the Company will be required to meet the continued listing requirements for minimum closing bid price of its common stock and all other initial listing standards (with the exception of the minimum MVLS requirement). If the Company does not qualify for the second compliance period or fails to regain compliance during the second 180-day period, then Nasdaq will notify the Company that its common stock is subject to delisting. At that time, the Company may appeal the delisting determination to a Nasdaq Hearings Panel. The Company will continue to monitor its MVLS and consider its available options to regain compliance with the Nasdaq minimum MVLS requirements, which may include applying for an extension of the compliance period or appealing to a Nasdaq Hearings Panel.

The Company's existence is dependent upon management's ability to obtain additional funding sources or to enter into strategic alliances. Adequate additional financing may not be available to the Company on acceptable terms, or at all. If the Company is unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, it would be forced to delay, reduce, or eliminate its research and development programs or any commercialization efforts. There can be no assurance that the Company's efforts will result in the resolution of the Company's liquidity needs. If the Company is not able to continue as a going concern, it is likely that holders of its common stock will lose all of their investment. The accompanying interim condensed consolidated financial statements do not include any adjustments that might result should the Company be unable to continue as a going concern.

The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales. These circumstances raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. Additional working capital will be required to continue operations. Operations of the Company are subject to certain risks and uncertainties, including, among others, uncertainty of product development and clinical trial results; uncertainty regarding regulatory approval; technological uncertainty; uncertainty regarding patents and proprietary rights; comprehensive government regulations; limited commercial manufacturing, marketing, or sales experience; and dependence on key personnel.

### ***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 September 30, 2022 and 2021; however, certain information and footnote disclosures normally included in our audited consolidated financial statements included in our Annual Report on Form 10-K 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***

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, 2021.

### ***Reclassifications***

Certain prior period balances have been reclassified in order to conform to current period presentation. These reclassifications have no effect on previously reported results of operations or loss per share.

### ***Recently Adopted Accounting Pronouncements***

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2020-06, "Accounting for Convertible Instruments and Contracts in an Entity's Own Equity." ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. ASU 2020-06 requires entities to provide expanded disclosures about the terms and features of convertible instruments and amends certain guidance in Accounting Standards Codification 260, Earnings per Share, relating to the computation of earnings per share for convertible instruments and contracts in an entity's own equity. The guidance becomes effective for the Company on January 1, 2024, with early adoption permitted. The Company early adopted ASU 2020-06 on January 1, 2022 and the adoption did not have any immediate effect on the Company's condensed consolidated financial statements. Going forward, the Company will no longer be required to assess convertible instruments for beneficial conversion features.

In October 2020, the FASB issued ASU 2020-10 "Codification Improvements", which improves consistency by amending the Codification to include all disclosure guidance in the appropriate disclosure sections and clarifies application of various provisions in the Codification by amending and adding new headings, cross referencing to other guidance, and refining or correcting terminology. The guidance was effective for the Company beginning in the first quarter of fiscal year 2022 with early adoption permitted. The Company adopted this guidance on January 1, 2022 and it did not have a material impact on its condensed consolidated financial statements.

On May 3, 2021, the FASB issued ASU 2021-04, "Earnings Per Share" (Topic 260), "Debt—Modifications and Extinguishments" (Subtopic 470-50), "Compensation—Stock Compensation" (Topic 718), and "Derivatives and Hedging—Contracts in Entity's Own Equity" (Subtopic 815-40): "Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options." This new standard provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. This standard is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Issuers should apply the new standard prospectively to modifications or exchanges occurring after the effective date of the new standard. Early adoption is permitted, including adoption in an interim period. If an issuer elects to early adopt the new standard in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The Company adopted this guidance on January 1, 2022 and it did not have a material impact on its condensed consolidated financial statements.

## **(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. Restricted cash does not include required minimum balances.

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Cash, cash equivalents, and restricted cash balances were as follows (in thousands):

	September 30, 2022	December 31, 2021
Cash and cash equivalents	\$ 9,831	\$ 22,802
Restricted balance for loan agreement	4,000	4,000
Letters of credit	101	101
Security for credit cards	50	50
Total cash, cash equivalents and restricted cash shown in the statements of cash flows	<u>\$ 13,982</u>	<u>\$ 26,953</u>

Under the terms of a sub-lease agreement for office space at 1633 Broadway, New York, NY, the Company is required to maintain a letter of credit which will expire with the sub-lease in February 2023.

### (3) Inventories

Inventories consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Raw materials	\$ 810	\$ 767
Work-in-process	1,014	645
Finished goods	102	—
Total inventories	<u>\$ 1,926</u>	<u>\$ 1,412</u>

### (4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Clinical trial expenses	\$ 1,630	\$ 1,630
Insurance premiums	158	890
Professional services	210	15
Other	37	208
Total prepaid expenses and other current assets	<u>\$ 2,035</u>	<u>\$ 2,743</u>

### (5) Property, Plant, and Equipment

Property, plant, and equipment consist of the following (in thousands):

	September 30, 2022	December 31, 2021	Estimated Useful Life
Buildings and land	\$ 1,301	\$ 1,222	30 years - Buildings
Enterprise hardware and software	1,849	1,858	3 years
Leaseholds			Lesser of lease term or estimated useful life
	1,745	1,796	
Equipment	1,220	1,094	7 years
Furniture	200	203	5 years
Property, plant and equipment, gross	6,315	6,173	
Accumulated depreciation	(4,863)	(4,825)	
Property, plant and equipment, net	<u>\$ 1,452</u>	<u>\$ 1,348</u>	

Depreciation expense for the nine months ended September 30, 2022 was approximately \$98,000 as compared to approximately \$115,000 for the same period in 2021.

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### (6) Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Clinical expenses	\$ 2,267	\$ 1,517
Compensation, excluding taxes	1,056	893
Short-term financing	—	551
Professional fees	1,229	603
Interest on convertible note	513	393
Other	72	152
Total accrued expenses	<u>\$ 5,137</u>	<u>\$ 4,109</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.

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The following table summarizes the Company's operating leases as of and for the nine months ended September 30, 2022 (in thousands):

	<u>U.S.</u>	<u>Ireland</u>	<u>Total</u>
<b>Lease cost</b>			
Operating lease cost	\$ 304	\$ 35	\$ 339
<b>Other information</b>			
Operating cash flows out from operating leases	(304)	(35)	(339)
Weighted average remaining lease term	0.4	3.8	
Weighted average discount rate - operating leases	8%	8%	

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

	<u>U.S.</u>	<u>Ireland</u>	<u>Total</u>
Three Months Remaining December 31, 2022	\$101	\$ 10	\$111
Year ended December 31, 2023	67	39	106
Year ended December 31, 2024	—	39	39
Year ended December 31, 2025	—	39	39
Year ended December 31, 2026	—	23	23
Total	168	150	318
Less present value discount	(3)	(21)	(24)
Operating lease liabilities included in the condensed consolidated balance sheets at September 30, 2022	<u>\$165</u>	<u>\$ 129</u>	<u>\$294</u>

### (8) Loans and Convertible Notes Payable

<i>(in thousands)</i>	<u>September 30, 2022</u>			<u>December 31, 2021</u>		
	<u>Gross</u>	<u>Discount</u>	<u>Net</u>	<u>Gross</u>	<u>Discount</u>	<u>Net</u>
Loan - Avenue <sup>(1)</sup>	12,638	(1,167)	11,471	12,638	(1,645)	10,993
Loan - Avenue <sup>(1)</sup> - Less Current Portion	(7,140)	659	(6,481)	(714)	93	(621)
Total - Loans Payable, Non-Current	<u>\$ 5,498</u>	<u>\$ (508)</u>	<u>\$ 4,990</u>	<u>\$ 11,924</u>	<u>\$ (1,552)</u>	<u>\$10,372</u>
Convertible Note Payable - Rosalind	2,000	—	2,000	2,000	—	2,000
Convertible Portion of Loan Payable - Avenue	3,000	(263)	2,737	3,000	(361)	2,639
Total - Convertible Notes Payable - Non-Current	<u>\$ 5,000</u>	<u>\$ (263)</u>	<u>\$ 4,737</u>	<u>\$ 5,000</u>	<u>\$ (361)</u>	<u>\$ 4,639</u>

<sup>(1)</sup> The gross amount includes the 4.25% final payment of \$638,000.

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

	Loans	Convertible Notes	Total
Year ended December 31, 2022	\$ 714	\$ —	\$ 714
Year ended December 31, 2023	8,571	—	8,571
Year ended December 31, 2024	3,353	5,000	8,353
Total	<u>\$ 12,638</u>	<u>\$ 5,000</u>	<u>\$ 17,638</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 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 September 30, 2022 was 13.2% and increased to 13.95% starting October 2022. 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 which has been funded into a restricted account and will 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 U.S. Food and Drug Administration, 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. Pursuant to the Avenue Loan Agreement, the Company may request an additional \$5 million of gross proceeds between October 1, 2022 and December 31, 2022, with funding, subject to the approval of Avenue's Investment Committee. Since the Company did not achieve a net equity raise of \$20 million of gross proceeds, the Company will not request an additional \$5.0 million of funding during the period from October 1, 2022 through December 31, 2022.

Up to \$3 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.

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. The Company paid an aggregate commitment fee of \$150,000 at closing.

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 \$563,000 of cash issuance costs, \$519,000 was allocated to the Avenue Loan and was recorded as debit discount, while \$44,000 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 \$418,000 was allocated to the convertible portion of the Avenue Loan. Aggregate debt discount amortization of \$0.6 million was recorded during the nine months ended September 30, 2022. 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 \$1.3 million for the nine months ended September 30, 2022.

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The Avenue Warrant was valued at issuance at \$1.3 million using the Black-Scholes option pricing method using the following assumptions:

	<u>August 6, 2021</u>
Contractual term (years)	5.07
Expected volatility	187.0%
Risk-free interest rate	0.77%
Expected dividends	0.00%

### ***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 \$120,000 for the nine months ended September 30, 2022 and 2021, 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 (a) 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) Stockholders’ Equity (Deficit)**

### ***Authorized Shares***

The Company is authorized to issue 40,000,000 shares of common stock, \$0.01 par value, and 10,000,000 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) and Series E-1 (12,960 shares).

### ***Preferred Stock***

As of September 30, 2022, 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 September 30, 2022, there are 2,475,000 shares of common stock reserved under the 2020 Plan, of which 803,105 remained available to be issued.

### ***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 (ESPP). The Company ESPP’s plan provides for a maximum of 260,295 shares of common stock to be purchased by participating employees. Employees who elect to participate in the Company’s 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.

### ***Equity Offerings and Placements***

#### ***At-the-Market Offering***

On August 18, 2020, the Company entered into a sales agreement with Cantor Fitzgerald & Co. (“Cantor Fitzgerald”), pursuant to which the Company may offer and sell, from time to time, through Cantor Fitzgerald, as sales agent or principal, shares of the

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Company's common stock, (the "Placement Shares"), having an aggregate offering price of up to \$10.0 million (the "ATM Offering"). The Company has no obligation to sell any Placement Shares under the sales agreement. Subject to the terms and conditions of the sales agreement, Cantor Fitzgerald 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 Placement Shares 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 Cantor Fitzgerald a commission of 3.0% of the aggregate gross proceeds from each sale of Placement Shares, reimburse Cantor Fitzgerald's legal fees and disbursements up to \$50,000 and provide Cantor Fitzgerald with customary indemnification and contribution rights. The sales agreement may be terminated by Cantor Fitzgerald or the Company upon notice to the other party as provided in the sales agreement, or by Cantor Fitzgerald 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 the Placement Shares or to enforce contracts for the sale of the Placement Shares.

In connection with the ATM Offering, in consideration for a fee equal to 1.05% of the gross sales price per share sold in the ATM Offering, ROTH Capital Advisors, LLC ("Roth") waived, solely with respect to the ATM Offering, (i) Roth's right, pursuant to certain engagement letters dated August 14, 2019 and January 13, 2020 between Roth and the Company, to act as placement agent or underwriter with respect to offerings of the Company's securities and to receive a minimum of 35% of the fees paid to the agents or underwriters for such offerings and (ii) the lock-up provision included in a certain underwriting agreement dated May 1, 2020 between Roth and the Company requiring the prior written consent of Roth for any offer or sale of the Company's common stock by the Company during the 90-day period following the date of such underwriting agreement.

There were no shares sold during the nine months ended September 30, 2022.

### *Private Placement*

On July 20, 2022, the Company closed a private placement for the issuance and sale of 690,954 shares of common stock (the "Common Stock") and 566,751 pre-funded warrants to purchase common stock (the "Pre-Funded Warrants") 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. The Company intends to use the net proceeds from the private placement for working capital purposes and other general corporate purposes.

### *Stock Options*

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

	Nine months ended September 30,	
	2022	2021
Expected terms (years)	0.7 - 8.4	5.1 - 6.3
Expected volatility	166.4% - 180.3%	178.3% - 181.3%
Risk-free interest rate	1.8% - 2.9%	0.7% - 1.1%
Expected dividends	0.00%	0.00%

The weighted average estimated fair value of the stock options granted during the nine months ended September 30, 2022 and 2021 was approximately \$6.31 and \$9.69 per share, respectively.



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The following is a summary of stock option activity for the nine months ended September 30, 2022:

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2022	1,732,460	\$ 11.69		
Granted	650,083	7.05		
Expired	(36,628)	10.44		
Cancelled/Forfeited	(95,960)	9.69		
Outstanding at September 30, 2022	<u>2,249,955</u>	<u>\$ 10.46</u>	<u>8.4</u>	<u>\$ —</u>
Exercisable at September 30, 2022	<u>1,143,154</u>	<u>\$ 11.27</u>	<u>8.1</u>	<u>\$ —</u>

The following table summarizes information for stock option shares outstanding and exercisable at September 30, 2022:

Range of Exercise Prices	Outstanding Number of Options	Options Exercisable	
		Weighted Average Remaining Option Term (in years)	Number of Options
\$6.24 - \$53.85	2,249,456	8.4	1,142,655
\$53.85+	499	6.3	499
	<u>2,249,955</u>	<u>8.1</u>	<u>1,143,154</u>

The following is a summary of share-based compensation expense in the statement of operations for the three and nine months ended September 30, 2022 and 2021 (in thousands):

	Three months ended September 30		Nine months ended September 30	
	2022	2021	2022	2021
Selling, general and administrative	\$ 857	\$1,655	\$2,816	\$4,245
Research and development	346	734	1,370	1,827
Cost of goods sold	52	60	160	152
Total	<u>\$1,255</u>	<u>\$2,449</u>	<u>\$4,346</u>	<u>\$6,224</u>

At September 30, 2022, there was \$6.3 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 1.7 years.

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### **Warrants**

The following is a summary of warrant activity for the nine months ended September 30, 2022:

	<u>Warrants</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Life (in years)</u>
Outstanding at January 1, 2022	3,894,498	\$ 9.27	
Warrants issued	566,751	.01	
Warrants exercised	—	—	
Warrants expired	—	—	
Outstanding at September 30, 2022	<u>4,461,249</u>	<u>\$ 8.09</u>	<u>2.8</u>
Exercisable at September 30, 2022	<u>4,461,249</u>	<u>\$ 8.09</u>	<u>2.8</u>

The following table presents information related to stock warrants at September 30, 2022:

Range of Exercise Prices	<u>Outstanding Number of Warrants</u>	<u>Warrants Exercisable</u>	
		<u>Weighted Average Remaining Warrant Term</u>	<u>Number of Warrants</u>
\$0.01	850,506	4.3	850,506
\$10.00	3,610,743	2.4	3,610,743
	<u>4,461,249</u>	<u>2.8</u>	<u>4,461,249</u>

### **(10) Net Loss per Common 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 and warrants are generally deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal.

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The following potentially dilutive securities were excluded from the computation of earnings per share as of September 30, 2022 and 2021 because their effects would be anti-dilutive:

	September 30,	
	2022	2021
Common stock warrants - equity	4,461,249	3,894,509
Assumed conversion of Series E and Series E-1 Preferred Stock	1,135,721	1,170,721
Assumed conversion of convertible notes	488,031	488,031
Stock options	2,249,955	1,698,249
Total	<u>8,334,956</u>	<u>7,251,510</u>

At September 30, 2022, the Company had 850,506 pre-funded warrants outstanding. The following table provides a reconciliation of the weighted average shares outstanding calculation for the three and nine months ended September 30, 2022 and 2021:

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Weighted average shares issued	8,470,006	7,354,428	8,096,551	6,665,826
Weighted average pre-funded warrants	745,780	233,215	439,455	257,715
Weighted average shares outstanding	<u>9,215,786</u>	<u>7,587,643</u>	<u>8,536,006</u>	<u>6,923,541</u>

### (11) Income Taxes

As discussed in Note 14 Income Taxes of the Company's 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.

### (12) Commitments and Contingencies

#### *Litigation, Claims and Assessments*

##### *medac Matter*

In April 2021, the Company issued an invoice for €1 million (which currently converts to approximately \$1.0 million) to medac GmbH, a privately held, multi-national pharmaceutical company based in Germany ("medac"), the Company's EU product distribution partner, for a milestone payment due under the License, Supply and Marketing Agreement (the "License Agreement") dated December 10, 2018, between the Company and medac. Pursuant to the License Agreement, a milestone is due upon achieving positive efficacy in the FOCUS Trial as defined by the FOCUS Trial protocol. Per the trial protocol and associated Statistical Analysis Plan, positive efficacy is based on whether the Objective Response Rate (ORR) exceeds a pre-specified threshold. A preliminary analysis of the FOCUS Trial data based on 87% of enrolled patients was released on March 31, 2021, and subsequently presented at the American Society of Clinical Oncology (ASCO) Annual Meeting held virtually from the 4th through the 8th of June 2021. Per that analysis, the ORR exceeded the pre-specified threshold. While the final ORR was not known at the time, given the magnitude by which the ORR exceeded the pre-specified endpoint and the small number of patients yet to be assessed, the final ORR will be greater than the pre-specified endpoint regardless of the responder status of the remaining patients. medac disagreed that the milestone was due and claimed that a full clinical study report is required in addition to the existing ORR analysis. medac has not disputed the accuracy of the ORR analysis or underlying data, but simply asserts that a full clinical study report is required prior to payment. While the Company disagrees with this interpretation, since medac had stated it did not intend to pay the invoice at this time, under revenue recognition criteria set out in ASC 606, the Company did not recognize the revenue.

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On October 12, 2021, the Company notified medac in writing that it was terminating the License Agreement due to medac's nonpayment of the milestone payment due under the License Agreement, with the effective date of termination of the License Agreement being April 12, 2022. medac disputed having an obligation to make a milestone payment under the Agreement and demanded withdrawal of the termination notice. The Company declined to withdraw the termination notice and, on December 16, 2021, the Company initiated an arbitration proceeding pursuant to the dispute resolution provisions of the License Agreement.

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 License Agreement with immediate effect. In the letter, medac reserved its rights in full, including a purported claim for damages for wrongful termination. In a separate letter, medac agreed to an 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 October 25, 2022, the parties reached a tentative agreement regarding the terms for a final settlement of the matter subject to the execution of a definitive settlement agreement on or before December 31, 2022. Under the agreed on settlement terms, Delcath has 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 in the event the annual royalty payment does not reach the agreed on minimum payment amount. There is no assurance that the parties will enter into a definitive agreement for the settlement of the matter on or before December 31, 2022. As of September 30, 2022, the Company has estimated the settlement to be \$1.2 million and recorded it as other liabilities, non-current on the condensed consolidated balance sheet and a charge in selling, general and administrative expenses in the condensed consolidated statement of operations and comprehensive loss.

## 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, 2021 to provide an understanding of its results of operations, financial condition and cash flows.*

*All references in this Quarterly Report to “we,” “our,” “us” and the “Company” refer to Delcath Systems, Inc., and its subsidiaries unless the context indicates otherwise.*

### 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 Market this Quarterly Report on Form 10-Q in Item 1A under “Risk, Factors” and the risks discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 in Item 1A under “Risk Factors” and the risks detailed from time to time in our future reports filed with the Securities and Exchange Commission (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;
- 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;
- the impact of macroeconomic conditions, including inflation, recession, and changes in fiscal policies on our business;
- 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. HEPZATO has not been approved for sale in the United States. 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.

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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, or 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 which will maximize the value of the HEPZATO platform.

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, or 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, hepatocellular carcinoma, intrahepatic cholangiocarcinoma, and neuroendocrine tumors) and one for doxorubicin in the treatment of patients with hepatocellular carcinoma).

Our most advanced development program is the treatment of ocular melanoma liver metastases, or mOM, a type of primary liver cancer. 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 indications which will maximize the value of the HEPZATO platform. 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. Based on the FOCUS Trial results, the Company is preparing to submit a new drug application, or NDA, to the FDA for HEPZATO. The Company held a pre-NDA meeting with the FDA in April 2022. Based on the feedback from FDA, the Company does not believe any additional pre-clinical or clinical studies are required to re-file the NDA. Due to vendor delays in delivering certain reports, we plan to submit an NDA to the FDA by the end of the year. The Company has opened two Expanded Access Program sites to provide access to patients who meet the inclusion criteria during the pendency of FDA's review of HEPZATO.

On February 28, 2022, CHEMOSAT received Medical Device Regulation 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.

### **Results of Operations for the three and nine months ended September 30, 2022**

#### *Three months ended September 30, 2022 compared with three months ended September 30, 2021*

##### Revenue

We recorded approximately \$0.9 million in revenue for the three months ended September 30, 2022 compared to \$0.5 million for the three months ended September 30, 2021. The increase in product revenue was primarily due to the transition to direct sales in Europe beginning in March 2022 which increased the average price per unit sold.

##### Cost of Goods Sold

For the three months ended September 30, 2022, cost of goods was relatively flat at \$0.2 million for the three months ended September 30, 2022 and 2021 as cost per unit sold were similar.

##### 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, conducting clinical trials and preparation costs for submission of HEPZATO to the FDA. For the three months ended September 30, 2022, research and development expenses increased to \$4.0 million from \$3.0 million in the prior year period. The increase of \$1.0 million is primarily due to higher expenses in preparation of the NDA submission.

##### 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 September 30, 2022 and 2021, selling, general and administrative expenses were \$4.5 million and \$4.0 million, respectively. The increase is primarily due the settlement of the medac litigation offset by lower share-based compensation expense.

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### Other Income/Expense

Other income (expense) is primarily related to income or expense associated with financial instruments. For the three months ended September 30, 2022 and 2021, other expenses were \$0.7 million and \$0.4 million, respectively. The increase in other expenses is primarily due to the interest expense and amortization expense for the original issue discount on the debt financing transaction discussed below between the Company and its lender, Avenue Venture Opportunities Fund, L.P.

### *Nine months ended September 30, 2022 compared with nine months ended September 30, 2021*

#### Revenue

We recorded approximately \$2.1 million in revenue for the nine months ended September 30, 2022 compared to \$1.4 million for the nine months ended September 30, 2021. The increase in product revenue was primarily due to the transition to direct sales in Europe beginning in March 2022 which increased the average price per unit sold.

#### Cost of Goods Sold

For the nine months ended September 30, 2022, cost of goods slightly decreased from \$0.5 million for the nine months ended September 30, 2021 to \$0.4 million for the nine months ended September 30, 2022 primarily due to the revaluation of inventory items during 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, conducting clinical trials and preparation costs for submission of HEPZATO to the FDA. For the nine months ended September 30, 2022, research and development expenses increased to \$13.6 million from \$10.2 million in the prior year period. The increase of \$3.4 million is primarily due to higher expenses in preparation for the pre-NDA meeting in April 2022 and preparation for the NDA submission this year.

#### 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 nine months ended September 30, 2022 and 2021, selling, general and administrative expenses were \$12.3 million and \$10.6 million, respectively. The increase is primarily higher costs in the preparation for commercialization of HEPZATO in the United States next year, and the settlement of medac litigation.

### Other Income/Expense

Other income (expense) is primarily related to income or expense associated with financial instruments. For the nine months ended September 30, 2022, other income/expense was a net expense of \$2.0 million compared to \$0.4 million for the nine months ended September 30, 2021. The increase in other expenses is primarily due to 2022 including a full year of interest expense and amortization expense for the original issue discount on the debt financing transaction between the Company and its lender, Avenue Venture Opportunities Fund, L.P.

### Liquidity and Capital Resources

At September 30, 2022, we had cash, cash equivalents and restricted cash totaling \$14.0 million. During the nine months ended September 30, 2022, the Company used \$17.6 million of cash in our operating activities.

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 consistent profitability. We have historically funded our operations through a combination of private placements and public offerings of our securities. We will need to raise additional capital under structures available to us, including debt and/or equity offerings.

On October 26, 2022, the Company received a letter from the Nasdaq indicating that, for the last thirty consecutive business days, the Market Value of Listed Securities, as defined by Nasdaq ("MVLS") had been below the \$35 million minimum requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company has been provided an initial period of 180 calendar days, or until April 24, 2023, to regain compliance. The letter states that the Nasdaq staff will provide written notification that the Company has achieved compliance with

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Rule 5550(b)(2) if at any time before April 24, 2023, the Company maintains its MVLS at \$35 million or more for a minimum of ten consecutive business days (or such longer period of time as the Nasdaq staff may require in some circumstances, but generally not more than 20 consecutive business days). The Nasdaq deficiency letter has no immediate effect on the listing or trading of the Company's common stock. If compliance is not achieved by April 24, 2023, the Company may be eligible for an additional 180 calendar day compliance period to demonstrate compliance with the minimum MVLS requirement. To qualify for the additional 180-day period, the Company will be required to meet the continued listing requirements for minimum closing bid price of its common stock and all other initial listing standards (with the exception of the minimum MVLS requirement). If the Company does not qualify for the second compliance period or fails to regain compliance during the second 180-day period, then Nasdaq will notify the Company that its common stock is subject to delisting. At that time, the Company may appeal the delisting determination to a Nasdaq Hearings Panel. The Company will continue to monitor its MVLS and consider its available options to regain compliance with the Nasdaq minimum MVLS requirements, which may include applying for an extension of the compliance period or appealing to a Nasdaq Hearings Panel.

These circumstances raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. Our financial statements do not include adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern depends on our ability to raise additional capital through the sale of equity or debt securities to support our future operations.

Our capital commitments over the next twelve months include \$8.6 million to satisfy September 30, 2022 accounts payable, accrued expenses and lease liabilities and \$7.1 million of loan principal payments. Our capital commitments past the next twelve months include (a) \$0.1 million of lease liabilities; (b) \$5.5 million of loan principal payments; (c) \$1.2 million of estimated settlement of litigation and (d) \$5.0 million of convertible note principal payments, if the holders do not elect to convert the notes into equity.

We also expect to use cash, cash equivalents and investment proceeds to fund our clinical research 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.

If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash.

On August 6, 2021, the Company entered into a Loan and Security Agreement (the "Avenue Loan Agreement") with Avenue Venture Opportunities Fund, L.P. (the "Lender," or "Avenue") for a term loan in an aggregate principal amount of up to \$20.0 million (the "Avenue Loan"). The Avenue Loan bears interest at an annual rate equal to the greater of (a) the sum of 7.70% plus the prime rate as reported in The Wall Street Journal and (b) 10.95%. The interest rate at September 30, 2022 was 13.2% and increased to 13.95% for October 2022. The Avenue Loan is secured by all of the Company's assets globally, including intellectual property. The Avenue Loan matures on August 1, 2024. Additional information regarding the Avenue Loan can be found in Note 8 to the Company's unaudited interim consolidated financial statements contained in this Quarterly Report on Form 10-Q.

On July 20, 2022, the Company closed a private placement for the issuance and sale of 690,954 shares of common stock (the "Common Stock") and 566,751 pre-funded warrants to purchase common stock (the "Pre-Funded Warrants") 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. The Company intends to use the net proceeds from the private placement for working capital purposes and other general corporate purposes.

### **Critical Accounting Estimates**

During the nine months ended September 30, 2022, there were no material changes to critical accounting estimates as reported in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, which was filed with the Securities and Exchange Commission (the "SEC") on March 30, 2022 and may also be found on the Company's website ([www.delcath.com](http://www.delcath.com)).



### **Application of Critical Accounting Policies**

Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America. During the nine months ended September 30, 2022, there were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. A description of certain accounting policies that may have a significant impact on amounts reported in the financial statements is disclosed in Note 3 to the Company's Annual Report for the fiscal year ended December 31, 2021.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Not required.

### **Item 4. Controls and Procedures**

#### *Evaluation of Disclosure Controls and Procedures*

The Company's management, with the participation of our principal executive and principal accounting officer, evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act). Based on that evaluation, our principal executive and principal accounting officer concluded that our disclosure controls and procedures as of September 30, 2022 (the end of the period covered by this Quarterly Report on Form 10-Q), have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our principal executive and principal accounting officer, as appropriate to allow timely decisions regarding required disclosure.

#### *Changes in Internal Controls over Financial Reporting*

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended September 30, 2022 that has materially affected, or is 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 issued an invoice for €1.0 million (which currently converts to approximately \$1.0 million) to medac GmbH, a privately held, multi-national pharmaceutical company based in Germany ("medac"), the Company's EU product distribution partner, for a milestone payment due under the License, Supply and Marketing Agreement (the "License Agreement") dated December 10, 2018, between the Company and medac. Pursuant to the License Agreement, a milestone is due upon achieving positive efficacy in the FOCUS Trial as defined by the FOCUS Trial protocol. Per the trial protocol and associated Statistical Analysis Plan, positive efficacy is based on whether the Objective Response Rate (ORR) exceeds a pre-specified threshold. A preliminary analysis of the FOCUS Trial data based on 87% of enrolled patients was released on March 31, 2021, and subsequently presented at the American Society of Clinical Oncology (ASCO) Annual Meeting held virtually from the 4th through the 8th of June 2021. Per that analysis, the ORR exceeded the pre-specified threshold. While the final ORR was not known at the time, given the magnitude by which the ORR exceeded the pre-specified endpoint and the small number of patients yet to be assessed, the final ORR will be greater than the pre-specified endpoint regardless of the responder status of the remaining patients. medac disagreed that the milestone was due and claimed that a full clinical study report was required in addition to the existing ORR analysis. medac has not disputed the accuracy of the ORR analysis or underlying data, but simply asserted that a full clinical study report is required prior to payment. While the Company disagrees with this interpretation, since medac had stated they did not intend to pay the invoice at this time, under revenue recognition criteria set out in ASC 606, the Company did not recognize the revenue.

On October 12, 2021, the Company notified medac in writing that it was terminating the License Agreement due to medac's nonpayment of the milestone payment due under the License Agreement, with the effective date of termination of the License Agreement being April 12, 2022. medac disputed having an obligation to make a milestone payment under the Agreement and demanded withdrawal of the termination notice. The Company declined to withdraw the termination notice and, on December 16, 2021, the Company initiated an arbitration proceeding pursuant to the dispute resolution provisions of the License Agreement.

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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 License Agreement with immediate effect. In the letter, medac reserved its rights in full, including a purported claim for damages for wrongful termination. 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 October 25, 2022, the parties reached a tentative agreement regarding the terms for a final settlement of the matter subject to the execution of a definitive settlement agreement on or before December 31, 2022. Under the agreed on settlement terms, Delcath will 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 in the event the annual royalty payment does not reach the agreed on minimum payment amount. There is no assurance that the parties will enter into a definitive agreement for the settlement of the matter on or prior to December 31, 2022. As of September 30, 2022, the Company has estimated the settlement to be \$1.2 million and recorded it as other liabilities, non-current on the condensed consolidated balance sheet and a charge in selling, general and administrative expenses in the condensed consolidated statement of operations and comprehensive loss.

### **Item 1A. Risk Factors**

In addition to the other information set forth in this report, you should carefully consider the factors discussed in "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021. Aside from the risk factors below, there have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021.

#### ***Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock.***

On October 26, 2022, the Company received a letter from the Nasdaq indicating that, for the last thirty consecutive business days, the Market Value of Listed Securities, as defined by Nasdaq ("MVLS") had been below the \$35 million minimum requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company has been provided an initial period of 180 calendar days, or until April 24, 2023, to regain compliance. The letter states that the Nasdaq staff will provide written notification that the Company has achieved compliance with Rule 5550(b)(2) if at any time before April 24, 2023, the Company maintains its MVLS at \$35 million or more for a minimum of ten consecutive business days (or such longer period of time as the Nasdaq staff may require in some circumstances, but generally not more than 20 consecutive business days). The Nasdaq deficiency letter has no immediate effect on the listing or trading of the Company's common stock. If compliance is not achieved by April 24, 2023, the Company may be eligible for an additional 180 calendar day compliance period to demonstrate compliance with the minimum MVLS requirement. To qualify for the additional 180-day period, the Company will be required to meet the continued listing requirements for minimum closing bid price of its common stock and all other initial listing standards (with the exception of the minimum MVLS requirement). If the Company does not qualify for the second compliance period or fails to regain compliance during the second 180-day period, then Nasdaq will notify the Company that its common stock is subject to delisting. At that time, the Company may appeal the delisting determination to a Nasdaq Hearings Panel. The Company will continue to monitor its MVLS and consider its available options to regain compliance with the Nasdaq minimum MVLS requirements, which may include applying for an extension of the compliance period or appealing to a Nasdaq Hearings Panel.

The delisting of our common stock from Nasdaq may make it more difficult for us to raise capital on favorable terms in the future. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from Nasdaq, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities. Moreover, while the Company is exercising diligent efforts to maintain the listing of our common stock on the Nasdaq Capital Market, there is no assurance that any actions that we take to restore our compliance with the minimum MVLS requirement would prevent future non-compliance with the minimum MVLS requirement or other Nasdaq listing requirements.

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

On July 18, 2022, the Company and certain accredited investors entered into a securities purchase agreement pursuant to which the Company agreed to sell and issue to the investors in a private placement (i) 690,954 shares of the Company's common stock at a purchase price of \$3.98 per share and (ii) 566,751 pre-funded warrants to purchase common stock at a purchase 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. Upon the closing of the private placement on July 20, 2022, the Company received gross proceeds of

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approximately \$5.0 million, before the deduction of offering expenses. The Company intends to use the net proceeds of the private placement for working capital and other general corporate purposes. Based in part upon the representations of the investors in the securities purchase agreement, the offering and sale of the securities was made in reliance on the exemption afforded by Regulation D under the Securities Act of 1933, as amended, and corresponding provisions of state securities or “blue sky” laws.

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### Item 6. Exhibits

Exhibit No.	Description
3.1	<a href="#">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).</a>
3.2	<a href="#">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).</a>
3.3	<a href="#">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).</a>
3.4	<a href="#">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).</a>
3.5	<a href="#">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).</a>
3.6	<a href="#">Amended and Restated By-Laws of the Company (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to Company's Registration Statement on Form SB-2).</a>
10.1	<a href="#">Form of Securities Purchase Agreement, dated July 18, 2022 by and among the Company and private parties thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 20, 2022).</a>
10.2	<a href="#">Form of Registration Rights Agreement, dated July 18, 2022, by and among the Company and private parties thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 20, 2022).</a>
31.1	<a href="#">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.*</a>
31.2	<a href="#">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.*</a>
32.1	<a href="#">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.**</a>
32.2	<a href="#">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.**</a>
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.

November 8, 2022

DELCATH SYSTEMS, INC.

/s/ Gerard Michel

Gerard Michel  
Chief Executive Officer (Principal Executive Officer)

November 8, 2022

/s/ Anthony Dias

Anthony Dias  
Principal Accounting Officer

## DELCATH SYSTEMS, INC.

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

I, Gerard Michel, certify that:

- 1) I have reviewed this Quarterly Report on Form 10-Q of Delcath Systems, Inc.;
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 8, 2022

/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.

November 8, 2022

/s/ Anthony Dias

Anthony Dias  
Principal Accounting 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 September 30, 2022, 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.

November 8, 2022

/s/ Gerard Michel

Gerard Michel

Chief Executive Officer (Principal Executive 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 September 30, 2022, 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.

November 8, 2022

/s/ Anthony Dias

Anthony Dias

Principal Accounting Officer