

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-QSB

[X] Quarterly report under Section 13 or 15(d) of the Securities and Exchange Act of 1934

For the quarterly period ended September 30, 2000

[ ] Transition report pursuant to Section 13 or 15(d) of the Securities and 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 X No ---

As of December 1, 2000, 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 X ---

DELCATH SYSTEMS, INC.

INDEX

PAGE ----

PART I. - FINANCIAL INFORMATION

Item 1. Financial Statements

Balance Sheet - September 30, 2000	3
Statements of Operations - Three Months and Nine Months Ended September 30, 2000 and 1999 and Cumulative from Inception (August 5, 1988) to September 30, 2000	4
Statements of Cash Flows - Nine Months Ended September 30, 2000 and 1999 and Cumulative from Inception (August 5, 1988) to September 30, 2000	5
Notes to Financial Statements	6

Item 2. Plan of Operation 7

PART II. - OTHER INFORMATION

Item 2. Changes in Securities and Use of Proceeds 9

Item 6. Exhibits and Reports on Form 8-K 9

Signatures 9

PART I. FINANCIAL INFORMATION  
ITEM 1. FINANCIAL STATEMENTS

DEL CATH SYSTEMS, INC.  
BALANCE SHEET  
(Unaudited)  
September 30, 2000

ASSETS

Current assets:

Cash and cash equivalents	\$ 453,344
Interest receivable	993
Prepaid rent	21,845
Prepaid insurance	14,583
Deferred IPO costs	516,545

Total current assets 1,007,310

Furniture and fixtures, net	6,000
Due from affiliate	24,000

Total assets \$ 1,037,310  
=====

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable and accrued expenses	\$ 363,710
Short term borrowings	230,000

Total current liabilities 593,710  
-----

Stockholders' equity

Class A preferred stock	20,000
Class B preferred stock	4,167
Common stock	10,941
Additional paid-in capital	12,266,752
Deficit accumulated during development stage	(11,858,260)

Total stockholders' equity 443,600  
-----

Total liabilities and stockholders' equity \$ 1,037,310  
=====

See notes to financial statements

DELCATH SYSTEMS, INC.  
STATEMENTS OF OPERATIONS  
(Unaudited)

	THREE MONTHS ENDED 2000	SEPTEMBER 30, 1999	NINE MONTHS ENDED 2000	SEPTEMBER 30, 1999	CUMULATIVE FROM INCEPTION (AUGUST 5, 1988) TO SEPTEMBER 30, 2000
	-----	-----	-----	-----	-----
Costs and expenses:					
Legal consulting and accounting fees	\$ 51,344	\$ 122,243	\$ 224,270	\$ 511,496	\$ 4,741,439
Stock option compensation expense (reversal)	--	--	--	(456,185)	2,520,170
Compensation and related expenses	54,437	37,709	159,202	161,442	2,647,372
Other operating expenses	50,365	49,237	177,481	198,618	2,368,757
	-----	-----	-----	-----	-----
Total costs and expenses	156,146	209,189	560,953	415,371	12,277,738
	-----	-----	-----	-----	-----
Operating loss	(156,146)	(209,189)	(560,953)	(415,371)	(12,277,738)
Interest income	5,889	10,992	18,925	34,689	556,621
Interest expense	(4,270)	--	(4,270)	(17,925)	(137,143)
	-----	-----	-----	-----	-----
Net loss	\$ (154,527)	\$ (198,197)	\$ (546,298)	\$ (398,607)	\$(11,858,260)
	=====	=====	=====	=====	=====
Common Share data:					
Basic and diluted loss per share	\$ (0.14)	\$ (0.23)	\$ (0.54)	\$ (0.48)	
	=====	=====	=====	=====	
Weighted average number of shares of common stock outstanding	1,094,070	863,197	1,017,112	836,327	

See notes to financial statements

DEL CATH SYSTEMS, INC.  
STATEMENT OF CASH FLOWS  
(Unaudited)

	NINE MONTHS ENDED 2000	SEPTEMBER 30, 1999	CUMULATIVE FROM INCEPTION (AUGUST 5, 1988) TO SEPTEMBER 30, 2000
	-----	-----	-----
Cash flow from operating activities:			
Net loss	\$ (546,298)	\$ (398,607)	\$(11,858,260)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense (reversal)	--	(456,185)	2,520,171
Stock compensation expense	--	--	34,485
Depreciation expense	2,250	2,250	9,000
Amortization of organization costs	--	--	42,165
(Increase) in prepaid expenses	(32,261)	(5,383)	(36,428)
(Increase) decrease in interest receivable	2,333	4,009	(993)
Due from affiliate	--	--	(24,000)
(Decrease) increase in accounts payable and accrued expenses	250,962	(61,215)	363,710
Net cash used in operating activities	(323,014)	(915,131)	(8,950,150)
	-----	-----	-----
Cash flows from investing activities:			
Purchase of furniture and fixtures	--	--	(15,000)
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	--	--	(57,165)
	-----	-----	-----
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	501,825	801,190	8,042,240
Deferred IPO costs	(516,545)	--	(516,545)
Proceeds from short-term borrowings	230,000	--	1,934,964
Net cash provided by financing activities	215,280	801,190	9,460,659
	-----	-----	-----
Increase (decrease) in cash and cash equivalents	(107,734)	(113,941)	453,344
Cash and cash equivalents at beginning of period	561,078	852,313	
	-----	-----	-----
Cash and cash equivalents at end of period	453,344	738,372	453,344
	=====	=====	=====
Supplemental cash flow activities:			
Conversion of debt to common stock	\$ --	\$ --	\$ 1,704,964
	=====	=====	=====
Cash paid for interest	\$ --	\$ --	\$ 114,948
	=====	=====	=====

See notes to financial statements

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 United States 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 September 30, 2000 and 1999.

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 for the year ended December 31, 1999, which are contained in the Company's Form SB-2 Registration Statement, which was declared effective by the Securities and Exchange Commission on October 19, 2000.

Costs incurred in connection with the initial public offering of the Company ("Deferred IPO costs") were deferred and offset against the proceeds of the initial public offering that closed in October 2000 (see Note 4).

Basic earnings per share is computed using the weighted average number of shares of common stock outstanding during the period.

Note 3: Short Term Borrowings

In August and September 2000, the Company borrowed \$230,000 for which the Company 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 principal amount was to M.S. Koly, Chief Executive Officer, President and a director of Delcath, and \$40,000 principal amount was issued to the mother of Samuel Herschkowitz, our Chairman of the Board and Chief Technology Officer in August and September 2000.

Note 4: Initial Public Offering

The Company completed an initial public offering underwritten by Whale Securities Co., L.P. on October 19, 2000 of 1,200,000 units, each unit consisting of one share of common stock and one redeemable warrant to purchase one share of common stock at a price of \$6.60 until October 18, 2005. The units were sold at a price of \$6.00 per unit. In connection with the initial public offering, the Company received \$7,200,000 before offering costs.

Note 5: 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.

In connection with the initial public offering, the holders of the 2,000,000 shares outstanding of the Company's Class A Preferred Stock and 416,675 shares outstanding of the Company's Class B Preferred Stock agreed to convert their shares into common stock prior to the closing of the offering, provided they received payment of accumulated dividends. Upon the conversion of the Company's Class A Preferred Stock and the Company's Class B Preferred Stock into approximately 833,874 shares of Common Stock, the holders of the Class A and Class B shares also received an aggregate of \$499,535 in cash and 690,910 shares of Common Stock in payment of the accrued dividends.

## 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 \$2,049,980 and \$572,581 for the years ended December 31, 1998 and 1999 and \$546,298 for the nine months ended September 30, 2000. Cumulative losses from inception through September 30, 2000 were \$11,858,260. 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.

We incurred non-cash compensation expense in connection with the grants of options to purchase common stock to founders, employees, and directors because those options had a weighted average exercise price below the fair value of the common stock at the dates of the grants. This compensation expense from inception on August 5, 1988, through September 30, 2000 totaled \$2,520,170.

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.

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 start recruiting patients in the first quarter of 2001.

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 the initial public offering, the Company financed its operations primarily through private placements of our common and preferred stock. Through September 30, 2000, the Company raised \$9,816,686 through the sale of shares of its Class A Preferred Stock, Class B Preferred Stock and Common Stock. In August and September 2000, we also borrowed \$230,000 for which we 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 principal amount was to M.S. Koly, Chief Executive Officer, President and a director of Delcath, and \$40,000 principal amount was issued to the mother of Samuel Herschkowitz, 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. Cash used to fund operations from inception through September 30, 2000 was \$8,950,150. Our cash and cash equivalents totaled \$453,344 at September 30, 2000, a decrease of \$107,734 from December 31, 1999.

In October 2000, the Company completed an initial public offering wherein the Company received \$7.2 million before offering costs and paid cash relating to dividends on preferred shares of approximately \$499,535.

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 first quarter of 2001.

The Company expects to incur significant additional operating losses over each of the next several years and expects cumulative losses to increase significantly as the Company continues to expand its 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 five additional employees in the areas of research and development, regulatory and clinical management, marketing and administrative functions at an estimated annual expense of \$325,000. 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, based primarily on the approximately \$5.3 million provided by our initial public offering, net of offering expenses, that its current cash balances will be sufficient to fund the Company's operations and capital requirements through the end of the year 2001. 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. Our available funds may not be sufficient to fund our clinical trials with respect to the use of the Delcath system with doxorubicin to treat liver cancer. We also may not be able to obtain additional financing if needed.



PART II. OTHER INFORMATION

Item 2. CHANGES IN SECURITIES AND USE OF PROCEEDS.

(a)-(c) Not applicable.

(d) The Company's Form SB-2 Registration Statement, Commission file no. 333-39470, for its initial public offering of 1,200,000 units at \$6.00 per unit, each unit consisting of one share of common stock and one redeemable warrant to purchase one share of common stock at a price of \$6.60 until October 18, 2005, was declared effective by the Commission on October 19, 2000. The managing underwriter for the initial public offering was Whale Securities Co., L.P. All securities were offered for the account of the registrant. The offering closed on October 24, 2000 with the sale of 1,200,000 units for \$7,200,000. (The underwriter's over-allotment option to purchase 180,000 units was not exercised.) The following securities were registered in connection with the offering: 1,380,000 units at an aggregate offering price of \$8,280,000, of which 1,200,000 units were sold for an aggregate sales price of \$7,200,000 and 1,380,000 shares of common stock underlying the common stock purchase warrants included in the units at an aggregate offering price of \$9,108,000, of which none of the shares has been sold as the warrants first become exercisable October 21, 2001 (unless earlier consented to by the managing underwriter). The Company also registered underwriter's warrants to purchase 120,000 units, which were issued to the underwriter for \$100, and 120,000 units underlying the underwriter's warrant for an aggregate offering price of \$864,000, and 120,000 shares of common stock underlying the warrants issuable upon exercise of the underwriter's warrant for an aggregate offering price of \$792,000, neither of which has yet been sold as the underwriter's warrant has not yet been exercised. Inasmuch as the effective date of the initial public offering occurred after the period covered by this report, information on the use of proceeds of the initial public offering will be included in the Company's next periodic report, its Form 10-KSB for the fiscal year ended December 31, 2000.

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

(a) Exhibits. The following exhibit is filed herewith:

27. Financial Data Schedule.

(b) No reports were filed on Form 8-K during the quarter for which this report is filed, as the registrant first became subject to the reporting requirements after September 30, 2000.

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.

-----  
(Registrant)

Date: December 4, 2000

/s/ Joseph P. Milana

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

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE COMPANY'S SEPTEMBER 30, 2000 FORM 10-QSB AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

9-MOS

	DEC-31-2000	
	SEP-30-2000	
		453,344
		0
		0
		0
		0
	1,007,310	16,500
		10,500
	1,037,310	
	593,710	
		0
		10,941
	0	
		24,167
		408,492
1,037,310		
		0
		0
		0
		560,953
		0
		0
		4,270
		(546,298)
		0
	(546,298)	
		0
		0
		0
		(546,298)
		(0.54)
		(0.54)