

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-QSB

- Quarterly report under Section 13 or 15(d) of the Securities Exchange Act of 1934 For the quarterly period ended March 31, 2001  
 Transition report under Section 13 or 15(d) of the Securities Exchange Act of 1934 For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-16133

Delcath Systems, Inc.

(Exact Name of Small Business Issuer as Specified in Its Charter)

Delaware

06-1245881

(State or Other Jurisdiction of Incorporation or Organization)

(I.R.S. Employer Identification No.)

1100 Summer Street, 3rd Floor, Stamford, CT 06905

(Address of Principal Executive Offices)

(203) 323-8668

(Issuer's Telephone Number, Including Area Code)

NONE

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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

As of May 14, 2001, there were 3,903,816 shares of the Issuer's Common Stock, \$0.01 par value, issued and outstanding.

Transitional Small Business Disclosure Format (check one): Yes  No

DELCATH SYSTEMS, INC.

INDEX

	Page No.
Part I. FINANCIAL INFORMATION	3
Item 1. Financial Statements (Unaudited)	3
Balance Sheet - March 31, 2001	3
Statements of Operations for the Three Months Ended March 31, 2001 and 2000 and Cumulative from Inception (August 5, 1988) to March 31, 2001	4
Statements of Cash Flows for the Three Months Ended March 31, 2001 and 2000 and Cumulative from Inception (August 5, 1988) to March 31, 2001	5
Notes to Financial Statements	6
Item 2. Plan of Operation	6
Part II. OTHER INFORMATION	8
Item 2. Changes in Securities	8
Item 6. Exhibits and Reports on Form 8-K	9
Signatures	10

DEL CATH SYSTEMS, INC.  
BALANCE SHEET  
(UNAUDITED)  
MARCH 31, 2001

ASSETS	MARCH 31, 2001
<hr style="border-top: 1px dashed black;"/>	
Current assets:	
Cash and cash equivalents	\$ 4,865,432
Interest receivable	8,566
Prepaid insurance	43,331
Total current assets	4,917,329
Furniture and fixtures, net	11,902
Due from affiliate	24,000
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Total assets	\$ 4,953,231
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LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Accounts payable and accrued expenses	\$ 223,994
Short term borrowings	230,000
Total current liabilities	453,994
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Stockholders' equity	
Common Stock	39,039
Additional Paid-In Capital	18,637,159
Deficit accumulated during development stage	(14,176,961)
Total stockholders' equity	4,499,237
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Total liabilities and stockholders' equity	\$ 4,953,231
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DELCATH SYSTEMS, INC.  
STATEMENTS OF OPERATIONS  
(UNAUDITED)

	THREE MONTHS ENDED MARCH 31, 2001	MARCH 31, 2000	CUMULATIVE FROM INCEPTION (AUGUST 5, 1988) TO MARCH 31, 2001
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Costs and expenses:			
Legal consulting and accounting fees	\$ 224,294	98,273	5,211,724
Stock option compensation expense	--	--	2,523,970
Compensation and related expenses	122,978	52,921	2,870,594
Other operating expenses	123,076	64,432	2,612,556
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Total costs and expenses	470,348	215,626	13,218,844
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Operating loss	(470,348)	(215,626)	(13,218,844)
Interest income	76,771	5,502	709,022
Interest expense	(12,632)	--	(168,534)
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Net loss	\$ (406,209)	(210,124)	(12,678,356)
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Common Share data:			
Basic and diluted loss per share	\$ (0.10)	(0.24)	
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Weighted average number of shares of common stock outstanding	3,903,852	863,196	

DELCATH SYSTEMS, INC.  
CASH FLOWS  
(UNAUDITED)

	THREE MONTHS ENDED		CUMULATIVE FROM INCEPTION (AUGUST 5, 1988) TO MARCH 31, 2001
	3/31/2001	3/31/2000	
Cash flow from operating activities:			
Net loss	\$ (406,209)	(210,124)	(12,678,356)
Adjustments to reconcile net loss to net cash used in operating activities			
Stock option compensation expense (reversal)	--	--	2,523,971
Stock compensation expense	--	--	34,485
Depreciation expense	1,140	750	10,890
Amortization of organization costs	--	--	42,165
(Increase) decrease in prepaid expenses	25,835	(93,449)	(43,331)
(Increase) decrease in interest receivable	23,802	3,082	(8,566)
Due from affiliate	--	--	(24,000)
(Decrease) increase in accounts payable and accrued expenses	(574,921)	9,621	223,994
Net cash used in operating activities	(930,353)	(290,120)	(9,918,748)
Cash flows from investing activities:			
Purchase of furniture and fixtures	(7,792)	--	(22,792)
Purchase of short-term investments	--	--	(1,030,000)
Proceeds from maturities of short-term investments	--	--	1,030,000
Organization costs	--	--	(42,165)
Net cash used in investing activities	(7,792)	--	(64,957)
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	--	--	13,413,708
Dividends Paid	--	--	(499,535)
Deferred IPO costs	--	(52,703)	--
Proceeds from short-term borrowings	--	--	1,934,964
Net cash provided by (used in) financing activities	--	(52,703)	14,849,137
Increase (decrease) in cash and cash equivalents	(938,145)	(342,823)	4,865,432
Cash and cash equivalents at beginning of period	5,803,577	561,078	--
Cash and cash equivalents at end of period	\$ 4,865,432	218,255	4,865,432
Supplemental cash flow activities:			
Conversion of debt to common stock	\$ --	--	1,704,964
Common stock issued for preferred stock dividends	\$ --	--	999,070
Conversion of preferred stock to common stock	\$ --	--	24,167
Common stock issued as compensation for stock sale	\$ --	--	510,000
Cash paid for interest	\$ 1,294	--	139,271

Delcath Systems Inc.  
Notes to Financial Statements

Note 1: Description of Business

Delcath Systems, Inc. (the "Company") is a development stage company which was founded in 1988 for the purpose of developing and marketing a proprietary drug delivery system capable of introducing, and removing, high dose chemotherapy agents to a diseased organ system while greatly inhibiting their entry into the general circulation system. In November 1989, the Company was granted an Investigational Device Exemption ("IDE") and an Investigational New Drug ("IND") status for its product by the Food and Drug Administration ("FDA").

Note 2: Basis of Presentation

The accompanying financial statements are unaudited and have been prepared by the Company in accordance with generally accepted accounting principles. Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. The interim financial statements, in the opinion of management, reflect all adjustments (including normal recurring accruals) necessary for a fair statement of the results for the interim periods ended March 31, 2001 and 2000.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the fiscal year. These interim financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2000, which are contained in the Company's Form 10-KSB as filed with the Securities and Exchange Commission on March 30, 2001.

Note 3: Capital Stock

The common stock and per share data for all periods gives effect to reverse stock splits of 1 for 2.2881 shares on September 28, 2000 and 1 for 1.2666 shares on October 11, 2000, resulting in an aggregate reverse split of approximately 1 for 2.8981 shares.

ITEM 2. PLAN OF OPERATION

OVERVIEW

The Company was founded in 1988 by a team of physicians. Since our inception, we have been a development stage company engaged primarily in developing and testing the Delcath system for the treatment of liver cancer. A substantial portion of our historical expenses have been in support of the development and the clinical trials of our product. Until our initial public offering, we had been dependent upon venture capital financing to fund our activities. Without an FDA pre-marketing approved product, we have generated minimal revenues from product sales. We have been unprofitable to date and have had losses of \$572,581 and \$960,185 for the years ended December 31, 1999 and 2000 and \$406,209 for the three months ended March 31, 2001. Cumulative losses from inception through March 31, 2001 were \$12,678,356. Losses have continued through the date of this report. We expect to incur additional losses over the next three years and anticipate these losses will increase significantly in this period due to continued requirements for product development, clinical studies, regulatory activities, manufacturing and establishment of a sales and marketing organization. The amount of future net losses and time required to reach profitability are uncertain. Our ability to generate significant revenue and become profitable will depend on our success in commercializing our device.

Development of the Company's platform technology for isolated perfusion began in 1988 and has progressed through Phase I and II human clinical trials using doxorubicin to treat cancers in the liver. In December 1999, the Company received approval from the FDA to conduct Phase III clinical trials using doxorubicin to treat

certain cancers in the liver. The Company is now contacting physicians at medical centers who have expressed interest in participating in these clinical trials. While there can be no assurance regarding the start of these trials, the Company anticipates the physicians will be ready to start recruiting patients in the second quarter of 2001.

The Company continues to expend substantial resources on the testing of its initial product for isolated perfusion of the liver. These expenditures are expected to rise substantially now that the Company has completed its initial public offering and received FDA approval to proceed with Phase III human clinical trials using doxorubicin for the treatment of malignant melanoma that has spread to the liver. The Phase III trials will seek to demonstrate the safety and efficacy of the Delcath system for this use. There can be no assurance that the trials will be completed or that the FDA will approve marketing of the Company's product once they are complete.

Sale of medical devices in the United States requires approval by the FDA, which is contingent upon the results of the Phase III human clinical trials. Sale of medical devices outside of the United States is controlled by local regulations and the FDA regulates export of the devices from the United States.

The Company will also continue to expend resources on other projects, including research and development stage clinical trials for other chemotherapy agents. If additional funds are raised, other projects may be started as well.

#### FORWARD LOOKING STATEMENTS

This report contains forward-looking statements, which are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include but are not limited to, uncertainties relating to our ability to successfully complete Phase III clinical trials and secure regulatory approval of any of our current or future drug-delivery systems, uncertainties regarding our ability to obtain financial and other resources for our research, development and commercial activities. These factors, and others, are discussed from time to time in the Company's filings with the Securities and Exchange Commission. You should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. We undertake no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.

#### LIQUIDITY AND CAPITAL RESOURCES

Until completion of its initial public offering, the Company financed its operations primarily through private placements of our common and preferred stock. Prior to the completion of the initial public offering, the Company raised \$9,816,686 through the private sale of shares of its Class A Preferred Stock, Class B Preferred Stock and Common Stock. In August and September 2000, the Company also borrowed \$230,000 for which it issued \$230,000 principal amount of promissory notes, which bear interest at an annual rate of 22% and are due on May 27, 2001. Of these notes, \$50,000 in principal amount was subscribed to by M.S. Koly, Chief Executive Officer, President and Director of the Company, and \$40,000 principal amount was subscribed to by the mother of Samuel Herschkowitz, M.D., our Chairman of the Board and Chief Technology Officer. The Company expects to pay approximately \$267,400 (including interest) to the holders of these notes in May 2001. In October 2000, the Company completed an initial public offering. We sold 1,200,000 units for \$6.00 per unit, each unit consisting of one share of our Common Stock and one redeemable warrant to purchase one share of our Common Stock for \$6.60 per share until October 18, 2005. The Company received \$7.2 million before offering costs and before paying cash dividends on preferred shares of approximately \$499,535. After underwriting discounts and cash expenses of the offering, the net proceeds to us were approximately \$5.4 million.

Our cash and cash equivalents totaled \$4,865,432 on March 31, 2001, a decrease of \$938,145 from December 31, 2000.

Over the next 12 months, the Company expects to continue to incur expenses related to the research and development of our technology, including Phase III clinical trials using doxorubicin with the Delcath system and pre-clinical and clinical trials for the use of other chemotherapy agents with the Delcath System for the treatment of cancers in the liver.

We expect to begin doxorubicin trials during the second quarter of 2001. These trials are expected to take 12 to 18 months to complete. The collation, analysis and submission of the results of the trials to the FDA will take an additional three months and we estimate that the FDA will respond to our submission within three months.

We expect to incur significant additional operating losses over each of the next several years and expect cumulative losses to increase significantly as we continue to expand our research and development, clinical trials and marketing efforts. During the next 12 months, we expect to purchase approximately \$50,000 in computer, laboratory and testing equipment. We also expect to hire approximately two additional employees in the areas of research and development, regulatory and clinical management, marketing and administrative functions at an estimated annual expense of \$235,000. The number and timing of such hiring will vary depending upon the success of the international marketing efforts and progress of the clinical trials.

The Company anticipates that the net proceeds of our initial public offering, together with our other available funds, will be sufficient to meet our anticipated needs for working capital and capital expenditures through at least the next 12 months. These operating expenses are expected to be at significantly higher levels than past periods primarily in order to support and monitor the envisioned Phase III clinical trials. Our future liquidity and capital requirements, however, will depend on numerous factors, including: the progress of our research and product development programs, including clinical studies; the timing and costs of various United States and foreign regulatory filings; the timing and effectiveness of product commercialization activities, including marketing arrangements overseas; the timing and costs involved in obtaining regulatory approvals, if ever, and complying with regulatory requirements; 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 the proceeds of the initial public offering, together with our currently available funds, are not sufficient to satisfy our spending plans, we will be required to revise our capital requirements or to seek additional funding through borrowings and/or additional sales of securities. We cannot assure you that our available funds will be sufficient to fund our clinical trials with respect to the use of the Delcath system with doxorubicin to treat liver cancer. We also cannot assure you that additional financing will become available if needed.

## PART II. OTHER INFORMATION

### Item 2. Changes in Securities and Use of Proceeds.

(a) - (c) Not applicable.

(d) The effective date of our first registration statement, filed on Form SB-2 under the Securities Act of 1933 (no. 333-39470) relating to our initial public offering of our Common Stock, was October 19, 2000. A total of 1,200,000 units were sold for \$6.00 per unit, each unit consisting of one share of our Common Stock and one redeemable warrant to purchase one share of our Common Stock for \$6.60 per share until October 18, 2005. The initial public offering generated gross proceeds to the Company of \$7.2 million, of which \$720,000 was deducted for the underwriting discount. Cash expenses relating to the offering, including the discount and non-accountable expense reimbursement to the underwriter, totaled approximately \$1.8 million. Net proceeds to

Delcath were approximately \$5.4 million. The cash expenses related to the underwriting were \$350,000 higher than expected, resulting in the actual net proceeds to Delcath being \$350,000 lower than estimated in the registration statement. The Company has adjusted the use of proceeds to reflect the change in net proceeds. We expect to use the net proceeds as follows:

	Approximate dollar amount
	-----
Research and development:	
Phase III clinical trials using the Delcath system with doxorubicin	\$ 3,750,000
Research and development stage clinical trials for other chemotherapy agents	\$ 425,000
Repayment of indebtedness	\$ 270,000
Working capital and general corporate purposes	\$ 955,000
	-----
Total	\$ 5,400,000
	=====

From the time of receipt through March 31, 2001, approximately \$790,000 of the net proceeds were expended as shown in the table below. The remaining net proceeds are being held in temporary investments in short-term commercial paper.

	Actual through March 31, 2001
	-----
Research and development:	
Phase III clinical trials using the Delcath system with doxorubicin	\$ 575,000
Research and development stage clinical trials for other chemotherapy agents	\$ 15,000
Repayment of indebtedness	--
Working capital and general corporate purposes	\$ 200,000
	-----
Total	\$ 790,000
	=====

PART II  
OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K.

(a) Exhibits.

None.

(b) Reports on Form 8-K.

No reports on Form 8-K were filed by the Company during the quarter for which this report is being filed.



SIGNATURES

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

DELCATH SYSTEMS, INC.

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(Registrant)

Date: May 15, 2001

/s/ Joseph P. Milana

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Joseph P. Milana  
Chief Financial Officer (on behalf of the  
registrant and as the Principal Financial  
Officer of the registrant)