

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Amendment No. 2

to

FORM SB-2  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

DEL CATH SYSTEMS, INC.

(Exact name of Registrant as specified in its charter)

Delaware

3841

06-1245881

(State or Other Jurisdiction of  
Incorporation or organization)

(Primary Standard Industrial  
Classification Code Number)

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

1100 Summer Street  
Stamford, Connecticut 06905  
(203) 323-8668  
(Address, including zip code, and telephone number,  
including area code, of registrant's executive offices)

M. S. KOLY  
Chief Executive Officer  
Delcath Systems, Inc.  
1100 Summer Street  
Stamford, Connecticut 06905  
(203) 323-8668  
(Name, address, including zip code, and telephone number,  
including area code of agent for service)

Copies to:

Stephen A. Zelnick, Esq.  
Morse, Zelnick, Rose & Lander, LLP  
450 Park Avenue  
New York, NY 10022  
(212) 838-8040  
(212) 838-9190 (Facsimile)

Robert J. Mittman, Esq.  
Blank Rome Tenzer Greenblatt LLP  
405 Lexington Avenue  
New York, NY 10174  
(212) 885-5000  
(212) 885-5001 (Facsimile)

Approximate date of commencement of proposed sale to the public: As soon as  
practicable after the Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered  
on a delayed or continuous basis pursuant to Rule 415 under the Securities Act  
of 1933, as amended (the "Securities Act"), check the following box. /X/

If this Form is filed to register additional securities for an offering  
pursuant to Rule 462 (b) under the Securities Act, please check the following  
box and list the Securities Act registration statement number of the earlier  
effective registration statement for the same offering. / /

If this Form is a post-effective amendment filed pursuant to Rule 462(c)  
under the Securities Act, check the following box and list the Securities Act  
registration statement number of the earlier effective registration statement  
for the same offering. / /

If this Form is a post-effective amendment filed pursuant to Rule 462(d)  
under the Securities Act, check the following box and list the Securities Act  
registration statement number of the earlier registration statement for the  
same offering. / /

If delivery of the prospectus is expected to be made pursuant to Rule 434  
under the Securities Act, please check the following box. / /

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES  
AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE  
A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT  
SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE  
SECURITIES ACT OR UNTIL THIS REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON  
SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID  
SECTION 8(a), MAY DETERMINE.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION

DATED SEPTEMBER 20, 2000

[GRAPHIC OMITTED]

2,000,000 Shares of Common Stock

\$6.00 per Share

Delcath Systems, Inc. is offering 2,000,000 shares of its common stock. This is our initial public offering and there currently is no public market for our common stock. We expect that the initial public offering price will be \$6.00 per share. The offering price may not reflect the market price of our shares after the offering. We anticipate that our common stock will be listed on the Nasdaq SmallCap Market under the symbol "DCTH."

Investing in the common stock involves risks. See "Risk Factors" beginning on page 6.

	Public Offering Price	Underwriting Discounts and Commissions	Proceeds to Company
Per Share .....	\$ 6.00	\$ .60	\$ 5.40
Total .....	\$12,000,000	\$1,200,000	\$10,800,000

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

We have granted Whale Securities Co., L.P., the representative of the underwriters, a 45-day option to purchase up to an additional 300,000 shares to cover over-allotments. The underwriters are offering the shares on a firm commitment basis. The underwriters expect to deliver the shares to purchasers against payment on \_\_\_\_\_, 2000.

Whale Securities Co., L.P.

, 2000

Notice to California investors: Each purchaser of our common stock in California must be an accredited investor as that term is defined in Rule 501(a) of Regulation D promulgated under the Securities Act of 1933, or satisfy one of the following suitability standards:

- o minimum gross income of \$65,000 and a net worth, exclusive of home, home furnishings and automobiles, of \$250,000; or
- o minimum net worth, exclusive of home, home furnishings and automobiles, of \$500,000.

Notice to Ohio, South Carolina and Washington investors: Each purchaser of our common stock in Ohio, South Carolina and Washington must be an accredited investor as that term is defined in Rule 501(a) of Regulation D promulgated under the Securities Act.

Notice for New Jersey investors: Offers and sales in this offering in New Jersey may only be made to accredited investors as defined in Rule 501(a) of Regulation D under the Securities Act of 1933. Under Rule 501(a) to be an accredited investor an individual must have (a) a net worth or joint net worth with the individual's spouse of more than \$1,000,000 or (b) income of more than \$200,000 in each of the two most recent years or joint income with the individual's spouse of more than \$300,000 in each of those years and a reasonable expectation of reaching the same income level in the current year. Other standards apply to investors who are not individuals. There will be no secondary sales of the securities to persons who are not accredited investors for 90 days after the date of this offering in New Jersey by the underwriter and selected dealers.

## PROSPECTUS SUMMARY

This is a summary of the information contained in this prospectus. To understand this offering fully, you should read the entire prospectus, especially the risk factors.

Unless the context indicates to the contrary, all per share data and information relating to our common stock gives effect to a one-for-2.2881 reverse stock split of our common stock which will occur immediately before the date of this prospectus.

Unless the context indicates to the contrary, the terms "Delcath," "we," "us," and "our" refer to Delcath Systems, Inc.

### Our Business

Delcath has developed a drug-delivery system to isolate the liver from the general circulatory system and to administer chemotherapy and other therapeutic agents directly to the liver. Using the Delcath system, blood flowing into the liver, after being infused with chemotherapy agents, is redirected out of the patient's body, passed through filters which remove most of the chemotherapy agents and then returned to the patient's general circulatory system. Isolating the liver and cleansing the blood before its return into the patient's circulatory system protects other parts of the body from the harmful side-effects of chemotherapy. We believe that the use of the Delcath system in treatment of liver cancer will allow higher dosages of chemotherapy to be administered to the liver than can be administered with conventional intravenous delivery.

The Delcath system is not currently approved for marketing by the United States Food and Drug Administration, and it cannot be marketed in the United States without FDA pre-marketing approval. With the proceeds of this offering, we plan to conduct Phase III clinical trials under protocols which have been approved by the FDA. The Phase III trials will seek to demonstrate the safety and efficacy of the Delcath system in administering the chemotherapy agent, doxorubicin, to treat cancerous tumors that have originated in the liver, commonly known as primary liver cancer, and cancerous tumors from malignant melanoma that have spread to the liver. We believe that the Delcath system may provide cost savings in the treatment of liver cancer to the extent that it can reduce treatment and hospitalization costs associated with the side-effects of chemotherapy.

### Corporate Information

We were incorporated in Delaware on August 5, 1988 under the name BGH Medical Products. On May 7, 1990 we changed our name to Delcath Systems, Inc. Our executive offices are located at 1100 Summer Street, Stamford, Connecticut 06905. Our telephone number at this location is (203) 323-8668. Our web site is located at [www.delcath.com](http://www.delcath.com). Information contained on our web site does not constitute a part of this prospectus.

## The Offering

Common stock offered by  
Delcath..... 2,000,000 shares

Common stock to be outstanding  
after this offering..... 5,437,185 shares

The number of shares of common stock outstanding after this offering includes 1,926,426 shares to be issued immediately before the closing of this offering upon the conversion of all our outstanding convertible preferred stock, including 870,234 shares issued in payment of accumulated dividends as of the date of this prospectus, assuming this offering closes on September 30, 2000;

The number of shares of common stock outstanding after this offering does not include:

- o 559,416 shares reserved for issuance upon the exercise of options granted under our incentive and non-incentive stock option plans, exercisable at a weighted average exercise price of \$3.27 per share;
- o 21,852 shares reserved for issuance upon the exercise of non-plan options exercisable at a price of \$2.29 per share;
- o 21,468 shares reserved for issuance upon exercise of outstanding warrants with exercise prices of \$8.58 and \$11.74 per share;
- o 300,000 shares reserved for issuance upon exercise of options available for future grant under our 2000 stock option plan;
- o 200,000 shares reserved for issuance upon exercise of the representative's warrants; and
- o 300,000 shares reserved for issuance in this offering to cover over-allotments, if any, by the underwriter.

Use of proceeds..... We intend to use the net proceeds of this offering for research and development, introducing our Delcath system into foreign markets and for working capital and general corporate purposes.

Risk factors..... An investment in the common stock is speculative and involves a high degree of risk. You should purchase the shares only if you can afford a complete loss of your investment. You should consider carefully the risks listed in the "Risk Factors" section of this prospectus before making an investment in our shares.

Proposed Nasdaq SmallCap

Market symbol..... DCTH

Summary Financial Data

The following summary financial data as of December 31, 1999, and for the years ended December 31, 1998 and 1999, are derived from our audited financial statements. The summary financial data as of June 30, 2000, and for the six months ended June 30, 1999 and 2000 are derived from our unaudited financial statements. This information should be read in conjunction with the financial statements, including the notes, and "Plan of Operation" appearing elsewhere in this prospectus.

Statement of Operations Data:

	Years Ended December 31,		Six Months Ended June 30,	
	1998	1999	1999	2000
Total costs and expenses .....	\$ 2,124,443	\$ 598,126	\$ 206,182	\$ 404,807
Operating loss .....	(2,124,443)	(598,126)	(206,182)	(404,807)
Net loss .....	(2,049,980)	(572,581)	(200,410)	(391,771)
Net loss per share .....	(2.01)	(.54)	(.19)	(.32)
Weighted average number of shares of common stock outstanding .....	1,021,437	1,062,605	1,042,283	1,239,547

Balance Sheet Data:

The pro forma information gives effect to:

- o the payment in cash of \$496,390 in accumulated preferred stock dividends, assuming this offering closes on September 30, 2000.
- o the borrowing of \$230,000 of short-term indebtedness in August and September 2000.

The as adjusted information gives effect to:

- o the pro forma adjustments and sale of the 2,000,000 shares offered by this prospectus, including the receipt of estimated net proceeds of \$10,000,000 and the repayment of \$230,000 of indebtedness.

	As of	As of June 30, 2000		
	December 31, 1999	Actual	Pro Forma	As Adjusted
Cash and cash equivalents .....	\$561,078	\$417,549	\$151,159	\$10,212,522
Total assets .....	600,821	807,659	541,269	10,311,269
Total liabilities .....	112,748	209,532	439,532	209,532
Stockholders' equity .....	488,073	598,127	101,737	10,101,737

## RISK FACTORS

The shares offered by this prospectus are speculative and involve a high degree of risk. In addition to other information in this prospectus, you should consider carefully the following risks before making an investment decision.

### Risks related to our financial condition

We expect to incur continuing losses and our losses are expected to increase as we begin our Phase III clinical trials.

We expect to incur significant and increasing losses while generating minimal revenues over the next few years. Our future profitability will depend on our ability to successfully complete Phase III clinical trials of our Delcath system, obtain FDA pre-marketing approval for the system and successfully market it in the United States and internationally. From our inception on August 5, 1988 through June 30, 2000, we have incurred cumulative losses of \$11,703,733, substantially all of which were incurred in connection with our product development efforts. For the years ended December 31, 1998 and December 31, 1999 we incurred net losses of \$2,049,980 and \$572,581. If we continue to incur losses we may exhaust our capital resources, including those raised in this offering. In that case, unless we raise additional capital, we may be forced to terminate or curtail operations.

If the proceeds of this offering are not sufficient to complete our Phase III clinical trials and our efforts to raise additional financing are unsuccessful, we will likely be required to cease operations.

Based upon our assumptions, we expect that the net proceeds of this offering will enable us to complete our Phase III clinical trials and obtain FDA pre-marketing approval for the use of doxorubicin with our Delcath system. We cannot assure you that the proceeds of this offering will be sufficient for these purposes because of unanticipated delays or expenses, increased regulatory requirements by the FDA or other factors which we cannot foresee or control. If we do not obtain any financing that we may require, we will not be able to complete Phase III clinical trials and obtain FDA pre-marketing approval for the Delcath system which could result in the cessation of our business and the loss of your entire investment.

If we do not raise the additional capital required to commercialize the Delcath system, our potential to generate future revenues will be significantly limited.

The proceeds of this offering will be insufficient to fund the costs of commercializing the Delcath system. We will require significant additional capital to fund the costs associated with widescale marketing of the Delcath system. We have no commitments for any additional financing. If we are unable to obtain additional financing as needed, we will not be able to sell the system on a commercial scale and our business will be adversely impacted.

### Risks related to FDA and foreign regulatory approval

If Phase III clinical trials prove unsuccessful, we will be unable to obtain FDA pre-marketing approval and will be unable to sell the Delcath system in the United States.

We cannot market or sell the Delcath system in the United States without FDA pre-marketing approval. If Phase III clinical trials are unsuccessful, we will be unable to provide the FDA with the clinical data required to demonstrate that the Delcath system is safe and effective and to obtain approval to market the Delcath system in the United States. If we are unable to market the Delcath system in the United States, it is likely that our business will cease, resulting in the loss of your entire investment.

The FDA may reject the results of our clinical trials in whole or in part, which could result in the FDA refusing to grant marketing approval or limiting the circumstances under which the Delcath system may be used.

Pre-marketing approval requires a determination by the FDA that the data developed by our clinical trials show that the use of doxorubicin in our system is safe and effective in the treatment of primary liver cancer

and melanoma which has spread to the liver. Separate FDA pre-marketing approval is required for the treatment of each of these sources of liver cancer with the Delcath system and one approval is not contingent upon the other. The FDA requires that we demonstrate, for each of primary liver cancer and metastatic melanoma in a statistically rigorous manner, increased patient survival times for approval of our pre-market application. If regulatory approval is granted, approval may require limitations on the indicated uses for which the Delcath system may be marketed. Failure to obtain FDA pre-marketing approval to market the Delcath system, or obtaining FDA pre-marketing approval with substantial limitations on its indicated uses, could result in the cessation of our business and the loss of your entire investment.

If we do not obtain FDA pre-marketing approval, we may not be able to sell the Delcath System in foreign markets, which will limit our sales opportunities.

If we do not obtain FDA pre-marketing approval because our clinical trials are unsuccessful, we may not be able to obtain regulatory approval to market the Delcath system in foreign markets. If the FDA does not approve the Delcath system, we will not be able to export the Delcath system from the United States unless approval has been obtained from one of a number of developed industrialized nations. We have not begun to seek foreign regulatory approval and may not be able to obtain approval from one of those designated nations. If we are unable to market the Delcath system internationally, our market opportunity will be materially limited.

The conduct of Phase III clinical trials and obtaining FDA pre-marketing approval could be delayed. Delay may cause us to exhaust our financial resources prior to launching our product.

We may experience delays in beginning, conducting and completing the trials, caused by many factors, including our limited experience in arranging for clinical trials and in evaluating and submitting the data gathered from clinical trials. Any significant delay in completing clinical trials or in the FDA responding to our submission or a requirement by the FDA for us to conduct additional trials will delay the commercialization of the Delcath System and our ability to generate revenues and may result in our exhausting our financial resources prior to launching our product.

Our dependence on contract research organizations and non-employee physicians to conduct the Phase III clinical trials may jeopardize our successful completion of the trials.

The contract research organizations and physicians conducting the clinical trials are not our employees. As a result, we have limited control over their activities and can expect that only limited amounts of their time will be dedicated to the clinical trials. They may fail to meet their contractual obligations or fail to meet regulatory standards in the performance of their obligations. Failure to perform as expected, including their failure to enroll a sufficient number of patients for our trials could result in the failure of the trials and the failure to obtain FDA pre-marketing approval.

Third-party reimbursement may not be available to purchasers of the Delcath system, or may be inadequate, which would hamper our sales efforts.

Our ability to commercialize the Delcath system in the United States and in foreign markets, if regulatory approval of the system is obtained, will depend, in part, on the extent to which third-party reimbursement for the cost of the Delcath system will be available to purchasers. Physicians, hospitals and other health care providers may be reluctant to purchase our products if they do not receive substantial reimbursement for the cost of the procedures using our products from third-party payors, including Medicare, Medicaid and private health insurance plans.

Because the Delcath system currently is characterized by the FDA as an experimental device, its use is not reimbursable in the United States. We will not begin to seek to have third-party payors reimburse the use of the Delcath system until after its use is approved by the FDA. Each third-party payor independently determines whether and to what extent to reimburse for a medical procedure or product. We cannot assure you that third-party payors in the United States or abroad will cover procedures using the Delcath system. Further,



third-party payors may deny reimbursement if they determine that the Delcath system was not used in accordance with established payor protocols regarding cost effective treatment methods, or was used for forms of cancer or with drugs not specifically approved by the FDA.

Risks related to manufacturing, commercialization and market acceptance of the Delcath system

We obtain necessary components from sole-source suppliers. Because manufacturers must demonstrate compliance with FDA specifications, if we change any supplier, the successful completion of the clinical trials and/or the commercialization of the Delcath system could be jeopardized.

Many of the components of the Delcath system are manufactured by sole source suppliers. If any of our suppliers fail to meet our needs, or if we are forced for any reason to seek an alternate source of supply, we may be forced to suspend or terminate our Phase III trials. Further, if we need a new source of supply after commercial introduction of the Delcath System, we may face long interruptions in obtaining necessary components, which interruptions could jeopardize our ability to supply the Delcath System to the market. Any new supplier must demonstrate to the FDA that its components are manufactured in accordance with manufacturing and performance specifications of the Delcath system on file with the FDA.

We do not have any contracts with suppliers for the manufacture of components for the Delcath system and we may encounter difficulties in obtaining adequate supplies of components.

We do not have any contracts with suppliers for the manufacture of components for the Delcath system. To date, we have only had components of the Delcath system manufactured for us in small quantities for use in pre-clinical studies and clinical trials. We will require greater quantities for the Phase III clinical trials and significantly greater quantities to commercialize the product. If we are unable to obtain adequate supplies of components from our existing suppliers, or need to switch to an alternate supplier, the completion of our clinical trials and commercialization of the Delcath system could be delayed.

We may not be able to acquire a significant share of the market because of the numerous cancer treatment alternatives and the strength of our competitors, and therefore may not be able to achieve meaningful revenues or profitability.

The Delcath system competes with all forms of liver cancer treatments which are alternatives to resection, or surgical removal, of the tumor, including intravenous chemotherapy treatment, radiation, targeted chemotherapy delivery through implanted infusion pumps and radio frequency waves. Many of our competitors have substantially greater financial, technological, research and development, marketing and personnel resources. In addition, some of our competitors have considerable experience in conducting clinical trials and other regulatory approval procedures. Our competitors may develop more efficacious or more affordable products or treatment methods, or achieve earlier product development, patent protection, in which case our chances to achieve meaningful revenues or profitability will be substantially limited.

Risks related to this offering, our share price and corporate control

Your investment will be subject to immediate dilution of 69.0%.

Following this offering the net tangible book value of a share of common stock will be \$1.86 and you will have paid \$6.00 per share. As a result, you will experience immediate and substantial dilution of \$4.14 per share, or 69.0%, between the net tangible book value per share of common stock after this offering and the initial public offering price per share. This dilution is due to the fact that our earlier investors paid less than the initial public offering price when they purchased their shares of common stock and because we have incurred losses since our inception.

Because we currently have no specific use for a substantial portion of the net proceeds from this offering there is a greater risk that they may not be used effectively.

Approximately \$2,000,000 (20.0%) of the net proceeds from this offering have been allocated to working capital and general corporate purposes. Additionally, the anticipated application of the net proceeds is only an estimate and may be adjusted from time to time as our management determines to be appropriate. Accordingly, we will have broad discretion as to the use of the net proceeds, including uses with which the stockholders may not agree.

CAUTIONARY STATEMENT REGARDING  
FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. These statements relate to future events or our future financial performance, objectives, expectations and intentions. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other comparable terminology. These statements involve known and unknown risks, unknown certainties and other factors, including the risks outlined under "Risk Factors," that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. You should not place undue reliance on forward-looking statements in this prospectus which speak only as of the date they are made.

USE OF PROCEEDS

The net proceeds to Delcath from the sale of shares being offered by this prospectus, after deducting the underwriting discount and estimated expenses of this offering, are estimated to be \$10,000,000.

We expect to use these net proceeds approximately as follows:

Application of Net Proceeds	Approximate Dollar Amount	Approximate Percentage of Net Proceeds
-----		
Research and development:		
Phase III clinical trials using the Delcath system with doxorubicin .....	\$ 6,500,000	65.0%
Research and development stage clinical trials for other chemotherapy agents .....	600,000	6.0
Reduce the cost of the Delcath filtration system .....	400,000	4.0
Introduce the Delcath system into foreign markets .....	500,000	5.0
Repayment of indebtedness .....	270,000	2.7
Working capital and general corporate purposes .....	1,730,000	17.3
	-----	-----
Total .....	\$ 10,000,000	100.0%
	=====	=====

Phase III clinical trials using the Delcath system with doxorubicin. These costs represent:

- o the costs of recruiting medical centers to conduct the trials and patients to participate in the trials;
- o the costs of treating patients, including the costs of the Delcath system and payments for unreimbursed medical expenses for patients receiving treatment with the system; and
- o the costs of approximately \$950,000 for the fees and expenses of the clinical research organization which we anticipate hiring to conduct the trials, collect and process the data and prepare and file a pre-market approval application and approximately \$550,000 for associated overhead, including the costs of additional personnel and consultants.

We estimate that the average costs to treat a patient will be under \$20,000, and we expect to treat up to 274 patients.

Research and development stage clinical trials for other chemotherapy agents. This amount represents the costs of conducting research and development stage clinical trials for the use of other chemotherapy agents with the Delcath system for the treatment of liver cancer. These costs represent the costs of non-animal testing, animal testing, testing with humans, monitoring the testing and collecting and processing data. Additional financing will be required to conduct Phase II and III clinical trials.

Reduce the cost of the Delcath filtration system. This amount represents the costs to design, develop and test a filter which will cost less than the third-party filter currently used in the Delcath system and include the salaries of an engineer and technician.

Introduce the Delcath system into foreign markets. These costs represent the salaries of five employees to be hired, travel and promotional material to establish alliances with leading hospitals in countries being targeted and enlist their support in obtaining regulatory approval in their territories and to establish strategic partnerships with domestic and/or foreign marketing firms.

Repayment of indebtedness. Represents amounts to be used to repay \$230,000 principal amount of promissory notes plus interest. These notes were issued in August and September 2000, bear interest at an annual rate of 22% and are due May 27, 2001. We are using the proceeds of these loans for working capital.

Working capital and general corporate purposes. These costs include general and administrative costs, including the salaries of our executive officers. Pending the above uses, the net proceeds of this offering will be invested in short-term, interest-bearing, investment-grade securities.

If the representative exercises the over-allotment option in full, we will realize additional net proceeds of \$1,566,000, which will be added to working capital purposes.

The above allocation represents our best estimate of the allocation of the net proceeds of this offering based upon the current status of our business. We based this estimate on assumptions, including that the Delcath system will have obtained FDA pre-marketing approval within 24 months from the closing of this offering. If any of these factors change, we may find it necessary to reallocate a portion of the proceeds within the above described categories or use portions of the proceeds for other purposes. Our estimates may prove to be inaccurate, new programs or activities may be undertaken which will require considerable additional expenditures or unforeseen expenses may occur.

Based upon our current plans and assumptions relating to our business plan, we anticipate that the net proceeds of this offering will satisfy our capital requirements for at least 12 months following the closing of this offering. If our plans change or our assumptions prove to be inaccurate, we may need to seek additional financing sooner than currently anticipated or curtail our operations. We cannot assure you that the proceeds of this offering 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.

We will invest proceeds not immediately required for the purposes described above principally in United States government securities, short-term certificates of deposit, money market funds or other short-term interest-bearing investments.

DILUTION

The difference between the initial public offering price per share and the net tangible book value per share of common stock after this offering constitutes the dilution to investors in this offering. Net tangible book value per share is determined by dividing total tangible assets less total liabilities by the number of outstanding shares of common stock.

At June 30, 2000, we had a net tangible book value of \$306,764 or \$.22 per share. At June 30, 2000, our net tangible book value deficit would have been (\$189,626) or (\$.06) per share after giving pro forma effect to:

- o the conversion of all outstanding shares of our convertible preferred stock into 1,056,192 shares of common stock;
- o the payment of \$1,489,170 of estimated accumulated dividends assuming this offering closes on September 30, 2000 through the issuance of 870,234 shares of common stock and the payment of \$496,390 of estimated accumulated dividends in cash;
- o the issuance of 125,000 shares to Morse, Zelnick, Rose and Lander LLP for legal services, at the date of this prospectus.

After also giving effect to the sale of the 2,000,000 shares being offered at an initial public offering price of \$6.00 per share and after deducting estimated underwriting discounts and expenses of this offering, our adjusted net tangible book value at June 30, 2000 would have been \$10,101,737 or \$1.86 per share, representing an immediate increase in net tangible book value of \$1.92 per share to the existing stockholders and an immediate dilution of \$4.14 or 69.0% per share to new investors.

The following table illustrates the above information with respect to dilution to new investors on a per share basis:

Initial public offering price .....		\$ 6.00
Pro forma net tangible book value deficit at June 30, 2000 .....	\$(.06)	
Increase in pro forma net tangible book value attributable to new investors .....	1.92	
	-----	
Adjusted pro forma net tangible book value after offering .....		1.86
		-----
Dilution to new investors .....		\$ 4.14
		=====

The following table sets forth, on a pro forma basis as of June 30, 2000, with respect to our existing stockholders and new investors, a comparison of the number of shares of common stock we issued, the percentage ownership of those shares, the total consideration paid, the percentage of total consideration paid and the average price per share.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders .....	3,437,185	63.2%	\$10,566,686	46.8%	\$ 3.07
New investors .....	2,000,000	36.8	12,000,000	53.2	6.00
Total .....	5,437,185	100.0%	\$22,566,686	100.0%	
	=====	=====	=====	=====	

The above table assumes no exercise of the underwriter's over-allotment option. If the representative exercises the over-allotment option in full, we estimate that the new investors will have paid \$13,800,000 for the 2,300,000 shares of common stock being offered, representing approximately 56.6% of the total consideration for 40.1% of the total number of shares of common stock outstanding. In addition, the above table does not give effect to the shares issuable upon exercise of outstanding options and warrants. To the extent that any of these options or warrants are exercised, there will be further dilution to the new investors.

## DIVIDEND POLICY

We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future. We currently intend to retain all earnings for use in connection with the expansion of our business and for general corporate purposes. Our board of directors will have the sole discretion in determining whether to declare and pay dividends in the future. The declaration of dividends will depend on our profitability, financial condition, cash requirements, future prospects and other factors deemed relevant by our board of directors. Our ability to pay cash dividends in the future could be limited or prohibited by the terms of financing agreements that we may enter into or by the terms of any preferred stock that we may authorize and issue.

## CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2000:

- o on an actual basis;
- o on a pro forma basis to reflect:
  - o the issuance of 1,056,192 shares upon conversion of all of our preferred stock;
  - o the issuance of 870,234 shares as payment of \$992,780 of estimated accumulated dividends on our preferred stock as of the date of this prospectus, assuming this offering closes on September 30, 2000;
  - o the payment of \$496,390 for the remaining accumulated dividends on our preferred stock as of the date of this prospectus, assuming this offering closes on September 30, 2000;
  - o the issuance of 125,000 shares to Morse, Zelnick, Rose and Lander LLP for legal services, at the date of this prospectus which will be charged to paid-in capital as an expense of this offering; and
- o on an as adjusted basis to give effect to the pro forma adjustments and to the sale of shares, at an assumed initial public offering price of \$6.00 per share, after deducting the underwriting discounts and estimated offering expenses payable by us.

The following table excludes from the common stock outstanding 602,736 shares of common stock reserved for issuance upon exercise of outstanding options and warrants.

	June 30, 2000		
	Actual	Pro Forma	As Adjusted
Long-term debt .....	\$ 0	\$ 0	\$ 0
Stockholders' equity:			
Class A convertible preferred stock, par value \$.01; 5,000,000 shares authorized, 2,000,000 issued and outstanding (actual); no shares issued or outstanding (pro forma and as adjusted) .....	20,000	--	--
Class B convertible preferred stock, par value \$.01; 5,000,000 shares authorized, 416,675 shares issued and outstanding (actual); no shares issued or outstanding (pro forma and as adjusted) .....	4,167	--	--
Common stock, par value \$.01; 15,000,000 shares authorized, 1,385,759 shares issued and outstanding (actual); 3,437,185 and 5,437,185 shares issued and outstanding (pro forma and as adjusted) .....	13,857	34,371	54,371
Additional paid-in capital .....	12,263,836	13,260,270	23,240,270
Accumulated deficit .....	(11,703,733)	(13,192,904)	(13,192,904)
Total stockholders' equity .....	\$ 598,127	\$ 101,737	\$ 10,101,737
Total capitalization .....	\$ 598,127	\$ 101,737	\$ 10,101,737

SELECTED FINANCIAL DATA

The selected financial data set forth below should be read in conjunction with Management's "Plan of Operation" included elsewhere in this prospectus. The operating data for each of the years in the two-year period ended December 31, 1999 and for the period from inception through December 31, 1999, and the balance sheet data at December 31, 1999, are derived from our financial statements which have been audited by KPMG LLP, independent accountants, and are included in this prospectus. The operating data for the six month periods ended June 30, 1999 and 2000 and for the period from inception through June 30, 2000 and the balance sheet data as at June 30, 2000 are derived from our unaudited financial statements. The unaudited financial statements have been prepared on substantially the same basis as the audited financial statements and, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for the fair presentation of the results of operations for these periods. Historical results are not necessarily indicative of the results to be expected in the future, and the results of interim periods are not necessarily indicative of results for the entire year.

Operating Data:

	Years Ended December 31,	
	1998	1999
Costs and expenses:		
Legal, consulting and accounting .....	\$ 574,299	\$ 626,366
Stock option compensation expense (reversal) .....	759,229	(456,185)
Compensation and related expenses .....	466,644	200,128
Other operating expenses .....	324,271	227,817
Total costs and expenses .....	2,124,443	598,126
Operating loss .....	(2,124,443)	(598,126)
Interest income .....	74,463	43,470
Interest expense .....	--	(17,925)
Net loss .....	\$ (2,049,980)	\$ (572,581)
Net loss per share .....	\$ (2.01)	\$ (.54)
Weighted average number of shares of common stock outstanding .....	1,021,437	1,062,605

	Cumulative from Inception (August 5, 1988) to December 31, 1999	Six Months Ended June 30,		Cumulative from Inception (August 5, 1988) to June 30, 2000
		1999	2000	
<b>Costs and expenses:</b>				
Legal, consulting and accounting .....	\$ 4,517,169	\$ 389,253	\$ 172,926	\$ 4,690,095
Stock option compensation expense (reversal) .....	2,520,170	(456,185)	--	2,520,170
Compensation and related expenses .....	2,488,170	123,733	104,765	2,592,935
Other operating expenses .....	2,191,276	149,381	127,116	2,318,392
<b>Total costs and expenses .....</b>	<b>11,716,785</b>	<b>206,182</b>	<b>404,807</b>	<b>12,121,592</b>
<b>Operating loss .....</b>	<b>(11,716,785)</b>	<b>(206,182)</b>	<b>(404,807)</b>	<b>(12,121,592)</b>
Interest income .....	537,696	23,697	13,036	550,732
Interest expense .....	(132,873)	(17,925)	--	(132,873)
<b>Net loss .....</b>	<b>\$ (11,311,962)</b>	<b>\$ (200,410)</b>	<b>\$ (391,771)</b>	<b>\$ (11,703,733)</b>
<b>Net loss per share .....</b>		<b>\$ (.19)</b>	<b>\$ (.32)</b>	
<b>Weighted average number of shares of common stock out- standing .....</b>		<b>1,042,283</b>	<b>1,239,547</b>	

**Balance Sheet Data:**

	As of December 31, 1999	As of June 30, 2000
Cash and cash equivalents .....	\$561,078	\$417,549
Total assets .....	600,821	807,659
Total liabilities .....	112,748	209,532
Stockholders' equity .....	488,073	598,127



## PLAN OF OPERATION

### Background

We were 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. To date, we have 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 \$391,771 for the six months ended June 30, 2000. Cumulative losses from inception through June 30, 2000 were \$11,703,733. Losses have continued through the date of this prospectus. 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 June 30, 2000 totaled \$2,520,170.

### Liquidity and Capital Resources

We have financed our operations to date primarily through private placements of our common and preferred stock. Through June 30, 2000, we raised \$9,816,686 through the sale of our class A preferred stock, class B preferred stock and common stock. Cash used to fund operations from inception through June 30, 2000 was \$8,981,127. Our cash and cash equivalents totaled \$417,549 at June 30, 2000, a decrease of \$143,529 from December 31, 1999.

Since January 1, 1998, our principal source of cash has been the following financing transactions:

- o In January 1998, we sold 43,704 shares of common stock at a price of \$11.44 per share to Johnson & Johnson Development Corporation, and received proceeds of \$500,000.
- o In April 1998, we issued 10,926 shares of common stock upon exercise of options at a price of \$6.18 per share for proceeds of \$67,500.
- o In September 1998, we sold 4,370 shares of common stock to an individual at a price of \$13.04 per share and received proceeds of \$57,000.
- o In April 1999, we issued 2,913 shares of common stock upon exercise of warrants at a price of \$8.58 per share, and received proceeds of \$24,998.
- o In June 1999, we sold 59,514 shares of common stock at a price of \$13.04 per share and received proceeds of \$776,192.
- o In April 2000, we sold 292,426 shares of common stock at a price of \$1.72 per share, as part of a rights offering to our existing stockholders and option holders, and received proceeds of \$501,825.
- o In August and September 2000, we 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.

Over the next 12 months, we expect to continue to incur expenses related to the research and development of our technology, including:

- o phase III clinical trials using doxorubicin with the Delcath system.
- o pre-clinical and clinical trials for the use of other chemotherapy agents with the Delcath system for the treatment of liver cancer; and

- o the development of additional products and components, in particular a filter which will be more affordable than the third-party filter currently used in the Delcath system.

We expect to begin doxorubicin trials during the first 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 \$150,000 in computer, laboratory and testing equipment, primarily for testing of a lower cost filter. We also expect to hire approximately 12 additional employees in the areas of research and development, regulatory and clinical management, marketing and administrative functions at an estimated annual expense of \$600,000. The number and timing of such hiring will vary depending upon the success of the international marketing efforts and progress of the clinical trials.

Immediately prior to the closing of this offering, all of our preferred stock will convert into shares of common stock. As part of this conversion, the preferred stockholders will receive an estimated 870,234 shares of common stock and \$496,390 in cash in payment of accumulated dividends, assuming the offering closes on September 30, 2000.

We believe that existing cash and cash equivalents, together with net proceeds of approximately \$10,000,000 from this offering, will be sufficient to finance our operations for at least twelve months from the date of this prospectus. Our future liquidity and capital requirements, however, will depend on numerous factors, including:

- o the progress of our research and product development programs, including clinical studies;
- o the timing and costs of various United States and foreign regulatory filings;
- o the timing and effectiveness of product commercialization activities, including marketing arrangements overseas;
- o the timing and costs involved in obtaining regulatory approvals, if ever, and complying with regulatory requirements;
- o the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and
- o the effect of competing technological and market developments.

If the proceeds of this 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 the proceeds of this offering 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.

## Overview

Delcath has developed a system, the Delcath system, to isolate the liver from the general circulatory system and to administer chemotherapy and other therapeutic agents directly to the liver.

The Delcath system is not currently approved for marketing by the United States Food and Drug Administration, and it cannot be marketed in the United States without FDA pre-marketing approval. With the proceeds of this offering, we plan to conduct Phase III clinical trials designed to secure marketing approval for the system in the United States and possibly in foreign markets.

Delcath was originally formed by a team of physicians on August 5, 1988 as BGH Medical Products, Inc., a Delaware corporation. On August 22, 1988, BGH Medical Products Inc., a Connecticut corporation, was merged into it. On May 7, 1990, the surviving Delaware corporation changed its name to Delcath Systems, Inc.

## Strategy

Our objective is to establish the use of the Delcath system as the standard technique for delivering chemotherapy agents to the liver and to expand the Delcath technology so that it may be used in the treatment of other liver diseases and of cancers in other parts of the body. Our strategy includes the following:

- o Complete clinical trials to obtain FDA pre-marketing approval for use of the Delcath system with doxorubicin to treat primary liver cancer and malignant melanoma that has spread to the liver. Our highest priority is completing the Phase III clinical trials, data preparation, statistical analysis and regulatory documents associated with an application for pre-market approval of commercial sale of the Delcath system in the United States. FDA pre-marketing approval of our application will permit us to market the Delcath system to administer doxorubicin in the treatment of primary liver cancer and melanoma that has spread to the liver.
- o Obtain approval to market the Delcath system in the United States for the treatment of other forms of liver cancer using other chemotherapy agents and treatment of hepatitis using anti-viral drugs. In addition to researching the use of other chemotherapeutic agents with the Delcath system to treat cancer, we plan to research the use of other compounds with the Delcath system to treat other diseases, such as hepatitis. Our timing to begin these studies will depend on our ability to establish strategic alliances with pharmaceutical manufacturers or other strategic partners in conjunction with our research into other therapeutic compounds or raise additional funds for these purposes. FDA pre-marketing approval will be required to market the Delcath system for these uses.
- o Introducing the Delcath system into foreign markets. We will seek to establish strategic relationships with domestic and foreign firms that have recognized presence or experience in foreign markets that we intend to target. Our strategy is to focus on markets that have a high incidence of liver cancer and the means to provide and pay for cancer treatments. According to the World Health Organization, many Asian and European countries, including China, Japan, Hong Kong, the Philippines, France, Germany, Italy and Spain have a higher incidence of liver cancer than the United States. We intend to seek to enter into arrangements with strategic partners who have experience with obtaining regulatory approval or marketing medical devices in those markets.
- o Reduce the cost of the Delcath system's filtration system. The filters we currently use to detoxify blood outside the body comprise a significant portion of the cost of the Delcath system kit. We are researching technologies which may enable filters to be produced at a lower cost.
- o Leverage our core double balloon catheter technology to expand our product offerings to include systems for administering chemotherapy agents in other parts of the body. Early studies have indicated that the same principles employed in liver isolation may be applied to other organs. By

modifying the catheter, including the spacing, size and number of the balloons, the Delcath system initially may be adapted for use in treatment of cancers in other areas of the body, including the limbs, kidneys, lungs, and other organs of the abdominal cavity. Future studies may investigate the use of the Delcath system in other organs as well.

We have not yet begun to conduct this research and do not intend to do so until we obtain additional financing or enter strategic relationships.

#### The Cancer Treatment Market

The American Cancer Society projects that about 1,200,000 Americans will be diagnosed with cancer in 2000. According to the American Cancer Society's "Cancer Facts and Figures -- 2000", cancer remains the second leading cause of death in the United States. While researchers continue to develop innovative new treatments for some forms of this disease, surgical resection, chemotherapy, radiation and hormone therapy continue to be the most commonly used treatments.

The financial burden of cancer is great for patients, their families and society. The National Cancer Institute, in the American Cancer Society's "Facts and Figures," estimates the overall costs of cancer to be \$107 billion, including \$37 billion in direct medical costs, \$11 billion for indirect morbidity costs attributable to lost productivity due to illness, and \$59 billion for indirect mortality costs attributable to lost productivity due to death.

#### The Liver Cancer Market

Liver cancer is one of the most prevalent and lethal forms of cancer throughout the world. There are two forms of liver cancer: primary and metastatic. Primary liver cancer originates in the liver. Secondary, or metastatic, liver cancer results from the spread of cancer from other places in the body to the liver. In the liver, tumors can be surgically removed only when they are located in one of the liver's two lobes. According to a January 3, 2000 article on liver cancer in the Houston Chronicle, an estimated 75% of cancerous liver tumors cannot be surgically removed at the time of diagnosis. A significant number of patients treated for primary and metastatic liver cancer will experience a recurrence of their disease.

Metastatic liver cancer is characterized by microscopic pieces of other forms of cancer that detach from the primary site and travel via the blood stream and lymphatic system into the liver, where they grow into new tumors. This growth often continues even after removal of the primary cancer or cancerous organ. When cancer cells enter the liver and develop into tumors, they tend to grow very quickly. In many cases, the patient dies not from the primary cancer, but from the tumors in the liver; the liver becomes the "life limiting organ." People cannot survive without a liver capable of performing its critical biologic functions: facilitating the conversion of food into energy and filtering toxic agents from the blood. The liver is one of the three most common sites to which cancer may spread. Due to numerous factors, including the absence of viable treatment options, metastatic liver cancer often causes death.

According to a recent report, liver cancer is the third most common form of cancer worldwide. The worldwide incidence of primary liver cancer is estimated to be 1,000,000 new patients each year and there are an estimated 1,250,000 deaths worldwide caused by all forms of liver cancer. According to a 1999 article in the New England Journal of Medicine, researchers reported that annual new diagnoses of liver cancer increased from 1.4 cases per 100,000 persons in the late 1970s to 2.4 cases per 100,000 persons in the 1990s. The American Cancer Society has projected that in the United States there will be approximately 15,300 new cases of primary liver cancer and 47,700 new cases of malignant melanoma in 2000.

Liver cancer is among the most virulent forms of cancer. In the United States, five-year survival rates are usually less than 10%, according to the National Cancer Institute.

Primary liver cancer is particularly prevalent in Southern Europe, Asia and developing countries, where the primary risk factors for the disease are present. These risk factors include: hepatitis-B, hepatitis-C, relatively high levels of alcohol consumption, aflatoxin, cigarette smoking and exposure to industrial pollutants.

Our current product is designed to treat primary liver cancer and melanoma which has spread to the liver.

## Liver Cancer Treatments

The prognosis for primary and secondary liver cancers is poor. Although limited treatment options are currently available for liver cancer, they are typically ineffective, are generally associated with significant side-effects and can even cause death. Traditional treatment options include surgery, chemotherapy, cryosurgery, percutaneous ethanol injection and radiation.

### Surgery

While surgery is considered the "gold standard" treatment option to address liver tumors, an estimated 75% of liver cancer patients are unresectable, which means they do not qualify for surgical removal. This is most often due to the following:

- o Operative risk: limited liver function or poor patient health threatens survival as a result of the surgery; or
- o Technical feasibility: the proximity of a cancerous tumor to a critical organ or artery, or the size, location on the liver or number of tumors makes surgery not feasible.

For the few patients who qualify for surgery, there are significant complications related to the procedure. Recurrence of tumors is common and in that event, surgery typically cannot be repeated.

We believe that delivery of drugs with the Delcath system may enable surgical resection in some of the cases which are currently inoperable by reducing the size and number of tumors sufficiently to make resection feasible. Shrinking a tumor using chemotherapy and then removing the tumor is a procedure known as adjuvant therapy. After resection, chemotherapy can be administered through the Delcath system with the objective of destroying micrometastases in the liver that may remain undetected, thus preventing or delaying any recurrence of tumor growth.

### Chemotherapy

The most prevalent form of liver cancer treatment is intravenous chemotherapy. The effectiveness of this treatment, however, is limited by its side-effects. Generally, the higher the dosage of chemotherapy administered, the greater its ability to kill cancer cells. However, due to the toxic nature of chemotherapy agents, the higher the dosage administered, the greater damage chemotherapy agents cause to healthy tissues. As a result, the dosage of chemotherapy required to kill cancer cells can be lethal to patients.

The side-effects caused by doxorubicin, the drug we are seeking to have approved for use in the Delcath system, is representative of the side-effects associated with many chemotherapy agents. Doxorubicin causes irreversible heart tissue damage. Depending on dosage levels, the damage caused by doxorubicin can be serious and lead to congestive heart failure. Doxorubicin can also cause severe mucositis leading to ulceration of the mouth and digestive organs, damage to a patient's immune system through destruction of bone marrow cells, as well as acute nausea, severe vomiting, dermatological problems and hair loss. The use of doxorubicin can be fatal even when it is administered with careful patient monitoring.

The limited effectiveness of intravenous chemotherapy treatment and its debilitating, often life-threatening side-effects makes the decision to undergo chemotherapy treatment difficult. In some instances, in an attempt to shrink tumors, a physician may prescribe a radically high-dose of chemotherapy, despite its side-effects. In other cases, recognizing the inevitable result of liver cancer, the physician and patient choose only to manage the patient's discomfort from cancer with pain killers while foregoing treatment.

To address this trade-off between the efficacy of intravenous chemotherapy treatment and its dire side-effects, physicians have experimented with techniques to isolate the liver from the general circulatory system and to achieve a targeted delivery of chemotherapy agents to the liver. In the 1980s, a physician developed a procedure in which he surgically diverted the blood flow from the liver while infusing high dosages of chemotherapy agents into the liver. A filtration circuit reduced drug concentrations before returning the diverted blood to the patient. The treatment, however, was not embraced by the medical community because it is highly invasive, resulting in prolonged recovery times, long hospital stays and excessive costs.

Other physicians have experimented with the delivery of chemotherapy agents to the liver by catheter, attempting to use one or more catheters to remove chemotherapy agents before they enter the general circulatory system. We are unaware of any system, however, which contains the patented attributes of the Delcath design.

#### Cryosurgery

Cryosurgery is the destruction of cancer cells using sub-zero temperatures in an open surgical procedure. During cryosurgery, multiple stainless steel probes are placed into the center of the tumor and liquid nitrogen is circulated through the end of the device, creating an iceball. Cryosurgery involves a cycle of treatments in which the tumor is frozen, allowed to thaw and then refrozen.

While cryosurgery is considered to be relatively effective, we believe adoption of this procedure has been limited because:

- o It is not an option for patients who cannot tolerate an open surgical procedure;
- o It involves significant complications which are similar to other open surgical procedures, as well as liver fracture and hemorrhaging caused by the cycle of freezing and thawing;
- o It is associated with mortality rates estimated to be between one and five percent; and
- o It is expensive compared to other alternatives.

#### Percutaneous Ethanol Injection

Percutaneous ethanol injection, or PEI, involves the injection of alcohol into the center of the tumor. The alcohol causes cells to dry out and cellular proteins to disintegrate, ultimately leading to tumor cell death.

While PEI can be successful in treating some patients with primary liver cancer, it is generally considered ineffective on large tumors as well as metastatic tumors. Patients are required to receive multiple treatments, making this option unattractive for many patients. Complications include pain and alcohol introduction to bile ducts and major blood vessels. In addition, this procedure can cause cancer cells to be deposited along the needle tract when the needle is withdrawn.

#### Radiation Therapy

Radiation therapy uses high dose x-rays to kill cancer cells. Radiation therapy is not considered an effective means of treating liver cancer and is rarely used for this purpose. Radiation is often used as an adjunct to other cancer treatments.

#### Implanted Infusion Pumps

Implanted Infusion Pumps can be used to better target the delivery of chemotherapy agents to the tumor. Arrow International markets an implantable pump typically used to treat colorectal cancer which has metastasized to the liver. This pump, however, lacks a means of preventing the entry of chemotherapy agents into the patient's general circulation after it passes through the liver. This technique does not enable physicians to prescribe higher doses of chemotherapy.

#### Other Methods of Treatment

Still other liver cancer treatments include: liver transplants, embolization, tumor ablation through the use of radio frequency waves and the use of biological response modulators, monoclonal antibodies and liposomes. The effectiveness of these treatments is limited, many have dose limiting side-effects, and none is widely used.

The Delcath system is designed to address the critical shortcomings of conventional intravenous chemotherapy delivery. The Delcath system isolates the liver from the general circulatory system during liver cancer treatments with chemotherapy and then returns the blood exiting the liver to the general circulatory system only after the chemotherapy agent has been substantially removed by filtration outside the body. We believe that such protection from the side-effects of chemotherapy, that is provided by the Delcath system to other parts of the body, allows for higher chemotherapy doses to be administered to the liver than can be administered by conventional intravenous delivery. By filtering out a substantial portion of the chemotherapy agent before the blood is returned to the blood stream, other organs of the body receive less exposure than the liver to the chemotherapy agent. Therefore, these organs are less likely to suffer from the harmful side-effects of chemotherapy, including the cumulative harmful effect that doxorubicin has on the heart muscle.

The Delcath system kit includes the following disposable components:

- o Infusion catheter -- a thin-walled arterial infusion catheter used to deliver chemotherapy to the liver;
- o Double balloon catheter -- a multi-passageway catheter used to isolate and divert the drug-laden blood exiting the liver;
- o Extracorporeal filtration circuit -- a blood tubing circuit incorporating the disposable components used with a blood pump to push the isolated blood through the system's filters and guide the cleansed blood back to the patient;
- o Filters -- activated carbon blood filters used to remove most of the chemotherapy agent from the isolated blood after it has flowed through the liver and before it returns to the patient's general circulation; and
- o Return catheter -- a thin-walled blood sheath used to deliver the filtered blood from the extracorporeal filtration circuit back into one of the major veins returning blood to the right atrium of the heart.

The double balloon catheter has one large passageway and three smaller passageways. Each of two low-pressure balloons is inflated through one of the three smaller passageways. Blood flows out of the liver through the large passageway to the filtration system. A separate access port attaches to the large passageway and is designed for sampling fluid or flushing the system. The third smaller passageway allows blood exiting the legs and kidneys to bypass the liver and return to the heart.

The Delcath procedure involves a series of three catheter insertions, each of which is made through the skin. During test procedures, patients are treated with intravenous sedation and local anesthesia at catheter insertion sites. In some cases general anesthesia has been used. An infusion catheter is inserted into the artery through which blood normally flows to the liver. A second catheter -- the Delcath double balloon catheter -- is inserted through the inferior vena cava. The balloons on the double balloon catheter are then inflated. This procedure prevents the normal flow of blood from the liver to the heart through the inferior vena cava because the inferior vena cava has been blocked. A chemotherapy agent is then infused into the liver through the infusion catheter. The infused blood is prevented from flowing to the heart, but exits the liver through perforations on the double balloon catheter and flows through this catheter out of the body where the infused blood is pumped through activated charcoal filters to remove most of the chemotherapy agent. The filtered blood is returned to the patient through the jugular vein which leads to the superior vena cava and the heart, thus restoring the cleansed blood to normal circulation. Infusion is administered over a period of 30 minutes. Filtration occurs during infusion and for 30 minutes afterward. The catheters are removed and manual pressure is maintained on the catheter puncture sites for approximately 15 minutes. The entire procedure takes approximately two to three hours to administer.

During Phase I and II clinical trials, patients remained in the hospital overnight for observation after undergoing treatment with the Delcath system. Once physicians become familiar with using the Delcath system, we expect the procedure to be performed on an outpatient basis, with the patient resuming normal activities the day after the procedure is performed. We expect a patient to undergo an average of four treatments, one every three weeks. A new Delcath system kit is used for each treatment.

Integral to our research and development efforts is our program of clinical research with prominent researchers and physicians conducted at Yale University, M.D. Anderson Cancer Center, and the Robert Wood Johnson Medical School/Cancer Institute of New Jersey.

## Our Phase III Clinical Trials

Phase III human clinical trials are a prerequisite for FDA pre-marketing approval of Delcath's pre-marketing application. During these trials, administration of doxorubicin through the Delcath system must be proven to be safe and effective for the treatment of liver cancer. The FDA requires us to demonstrate that delivering doxorubicin using the Delcath system results in patient survival times that are longer than those obtained from administering chemotherapy agents intravenously.

We have conducted Phase I and II human clinical trials at three United States medical centers under investigational device and investigational new drug exemptions granted by the FDA. The trials were designed to demonstrate the system's "functionality," or its ability to administer to and extract from the liver approved and marketed chemotherapy agents. Forty-four patients participated in the trials. Twenty-one of these test subjects had primary liver cancer or melanoma which had spread to the liver and were treated with doxorubicin. The remaining 23 test subjects suffered from other forms of liver cancer, and/or were treated with another chemotherapy agent, 5-FU. These trials demonstrated that the Delcath system was capable of extracting approximately 70% to 85% of the chemotherapy agent administered to the liver. Therefore, the Delcath system permits the delivery of higher dosages of chemotherapy agents to the cancer site.

We believe the results of the clinical trials we have conducted indicate that the Delcath system delivered:

- o more chemotherapy agent to the tumor site; and
- o less chemotherapy agent to the general circulation than delivered by administration of the same dose by intravenous means.

In addition, clinicians involved in the Phase I and Phase II clinical trials observed:

- o reduction in tumor size; and
- o the safety of the system at higher dosage levels of chemotherapy than those used in conventional intravenous chemotherapy delivery.

Further, though not demonstrated in a statistically significant manner because of the limited number of patients, clinicians observed survival times of patients treated with the Delcath system which exceeded those that would generally be expected in patients receiving chemotherapy treatment through conventional intravenous means of delivery.

Based on the results of our Phase I and Phase II clinical trials, we submitted to the FDA our application for pre-market approval of the Delcath system as a medical device. In response to our application, the FDA classified the Delcath system as a drug delivery system and requires us to obtain approval of a new drug application, or a supplemental new drug application, for the chemotherapy agent being administered by the Delcath system. These applications must demonstrate the efficacy of a particular drug when administered through the Delcath system. To do so, we must demonstrate, in a statistically meaningful manner, that administering chemotherapy agents with the Delcath system results in survival times of patients that are longer than those obtained from administering chemotherapy agents intravenously.

With a substantial portion of the proceeds from this offering, we intend to conduct Phase III human clinical trials designed to demonstrate that administering doxorubicin with the Delcath system to treat primary liver cancer and malignant melanoma that has spread to the liver results in patient survival times that are longer than those obtained from administering chemotherapy agents intravenously.

In December 1999, the FDA approved the protocols for conducting the Phase III clinical trials.

We expect the Phase III clinical trials to be conducted in at least 10 medical centers and to involve approximately 274 test subjects, of which 124 will be treated for primary liver cancer and 150 will be treated for malignant melanoma that has spread to the liver. Half of these test subjects will be treated with doxorubicin administered using the Delcath system and half, the control group, will be treated with chemotherapy agents delivered intravenously. We have identified and approached a number of medical centers that have expressed an interest in conducting the clinical trials. We expect that within 90 days after the closing of this offering we will begin to enter agreements with medical centers to conduct the clinical trials. As a



result, we expect clinical trials to begin during the fourth quarter of this year. However, our timetable is subject to uncertainty and we cannot assure you that we can meet our planned schedule. We cannot assure you that all of the medical centers we have identified will be available to conduct the clinical trials when we are in a position to have them commence or that we will be ready to commence the trials within any particular time period.

We intend to hire a contract research firm to conduct these trials. However, we have not begun negotiations with a contract research organization and we cannot assure you that we will be able to engage an organization on acceptable terms and conditions in a timely manner or at all.

We believe that we will acquire sufficient data to obtain FDA pre-marketing approval of the Delcath system within 12 to 18 months of the commencement of the clinical trials. After acquiring sufficient data, we believe that our collation, analysis and submission of the trial results to the FDA will take an additional three months. Given the short life expectancy of liver cancer patients, we believe that the FDA will review our pre-market application expeditiously and will respond to our submission within three months. However, we may experience delays in beginning, conducting and completing the trials because of factors that include, but are not limited to, delays in designing the trials to conform to the trial protocols, complying with the requirements of investigational review boards at the sites where the trials will be conducted, our ability to identify clinical test sites and sponsoring physicians and the ability of the clinical test sites to identify patients to enroll in the trials. The trials may also take longer to complete because of difficulties we may encounter in entering into agreements with clinical testing sites to conduct the trials and the difficulties these sites may encounter in enrolling patients. Our ability to conduct the trials may also be impaired by our limited experience in arranging for clinical trials and in evaluating and submitting the data gathered from clinical trials. Further, the FDA monitors the progress of the clinical trials and may alter, suspend or terminate the trials based on the data that has been accumulated to that point and its assessment of the relative risks and benefits to the patients involved in the trials.

After acquiring sufficient data, we believe that our collation, analysis and submission of the trial results to the FDA will take an additional three months. Once we submit the data from the clinical trials to the FDA, we estimate that the FDA will respond to our submission within three months. However, the FDA may take longer than three months to evaluate our submission, may require that additional trials be conducted or may not grant approval.

The FDA pre-marketing approval we are currently seeking is limited to administration of doxorubicin with our Delcath system to treatment of liver cancer patients. If we are granted this approval, we plan to subsequently seek additional FDA pre-marketing approvals for using the Delcath system with other chemotherapy agents for treatment of other liver cancers and with anti-viral drugs for treatment of other diseases, such as hepatitis. In many instances, the process of applying for and obtaining regulatory approvals involves rigorous pre-clinical and clinical testing. The time resources and funds required for completing necessary testing and obtaining approvals is significant, and FDA pre-marketing approval may never be obtained for some medical devices or drug delivery systems. If we fail to raise the additional capital required or enter into strategic partnerships to finance this testing or if we fail to obtain the required approvals, our potential growth and the expansion of our business would likely be limited.

#### Research for Hepatitis Treatment

Another disease which attacks the liver is viral hepatitis. The incidence of viral hepatitis in the United States and worldwide is increasing. The long-range effects of some forms of hepatitis can include massive death of liver cells, chronic active hepatitis, cirrhosis and hepatoma. The current treatment for viral hepatitis is limited and includes long-term injections of interferon alpha, which is similar to chemotherapy in its toxicity and dosage limitations. We plan to seek a strategic partner to conduct clinical trials to determine the feasibility of using the Delcath system to administer anti-viral drugs, including interferon alpha, in the treatment of viral hepatitis. We have not entered into any arrangements, understandings or agreements with potential strategic partners.

## Sales and Marketing

We intend to focus our marketing efforts on the 34 comprehensive cancer centers in the United States recognized by the National Cancer Institute, beginning with the hospitals participating in the Phase III clinical trials. We will focus these efforts on two distinct groups of medical specialists in these comprehensive cancer centers:

- o oncologists who have primary responsibility for the patient; and
- o interventional radiologists who are members of the hospital staff and work with catheter-based systems.

Upon diagnosis of cancer, a patient is usually referred to a medical oncologist. This physician generally provides palliative treatments and refers the patient to a surgical oncologist if surgery appears to be an option. Both medical and surgical oncologists will be included in our target market. Generally, oncologists do not position catheters, instead enlisting the assistance of an interventional radiologist.

We plan to hire a marketing director at such time as we receive an indication from the FDA that approval of the Delcath system is forthcoming and then hire a sales manager and three sales representatives to market the system in the United States. We have not previously sold, marketed or distributed any products and currently do not have the personnel, resources, experience or other capabilities to adequately market the Delcath system. Our success will depend upon our ability to attract and retain skilled sales and marketing personnel. Competition for sales and marketing personnel is intense, and we cannot assure you that we will be successful in attracting or retaining such personnel. Our inability to attract and retain skilled sales and marketing personnel could materially adversely affect our business, financial condition and results of operations.

In addition, we plan to utilize distributors and/or one or more corporate marketing partners to market products outside the United States. We believe distribution or corporate partnering arrangements will be cost effective, will be implemented more quickly than a direct sales force established by us in such countries and will enable us to capitalize on local marketing expertise in the countries we target. However, any revenues we receive from the sale of the Delcath system in foreign markets will depend upon the efforts of these parties and may be less than we would otherwise receive if we marketed the product through our own sales force.

Since we plan to sell the Delcath system to a large number of hospitals and physician practices, we do not expect to be dependent upon one or a few customers.

Market acceptance of the Delcath system will depend upon:

- o the ability of our clinical trials to demonstrate a significant reduction in the mortality rate for the kinds of cancers treated at a cost effective price;
- o our ability to educate physicians on the use of the system and its benefits compared to other treatment alternatives; and
- o our ability to convince healthcare payors that use of the Delcath system results in reduced treatment costs of patients.

This will require substantial efforts and expenditures. We only have limited experience in these areas and we cannot assure you that we will be successful in achieving these goals. Moreover, the Delcath system replaces treatment methods in which many hospitals have made a significant investment. Hospitals may be unwilling to replace their existing technology in light of their investment and experience with competing technologies. Many doctors and hospitals are reluctant to use a new medical technology until its value has been demonstrated. As a result, the Delcath system may not gain significant market acceptance among physicians, patients and healthcare payors.

## Nissho Agreement

In December 1996, we entered into an agreement with Nissho Corporation, a large manufacturer and distributor of medical devices and pharmaceuticals based in Osaka, Japan which grants to Nissho the

exclusive right to distribute the Delcath system in Japan, China, Korea, Hong Kong and Taiwan until December 31, 2004. Nissho, which has previously invested \$1,000,000 in Delcath, has advised us that it expects to commence the clinical trials in Japan by the end of 2000. Nissho may also seek to conduct clinical trials in the other countries in the territory.

Products covered by the agreement include the Delcath system for the treatment of cancer in the liver and the lower extremities, as well as new products which may be added by mutual agreement. Nissho is required to purchase products from Delcath in connection with clinical trials and for resale in its market at prices to be determined by mutual agreement. Nissho has agreed, in its territory, not to engage in the business of manufacturing, distributing or selling systems similar to the Delcath system for the liver or other organs or body regions.

#### Third-Party Reimbursement

Currently, because the Delcath system is characterized by the FDA as an experimental device, its use is not reimbursable in the United States. We will not seek to have third-party payors, such as Medicare, Medicaid and private health insurance plans, reimburse the use of the Delcath system until after its use is approved by the FDA. Even if approved by the FDA, these payors may require us, as a condition to reimbursement, to provide extensive supporting scientific, clinical and cost effectiveness data for our Delcath system to the American Medical Association. New products are under increased scrutiny with respect to a determination as to whether or not they will be covered by the various healthcare plans and with respect to the level of reimbursement which will be applicable to respective covered products and procedures. Third-party payors may deny reimbursement for the treatment and medical costs associated with the Delcath system, notwithstanding FDA or other regulatory approval, if it is determined that the Delcath system is unnecessary, inappropriate, not cost effective, experimental or for a non-approved indication. Third-party payors currently provide reimbursement for many of the components of the Delcath system based on established general reimbursement codes, in connection with their use in liver perfusion and other therapies.

We believe that the Delcath system will provide significant cost savings to the extent that it can reduce treatment and hospitalization costs associated with the side-effects of chemotherapy. Our planned wholesale price for the Delcath system kit is \$4,000. A patient normally undergoes four treatments with the Delcath system, each requiring a new system kit. Each treatment with the system costs approximately \$12,000, resulting in a total treatment cost of approximately \$48,000. This compares to a total cost of conventional aggressive chemotherapy treatment of approximately \$160,000 to \$180,000, which includes the hospitalization and treatment costs associated with the side-effects of the systemic delivery of chemotherapy agents.

#### Manufacturing

We plan to utilize contract manufacturers to produce the components of the Delcath system. In order to maintain quality control, we plan to perform final assembly and packaging in our own facility. If we undertake these operations our facility will be required to comply with the FDA's good manufacturing practice regulations. If we sell the Delcath system in some foreign markets, our facility will also need ISO 9000 approval from the European Union.

The double balloon catheter will be manufactured domestically by the Burrton OEM division of B. Braun Medical, Inc. of Germany. The double balloon catheter must be manufactured in accordance with manufacturing and performance specifications that are on file with the FDA. Burrton has demonstrated that the components it manufactures meet these specifications. Burrton's manufacturing facility is ISO 9000 approved, which will allow the use of the catheter in European markets. B. Braun has experience in obtaining regulatory approval for medical products in European markets and has indicated informally, that it will assist us in this process. We have not entered into a written agreement with Burrton to manufacture the catheter either for the Phase III clinical trials or for commercial sale. To ensure sufficient supply of catheters to complete the clinical trials, we intend to purchase our total trial requirements before commencement of the trials.

Medtronic USA, Inc. manufactures the components of the blood filtration circuit located outside of the body, including the medical tubing through which a patient's blood flows and various connectors, as well as

the blood filtration pump head. Medtronic is a manufacturer of components used for extracorporeal blood circulation during cardiac surgery. The components manufactured by Medtronic have been cleared by the FDA for other applications and can, therefore, be sourced off the shelf. These components, however, must comply with manufacturing and performance specifications for the Delcath system that are on file with the FDA. Medtronic has demonstrated that the components it manufactures meet these specifications. Medtronic's manufacturing facility is also ISO 9000 approved and, thus, the components it manufactures may be used in European markets.

The activated charcoal filters used in the Delcath system are manufactured by Asahi Medical Products of Japan. These filters have been cleared by the FDA for other applications and can be sourced off the shelf. Asahi has demonstrated that the filters it supplies fall within the performance parameters and meet the specifications on file with the FDA. We have not entered into a written agreement with Asahi to supply the filters either for the Phase III clinical trials or for commercial sale.

## Competition

The healthcare industry is characterized by extensive research efforts, rapid technological progress and intense competition from numerous organizations, including biotechnology firms and academic institutions. Competition in the cancer treatment industry, and specifically the markets for systems and devices to improve the outcome of chemotherapy treatment for cancer, is intense. We believe that the primary competitive factors for products addressing cancer include safety, efficacy, ease of use, reliability and price. We also believe that physician relationships, especially relationships with leaders in the interventional radiology and oncology communities, are important competitive factors.

Delcath competes with all forms of liver cancer treatments which are alternatives to resection including radiation, implanted infusion pumps, liver transplants, embolization, cryosurgery, radiowave ablation and the use of biological response modulators, monoclonal antibodies and liposomes.

Many large pharmaceutical companies and research institutions are developing systems and devices to improve the outcome of chemotherapy treatment for cancer. Arrow International currently markets an implantable infusion pump, which has been successful in facilitating regional drug delivery. However, Arrow's pump lacks a means of preventing the entry of these agents into the patient's general circulation after they pass through the liver. Other companies, including Merck & Co., Inc., are developing various chemotherapy agents with reduced toxicity, while other companies are developing products to reduce the toxicity and side-effects of chemotherapy treatment. In addition, gene therapy, vaccines and other minimally invasive procedures are currently being developed as alternatives to chemotherapy.

Technological developments are expected to continue at a rapid pace in both industry and academia which could result in a short product life cycle for our Delcath system.

## Government Regulation

### United States Food and Drug Administration

General. The manufacture and sale of medical devices and drugs are subject to extensive governmental regulation in the United States and in other countries. The Delcath system is regulated in the United States as a drug delivery system by the FDA under the Federal Food, Drug, and Cosmetic Act. As such, it requires approval by the FDA of a pre-marketing application and a new drug application prior to commercial distribution.

Doxorubicin, the drug that we are initially seeking to have approved for delivery by the Delcath system, is a widely used chemotherapy agent which has been approved by the FDA since 1974. Like all approved drugs, the approved labeling includes indications for use, method of action, dosing, side-effects and contraindications. Because the Delcath system delivers doxorubicin through a mode of administration and at

dose levels which differ from those currently approved, we must obtain approval for revised labeling of a doxorubicin product permitting for its use with the Delcath system. This will require the filing of a supplemental or an original new drug application for the administration of doxorubicin through the Delcath system.

Under the Federal, Food, Drug, and Cosmetic Act, the FDA regulates the pre-clinical and clinical testing, design, manufacture, labeling, distribution, sales, marketing, post-marketing reporting, advertising and promotion of medical devices and drugs in the United States. Noncompliance with applicable requirements could result in different sanctions such as:

- o the refusal of the government to grant approvals;
- o suspension or withdrawal of clearances or approvals;
- o total or partial suspension of production, distribution, sales and marketing;
- o fines;
- o injunctions;
- o civil penalties;
- o recall or seizure of products; and
- o criminal prosecution of a company and its officers and employees.

Our contract manufacturers also are subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances.

Medical Devices. The Delcath system is a Class III medical device. It is subject to the most stringent controls applied by the FDA to reasonably assure safety and effectiveness. An application for pre-market approval must be supported by data, typically including the results of animal and laboratory testing and human clinical trials. The conducting of Phase III trials is subject to regulations and to continuing oversight by Institutional Review Boards and the FDA. These regulations include required reporting of adverse effects from use of the device during the trials. Before commencing clinical trials, we obtained an investigational device exemption providing for the initiation of clinical trials. We also obtained approval of our investigational plan, including the proposed protocols and informed consent statement that patients signed before undergoing treatment with the Delcath system, by the institutional review boards at the sites where the trials were conducted. Under the Federal Food, Drug, and Cosmetic Act, clinical studies for "significant risk" Class III devices require obtaining such approval by institutional review boards and the filing with the FDA of an investigational device exemption at least 30 days before initiation of the studies.

Given the short life expectancy of liver cancer patients, we believe the FDA will review our pre-market application expeditiously and respond to our submission of the Delcath system for commercial sale within three months. However, approval of the Delcath system may take longer if the FDA requests substantial additional information or clarification, or if any major amendments to the application are filed. In addition, the FDA may refer this matter to an advisory committee of experts to obtain views about the Delcath system. This process is referred to as "panel review", and could delay the approval of the Delcath system. The FDA will usually inspect the applicant's manufacturing facility to ensure compliance with quality systems regulations prior to approval of an application. The FDA also may conduct bioresearch monitoring inspections of the clinical trial sites and the applicant to ensure data integrity, and that the studies were conducted in compliance with the applicable FDA regulations, including good clinical practice regulations.

If the FDA's evaluations of the application, clinical study sites and manufacturing facilities are favorable, the FDA will issue either an approval letter, or an "approvable letter" containing a number of conditions that must be met in order to secure approval of an application. If and when those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue an order approving the application, authorizing commercial

marketing of the device under specified conditions of use. If the FDA's evaluation of the application, the clinical study sites or the manufacturing facilities are not favorable, the FDA will deny approval of the application or issue a "not approvable letter." The FDA may also determine that additional pre-clinical testing or human clinical trials are necessary.

The FDA's regulations require agency approval of an application supplement for changes to a device if they affect the safety and effectiveness of the device, including new indications for use; labeling changes; the use of a different facility or establishment to manufacture, process, or package the device; changes in vendors supplying components for the device; changes in manufacturing methods or quality control systems; and changes in performance or design specifications. Changes in manufacturing procedures or processes may be implemented and the device distributed 30 days after the FDA is provided with notice of these changes unless the FDA advises the pre-market approval application holder within 30 days of receipt of the notice that the notice is inadequate or that preapproval of an application supplement is required.

Approved medical devices remain subject to extensive regulation. Advertising and promotional activities are subject to regulation by the FDA and, in some instances, by the Federal Trade Commission. Other applicable requirements include the FDA's medical device reporting regulations, which require that we provide information to the FDA on deaths or serious injuries alleged to have been associated with the use of marketed devices, as well as product malfunctions that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If safety or efficacy problems occur after the product reaches the market, the FDA may take steps to prevent or limit further marketing of the product. Additionally, the FDA actively enforces regulations prohibiting marketing or promotion of devices or drugs for indications or uses that have not been cleared or approved by the FDA. Further, the Food, Drug, and Cosmetic Act authorizes the FDA to impose post-market surveillance requirements with respect to a Class III device which is reasonably likely to have a serious adverse health consequence or which is intended to be implanted in the human body for more than one year or to be a life sustaining or life supporting device used outside a device user facility.

The Food, Drug, and Cosmetic Act regulates a device manufacturer's quality control and manufacturing procedures by requiring the manufacturer to demonstrate and maintain compliance with quality systems including good manufacturing practice requirements as specified in the FDA quality systems regulations. These regulations require, among other things, that:

- o there are in place design controls, including initial design and design changes;
- o the manufacturing process be regulated, controlled, and documented by the use of written procedures; and
- o the ability to produce devices which meet the manufacturer's specifications be validated by extensive and detailed testing of every aspect of the process. The FDA monitors compliance with quality systems regulations, including good manufacturing practice requirements, by conducting periodic inspections of manufacturing facilities. If violations of the applicable regulations are found during FDA inspections, the FDA will notify the manufacturer of such violations and the FDA, administratively or through court enforcement action, can prohibit further manufacturing, distribution, sales and marketing of the device until the violations are cured. If violations are not cured within a reasonable length of time after the FDA provides notification of such violations, the FDA is authorized to withdraw approval of the pre-market approval application.

Investigational devices that require FDA pre-marketing approval in the United States but have not received such approval, may be exported to countries belonging to the European Union, European Economic Area, and to some other specified countries, provided that the device is intended for investigational use in accordance with the laws of the importing country; has been manufactured in accordance with the FDA's good manufacturing practices or ISO standards; is labeled on the outside of the shipping carton "for export only," is not sold or offered for sale in the United States; and complies with the specifications of the foreign purchaser. The export of an investigational device for investigational use to any other country requires prior authorization from the FDA. An investigational device may be exported for commercial use only as described below, under "Foreign Regulation."

Drugs. We, or a manufacturer of a chemotherapy agent, must obtain FDA pre-marketing approval of a supplemental or original new drug application for a chemotherapy product providing for its use with the Delcath system before the system may be marketed in the United States to deliver that agent to the liver or any other site. We have budgeted the coverage of the filing costs associated with obtaining such approval which, after it has been obtained, would not have a negative effect on the manufacturers of doxorubicin. Rather, they will have the opportunity to expand the use of the drug as a result of changing their label to include the Delcath labeling.

Clinical trials to support the relabeling of doxorubicin to provide for its use with the Delcath system must be conducted in accordance with the FDA's investigational new drug regulations. Phase III clinical trial protocols have been approved by the FDA under the Company's investigational new drug application. FDA regulations also require that prior to initiating the trials the sponsor of the trials obtain investigational review board approval from each investigational site that will conduct the trials. We have identified ten medical centers that have expressed an interest in conducting the trials. The investigational review boards at two of these medical centers have given their approval to have the clinical trials conducted at their institutions. We are seeking the approval of investigational review boards at additional medical centers by assembling and providing them with information with respect to the trials.

The FDA requires that, in order to obtain approval to relabel doxorubicin for delivery using the Delcath system, we demonstrate that delivering doxorubicin using the system results in patient survival times that are longer than those obtained from administering chemotherapy agents intravenously.

The approved Phase III trial protocols are designed to obtain approval of both a new drug application, or a supplemental new drug application, and a pre-marketing approval application providing for the use of doxorubicin with the Delcath system. The trial protocols were approved by both the FDA division that approves new drugs and the division that reviews applications to market new devices. All of the data generated in the trials will be submitted to both of these FDA divisions.

If we successfully complete the clinical trials, we believe the manufacturer of doxorubicin will submit to the FDA a new drug application or supplemental new drug application and pre-market approval to deliver doxorubicin to the liver through the Delcath system. Under the Food, Drug, and Cosmetic Act, the Delcath system cannot be marketed until the new drug application, or supplemental new drug application, and the pre-marketing approval application approvals are obtained, and then only in conformity with conditions of use set forth in the approved labeling.

Foreign Regulation. In order for us to market our products in Asia, Europe, Latin America and other foreign jurisdictions, we must obtain required regulatory approvals or clearances and otherwise comply with extensive regulations regarding safety and manufacturing processes and quality. These regulations, including the requirements for approvals or clearances to market, may differ from the FDA regulatory scheme. In addition, there may be foreign regulatory barriers other than pre-market approval or clearance.

In April 1996, FDA legislation was enacted that permits that a medical device which requires FDA pre-marketing approval but which has not received such approval to be exported to any country for commercial use, provided that the device:

- o complies with the laws of that country;
- o has valid marketing authorization or the equivalent from the appropriate authority in any of a list of industrialized countries including Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa and countries in the European Economic Union; and
- o meets other regulatory requirements regarding labeling, compliance with the FDA's good manufacturing practices or ISO manufacturing standards and notification to the FDA.

We must obtain a CE mark in order for us to market and sell the Delcath system in the European Union, except for limited use as a clinical trial device. Supplemental device approvals also might be required to market and sell the Delcath system.

## Patents, Trade Secrets and Proprietary Rights

Our success depends in large part on our ability to obtain patents, maintain trade secret protection and operate without infringing on the proprietary rights of third parties. Because of the length of time and expense associated with bringing new products through development and regulatory approval to the marketplace, the health care industry has traditionally placed considerable importance on obtaining patent and trade secret protection for significant new technologies, products and processes. We hold the following six United States patents, as well as three corresponding foreign patents in Canada, Europe and Japan:

Summary Description of Patents	Patent No.
Isolated perfusion method for cancer treatment	U.S. #5,069,662
Isolated perfusion device -- catheter for use in isolated perfusion in cancer treatment	U.S. #5,411,479
Device and method for isolated pelvic perfusion	U.S. #5,817,046
Catheter design to allow blood flow from renal veins and limbs to bypass occluded segment of IVC	U.S. #5,893,841
Balloon inside catheter to restrict blood flow or prevent catheter from moving	U.S. #5,897,533
Catheter with slideable balloon to adjust isolated segment	U.S. #5,919,163

We plan to vigorously enforce our intellectual property rights. In addition, we will conduct searches and other activity relating to the protection of existing patents and filing of new applications.

Litigation may be necessary to enforce any patents issued or assigned to us or to determine the scope and validity of third party proprietary rights. Litigation would be costly and divert our attention from our business. If others file patent applications with respect to inventions for which we already have issued patents or have patent applications pending, we may be forced to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, which would also be costly and divert our attention from our business. If a third party violates our intellectual property rights, we may be unable to enforce our rights because of our limited resources.

In addition to patent protection, we rely on unpatented trade secrets and proprietary technological expertise. We rely, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. These agreements may not provide meaningful protection of our proprietary technologies or other intellectual property if unauthorized use or disclosure occurs.

## Product Liability

Clinical trials, manufacturing, marketing and product sales may expose us to liability claims from the use of the Delcath system. Though participants in clinical trials are generally required to execute consents and waivers of liability they may still be able to assert product liability claims against us. Claims for damages, whether or not successful, could cause delays in the clinical trials and result in the loss of physician endorsement. We do not currently carry product liability insurance and we may not be able to acquire product liability insurance at sufficient coverage levels or at an acceptable cost. If we are unable to obtain sufficient insurance coverage at an acceptable cost, we may not be able to commercialize the Delcath system. A successful product liability claim or recall would have a material adverse effect on our business, financial condition and results of operations.

## Employees

As of April 30, 2000, we had four employees, three of whom were compensated and full-time. We intend to recruit additional personnel in connection with the research, development, manufacturing and marketing of



our products. None of our employees is represented by a union, and we believe relationships with our employees are good. Our success will depend, in large part, upon our ability to attract and retain qualified employees. We face competition in this regard from other companies, research institutions and other organizations.

In addition to our full time employees, we engage the services of medical and scientific consultants.

#### Facilities

We occupy approximately 3,300 square feet of office space in Stamford, Connecticut, pursuant to an informal arrangement with the landlord. According to this agreement we prepaid our rent, which is approximately \$7,500 a month, through December 2000. We have occupied these facilities since 1992. We believe that we will require additional space in 2001, and are beginning site selection for rental property in the same building or nearby and believe that satisfactory space is available at commercially reasonable rates.

#### Legal Proceedings

We are not involved in any legal proceedings and we are not aware of any such proceedings being contemplated.

MANAGEMENT

Executive Officers, Directors and Key Employees

Our executive officers and directors and their respective ages are as follows:

Name	Age	Positions
Samuel Herschkowitz, M.D. ....	50	Chairman of the Board and Chief Technical Officer
M. S. Koly .....	64	Chief Executive Officer, President, Treasurer and Director
Joseph P. Milana, CPA .....	37	Chief Financial Officer
Jonathan A. Foltz, CFA .....	38	Director of Operations
William I. Bergman .....	68	Director
Frank G. Mancuso, Jr. ....	41	Director
James V. Sorrentino, Ph.D. ....	63	Director

Samuel Herschkowitz, M.D. has been Chairman of the Board of Delcath since 1998 and Delcath's Chief Technical Officer since 1991. In 1987, he co-founded Venkol Ventures L.P. and Venkol Ventures, Ltd., two affiliated venture capital funds specializing in medical technology investments, which are no longer active. Dr. Herschkowitz is board certified in psychiatry and neurology. He is an assistant professor at New York University Medical Center, and has held academic positions at Beth Israel Hospital, Mount Sinai Medical School and Downstate Medical Center. Dr. Herschkowitz graduated from Syracuse University and received his medical degree from Downstate Medical Center College of Medicine.

M. S. Koly has been Chief Executive Officer and Treasurer of Delcath since 1998 and has served as a Director since 1988. From 1987 until June 1998, Mr. Koly managed Venkol Ventures, L.P. and Venkol Ventures, Ltd., firms he co-founded with Dr. Herschkowitz. From 1983 to 1987, Mr. Koly was president of Madison Consulting Corporation, a firm he founded. From 1978 to 1983, Mr. Koly was president of Becton-Dickinson Respiratory Systems. Prior to that time, he held various senior management positions at Abbott Laboratories, Stuart Pharmaceuticals and National Patent Development Corp. He received a B.A. from American University and an M.B.A. in marketing and finance from Northwestern University.

Joseph P. Milana, CPA, has been the Controller of Delcath since 1995. From 1984 to 1995, Mr. Milana was with KPMG LLP, most recently as a senior tax manager. He received a B.B.A. in accounting and an M.S. in taxation from Pace University, and received a CPA designation from the state of New York. Mr. Milana currently devotes one day a week to Delcath matters and will become a full-time employee once Delcath becomes a public company.

Jonathan A. Foltz, CFA, has been our Director Of Operations since 1992. Mr. Foltz was senior associate of Venkol Ventures from 1989 to 1992. During 1988 to 1989, he provided investment and acquisition research, consulting to corporations and brokerage firms including First Montauk Securities, Inc., Gilford Securities Inc., Texas American Energy Corporation and Computer Memories Inc. He was the research director of Nicholas, Lawrence and Co., a regional stock brokerage firm, reorganizing and managing their equity research department. Mr. Foltz earned a B.S. in finance and computer science from Lehigh University, an M.B.A. from the University of Connecticut and is a chartered financial analyst.

William I. Bergman has been a director of Delcath since 1996. A retired executive, Mr. Bergman was with Richardson-Vicks from 1956 through 1990 most recently as Vice President-controller of North American Operations, vice president-marketing of colds care business and Canadian operations, president and general manager of Vicks health care division, assistant general manager of Vicks International, and executive vice president of Richardson-Vicks Inc. Following the acquisition of Vicks by The Procter & Gamble Company in 1986, he became the president of Richardson-Vicks, U.S.A. and vice president of The Procter & Gamble Company prior to retirement in 1990. He is also a director of ZymeTx, Inc. a biotech company involved in the development of viral diagnostics. His education includes a B.S. from Drexel University and the advanced management program at Harvard University.

Frank G. Mancuso, Jr., has been a director of Delcath since 1998. Mr. Mancuso has been President of FGM Entertainment since 1985. In the past five years, he has produced numerous movies and television series within his own companies and for Paramount Pictures and MGM/United Artists. He has a B.A. from Upsala College.

James V. Sorrentino, Ph.D., has been a director of Delcath since 1996. Since 1992, Dr. Sorrentino has been President of Healthcare Products Development, Inc., a clinical research organization that designs, organizes and manages clinical trials for the pharmaceutical and biological industry. From 1974 to 1992, he held several research positions with Richardson-Vicks Inc., including director of over-the-counter products, Vice President & director of research and development. After Richardson-Vicks Inc. was acquired by The Procter & Gamble Company, he served as director of worldwide clinical development, non-prescription drug products of The Procter & Gamble Company. He received an A.B. in Biology, an M.S. in bacteriology, and a Ph.D. in virology/immunology from the Catholic University of America.

Our success will depend largely on the continuing efforts of Samuel Herschkowitz, our Chief Technical Officer and M.S. Koly, our Chief Executive Officer. Our business may be adversely affected if the services of either officer become unavailable to us.

We have agreed, for a period of three years from the date of this prospectus, if so requested by the representative of the underwriters, to nominate and use our best efforts to elect a designee of the underwriter as a director of Delcath or, at the representative's option, as a non-voting advisor to our board of directors. The representative has not yet exercised its right to designate a person.

#### Classified Board of Directors

Our board of directors is divided into three classes of directors serving staggered three-year terms. As a result, approximately one-third of the board of directors will be elected each year. These provisions, together with the provision of our amended and restated certificate of incorporation and by-laws, allow the board of directors to fill vacancies on or increase the size of the board of directors, and may deter a stockholder from removing incumbent directors and filling such vacancies with its own nominees in order to gain control of the board. The staggering of the election of our directors may have the effect of delaying, deferring or discouraging a change of control.

Each of our directors has been elected to serve until his successor has been elected and duly qualified. The directorship terms of Dr. Herschkowitz and Mr. Koly will expire at the annual meeting of stockholders in 2003; the directorship term of Mr. Mancuso will expire at the annual meeting of stockholders in 2001; and the directorship terms of Dr. Sorrentino and Mr. Bergman will expire at the annual meeting of stockholders in 2002.

#### Committees of the Board

We have established an audit committee and a stock option and compensation committee.

The audit committee approves the selection of our independent accountants and meets and interacts with the independent accountants to discuss questions in regard to the financial reporting. In addition, the audit committee reviews the scope and results of the audit with the independent accountants, reviews with management and the independent accountants our annual operating results, considers the adequacy of our internal accounting procedures and considers and reports to the board of directors with respect to other auditing and accounting matters, fees to be paid to our independent auditors and the performance of our independent auditors. After this offering, the audit committee will consist of Messrs. Bergman and Mancuso and Dr. Sorrentino.

The stock option and compensation committee reviews and recommends to the board of directors the salaries, benefits and stock option grants of all employees, consultants, directors and other individuals compensated by us. The stock option and compensation committee also administers our stock option and other employee benefits plans. The compensation committee currently consists of Mr. Koly, Dr. Sorrentino and Mr. Bergman. Mr. Bergman currently chairs the compensation committee.

## Director Compensation

Directors who are employees of Delcath do not currently receive any compensation for serving on the board of directors. Following this offering non-employee directors will receive \$750 for each meeting of the board of directors attended in person or participated in telephonically. Currently, non-employee directors do not receive any compensation. A new compensation rate for these directors will be established in our next shareholders meeting. In addition, each non-employee director received a one-time grant in January 1999 of options to purchase 43,704 shares of common stock at a price of \$3.89 per share, all of which are vested. Each non-employee director received a separate one-time grant in December 1999 of options to purchase 28,408 shares of common stock at a price of \$2.29 per share, half of which are vested, the remainder to vest in December 2000.

## Scientific Advisors and Consultants

We seek to expand the breadth of expertise and experience available to us through the use of consultants and advisors. We coordinate these advisors, including nine M.D.s and Ph.D.s to organize, conduct, and monitor clinical and pre-clinical testing, regulatory filings and responses, product development and manufacturing, and publication and presentation of the results of our research. These individuals bring a broad range of competencies to our operations. The scientific advisors are independent professionals who meet on an individual basis with management when so requested. We seek as scientific advisors recognized experts in relevant sciences or clinical medicine to advise us about present and long-term scientific planning, research and development.

There is no fixed term of service for the scientific advisors. Current members may resign or be removed at any time, and additional members may be appointed. Members do not serve on an exclusive basis with Delcath, are not under contract, other than with respect to confidentiality obligations, and are not obligated to present corporate opportunities to us. To our knowledge, none of the members is working on the development of competitive products. Inventions or products developed by a scientific advisor who is not otherwise affiliated with us will not become our property.

Scientific advisors who are not affiliated with us are paid a per diem fee for their services. All members receive reimbursement for expenses incurred in traveling to and attending meetings on behalf of Delcath.

Our scientific advisors and collaborators include the following doctors in the fields of surgical oncology and interventional radiology:

Name	Title	Specialty	Relationship to Delcath
Morton G. Glickman, M.D.	Associate Dean, Yale University School of Medicine	Cardiovascular and Interventional Radiology	Founder and stockholder
William N. Hait, M.D., Ph.D.	Director, The Cancer Institute of New Jersey	Medical Consultant and Scientific Advisor	Founder and stockholder
T.S. Ravikumar, M.D.	Chairman, Department of Surgery, Montefiore Medical Center	Surgical Oncology	Principal Investigator of the Delcath system

Morton G. Glickman, M.D. was educated at Cornell University (B.A.) and Washington University (M.D.). He also received an honorary M.A. from Yale. He was a resident at the University of California. He served as the chief of neuro and vascular radiology at San Francisco General Hospital from 1969 to 1973, and has held numerous academic and professional appointments at Yale University School of Medicine, currently serving as associate dean and vice chairman of diagnostic radiology and surgery. Dr. Glickman is a founder of Delcath.

William N. Hait, M.D., Ph.D. was educated at the University of Pennsylvania (B.A.) and The Medical College of Pennsylvania (M.D., Ph.D.). He was a resident in internal medicine and held numerous academic and professional appointments at Yale University School of Medicine, including chief of medical oncology. Dr. Hait is currently director of The Cancer Institute of New Jersey. Dr. Hait is a founder of Delcath.

T.S. Ravikumar, M.D. was educated in India at Madras University and Madras Medical College. He was the associate director of The Cancer Institute of New Jersey from 1993 through 1998. He also served as a resident in general surgery at Maimonides Medical Center at S.U.N.Y. -- Downstate and was a fellow in surgical oncology at the University of Minnesota. Dr. Ravikumar won a National Reserve Service Award in surgical oncology, and served as a fellow at Brigham and Women's Hospital and the Dana Farber Cancer Institute from 1982 through 1984. He has had a number of academic appointments, including at Harvard Medical School, Yale University School of Medicine, and hospital appointments, including at Yale Comprehensive Cancer Center and Robert Wood Johnson University Hospital.

In addition, Delcath uses the services of the following medical and scientific consultants for technical expertise:

Name	Title	Specialty
Anil R. Diwan, Ph.D.	Principal, Applied Biotech Concepts	Filtration Consultant
Harvey J. Ellis, C.C.P.	Chief of Cardiac Perfusion, Bridgeport Hospital	Perfusion Consultant
Durmus Koch	President, Bipore, Inc.	Manufacturing
James H. Muchmore, M.D.	Associate Professor of Surgery, Tulane University School of Medicine	Oncology and Perfusion Consultant
Gabriela Nicolau, Ph.D.	Director, Pharmacokinetics and Drug Metabolism, Innapharma	Metabolism and Pharmacokinetics
John Quiring, Ph.D.	Principal, QST Consulting	Biostatistician

#### Executive Compensation

The following table sets forth all compensation earned by our Chief Executive Officer for the years ended December 31, 1998 and 1999. No other executive officer of Delcath earned more than \$100,000 during the year ended December 31, 1999.

Summary Compensation Table

Name	Annual Compensation			Long-Term Compensation
	Year	Salary	Bonus	Shares of Common Stock Underlying Options
M.S. Koly, Chief Executive Officer, President and Treasurer	1999	\$101,250	\$0	177,002
	1998	60,000	0	--

The following tables show information with respect to incentive and non-qualified stock options granted during the fiscal year ended December 31, 1999 to the executives and the aggregate value at June 30, 2000 of those options. The per share exercise price of all options was equal to the estimated fair market value of a share of common stock on the date of grant. No options granted to any named executives have been exercised.

Option/SAR Grants in Fiscal Year Ending December 31, 1999

Name	Number of Shares of Common Stock Underlying Option	Percent of Total Options Granted to Employees in 1999	Exercise Price (\$/Sh)	Expiration Date
M.S. Koly	77,094	22.5%	3.89	January 2004
M.S. Koly	32,166	9.4%	3.89	January 2004
M.S. Koly	67,742	19.7%	2.29	December 2004

Aggregated Fiscal Year End Option Values

Name	Number of Shares of Common Stock Underlying Unexercised Options at June 30, 2000		Value of Unexercised In-the-Money Options at June 30, 2000	
	Exercisable	Unexercisable	Exercisable	Unexercisable
M.S. Koly	51,396	25,698	\$108,445	\$ 54,223
M.S. Koly	32,166	0	\$ 67,870	0
M.S. Koly	33,871	33,871	\$125,661	\$125,661

Employment Agreements

Delcath has entered into employment agreements with M.S. Koly and Sam Herschkowitz. Under the agreements, each officer will serve for a three-year term, beginning on the closing of this offering, with an automatic one-year renewal, unless either party provides notice of termination. Mr. Koly will receive a base salary of \$175,000 per year and Dr. Herschkowitz will receive a base salary of \$120,000 per year. Mr. Koly is required to devote his full business time to our business and affairs, and Dr. Herschkowitz is required to devote a substantial part of his business time to our business and affairs. In addition to his responsibilities at Delcath, Dr. Herschkowitz lectures and instructs students as an assistant professor at New York University on one day per week basis and conducts a clinical medical practice prior to 8:30 a.m. in the morning and after 6:00 p.m. in the evening. The remainder of his normal business time is generally devoted to Delcath.

Key-man Life Insurance

We have obtained "key-man" life insurance on each of the lives of Mr. Koly and Dr. Herschkowitz in the amount of \$2,000,000.

Stock Option Plans

On October 15, 1992, our board of directors and stockholders adopted our 1992 incentive stock option plan and our 1992 non-incentive stock option plan. On June 15, 2000, the board of directors adopted our 2000 stock option plan. Our 2000 stock option plan will be submitted for stockholder approval at our next annual meeting. We have reserved 299,375 shares of common stock for issuance upon exercise of options granted from time to time under the 1992 incentive stock option plan, 260,041 shares of common stock for issuance upon exercise of options granted from time to time under the 1992 non-incentive stock option plan and 300,000 shares of common stock for issuance from time to time under the 2000 stock option plan. The stock option plans are intended to assist us in securing and retaining key employees, directors and consultants by allowing them to participate in our ownership and growth through the grant of incentive and non-qualified options.

Under the 1992 incentive stock option plan we may grant incentive stock options only to key employees and employee directors. Under the 1992 non-incentive stock option plan, we may grant non-qualified options to our employees, officers, directors, consultants, agents and independent contractors. Under the 2000 stock option plan, we may grant incentive or non-qualified options to our officers, employees, directors, consultants, agents and independent contractors. The stock option plans are administered by a committee, currently the stock option and compensation committee, appointed by our board of directors.

Subject to the provisions of each of the stock option plans, the committee will determine who shall receive options, the number of shares of common stock that may be purchased under the options, the time and manner of exercise of options and exercise prices. The term of options granted under each of the stock option plans may not exceed ten years, or five years for an incentive stock option granted to an optionee owning more than 10% of our voting stock. The exercise price for incentive stock options shall be equal to or greater than 100% of the fair market value of the shares of the common stock at the time granted; provided that incentive stock options granted to an optionee owning more than 10% of our voting stock shall be exercisable at a price equal to or greater than 110% of the fair market value of the common stock on the date of the grant. The exercise price for non-qualified options will be set by the committee, in its discretion, but in no event shall the exercise price be less than the fair market value of the shares of common stock on the date of grant. Shares of common stock received upon exercise of options granted under each of the plans will be subject to restrictions on sale or transfer.

As of the date of this prospectus, we have granted incentive stock options to purchase 299,375 shares of common stock under our 1992 incentive stock option plan at a weighted average price of \$3.18 and non-incentive stock options to purchase 260,041 shares of common stock under our 1992 non-incentive stock option plan at a weighted average price of \$3.37. All of these options have been granted to our officers and directors and terminate on the fifth anniversary of their vesting date. We will not grant any additional options under these plans. As of the date of this prospectus, we have not granted any options under our 2000 stock option plan. For a period of one year following the effective date of this offering, we will not grant options to our employees, promoters or affiliates which, when added to options previously granted, will exceed 15% of our then outstanding shares of common stock.

Each of our stock option plans includes a provision that an optionholder, upon exercise of an option, must execute a stockholder's agreement containing provisions to be determined by Delcath at the time of such exercise.

#### Limitation on Liability and Indemnification Matters

As authorized by the Delaware General Corporation Law, our certificate of incorporation provides that none of our directors shall be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- o any breach of the director's duty of loyalty to Delcath or its stockholders;
- o acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- o unlawful payments of dividends or unlawful stock redemptions or repurchases; or
- o any transaction from which the director derived an improper personal benefit.

This provision limits our rights and the rights of our stockholders to recover monetary damages against a director for breach of the fiduciary duty of care except in the situations described above. This provision does not limit our rights or the rights of any stockholder to seek injunctive relief or rescission if a director breaches his duty of care. In addition, our certificate of incorporation provides that if the Delaware General Corporation Law is amended to further limit the liability of a director, then the liability of the directors shall be eliminated or limited to the fullest extent permitted by such amendment. These provisions will not alter the liability of directors under federal securities laws.

Our certificate of incorporation further provides for the indemnification of any and all persons who serve as our director, officer, employee or agent to the fullest extent permitted under the Delaware General Corporation Law.

We maintain a policy of insurance under which our directors and officers are insured, subject to the limits of the policy, against certain losses arising from claims made against our directors and officers by reason of any acts or omissions covered under this policy in their capacities as directors or officers, including liabilities under the Securities Act.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons under the above provisions, or otherwise, we have been advised that in the opinion of the SEC, indemnification is against public policy as expressed in the Securities Act, and is unenforceable.



PRINCIPAL STOCKHOLDERS

The following table presents information known to us, as of the date of this prospectus and as adjusted to reflect the sale by us of 2,000,000 shares common stock offered under this prospectus, relating to the beneficial ownership of common stock by:

- o each person who is known by us to be the beneficial holder of more than 5% of our common stock;
- o each of our directors; and
- o our directors and executive officers as a group.

We believe that all persons named in the table have sole voting and investment power with respect to all shares beneficially owned by them, except as noted.

A person is deemed to be the beneficial owner of securities that can be acquired by that person within 60 days from the date of this prospectus upon the exercise of options, warrants or convertible securities. Each beneficial owner's percentage ownership is determined by assuming that options, warrants or other convertible securities that are held by that person, but not those held by any other person, and which are exercisable within 60 days of the date of this prospectus, have been exercised and converted. The table also assumes

- o a base of 3,437,185 shares outstanding before this offering; and
- o a base of 5,437,185 shares outstanding immediately after this offering, before any consideration is given to outstanding options or warrants.

The number of shares beneficially owned by each individual includes shares to be issued in partial payment of accrued dividends.

The address for each listed director and officer is c/o Delcath Systems, Inc., 1100 Summer Street, Stamford, Connecticut 06905.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
M.S. Koly .....	1,917,331	53.9%	34.5%
Venkol Trust .....	1,777,429	51.7	32.7
Samuel Herschkowitz, M.D. ....	335,172	9.5	6.1
Frank G. Mancuso, Jr. ....	127,378	3.6	2.3
James V. Sorrentino, Ph.D. ....	72,767	2.1	1.3
William I. Bergman .....	66,649	1.9	1.2
All directors and executive officers as a group (six persons) .....	2,271,960	59.5%	39.1%

M.S. Koly's beneficially owned shares include;

- o 7,609 shares of the 15,218 shares held by Venkol Inc. as nominee for M.S. Koly;
- o 14,859 shares held by M. Ted Koly, M.S. Koly's minor son;
- o 117,434 shares issuable upon exercise of options; and
- o 1,773,933 shares and 3,496 shares issuable upon exercise of warrants held by Venkol Trust.

Mr. Koly is the trustee of Venkol Trust and is deemed the beneficial owner of its shares. His beneficially owned shares exclude 59,596 shares issuable upon exercise of options which become exercisable on December 7, 2000.

Samuel Herschkowitz's beneficially owned shares include;

- o 7,609 shares of the 15,218 shares held by Venkol Inc. as nominee for Dr. Herschkowitz;
- o 229,010 shares held by Venkol Trust as to which Dr. Herschkowitz has a beneficial remainder interest; and

- o 83,694 shares which are issuable upon exercise of options.

His beneficially owned shares exclude 23,382 shares issuable upon exercise of options which become exercisable on December 7, 2000.

Frank G. Mancuso's beneficially owned shares include;

- o 18,327 shares held by Venkol Trust as to which Mr. Mancuso has a beneficial remainder interest;
- o 57,908 shares issuable upon exercise of options; and
- o 1,804 shares issuable upon exercise of warrants.

His beneficially owned shares exclude 14,204 shares issuable upon exercise of options which become exercisable on December 7, 2000.

James V. Sorrentino's and William I. Bergman's beneficially owned shares include 57,908 shares issuable upon exercise of options. Their beneficially owned shares exclude 14,204 shares issuable upon exercise of options which become exercisable on December 7, 2000.

The number of shares beneficially owned by all directors and executive officers as a group include 1,773,933 shares and 3,496 shares issuable upon exercise of warrants held by Venkol Trust.

Upon the closing of this offering, our officers, directors and principal stockholders will beneficially own approximately 39.1% of our outstanding common stock, and 37.1% if the representative's over-allotment option is exercised in full. Consequently, these persons, as a group, will be able to control the outcome of all matters submitted for stockholder action, including the election of members to our board of directors and the approval of significant change-in-control transactions. Therefore, they will effectively control our management and affairs. This may have the effect of delaying or preventing a change in control.

## CERTAIN TRANSACTIONS

From September 1997 through January 1998, we sold 111,446 shares of common stock to 11 investors for an aggregate consideration to us of \$1,275,000. One of the investors was Johnson & Johnson Development Corporation, which invested \$500,000. As part of that offering, Venkol Ventures, L.P. and Venkol Ventures, Ltd. purchased an aggregate of 26,223 shares of common stock for approximately \$300,000 and Mr. Mancuso, a director of Delcath, purchased 8,741 shares of common stock for \$100,000.

In November 1998, Venkol Ventures, L.P. and Venkol Ventures, Ltd. distributed their shares in Delcath to their limited partners or their designees. The majority of shares were transferred to the Venkol Trust, which is managed by M.S. Koly, our Chief Executive Officer and a director. The shares transferred to the trust include all of our shares of Preferred A stock, 117,650 shares of our Preferred B stock and 45,694 common shares.

All of our preferred stockholders have agreed to convert their preferred stock into 1,056,192 shares of common stock. The preferred stockholders have also agreed to accept 870,234 shares of common stock as payment of \$992,780 of estimated accumulated dividends, and a cash dividend of \$496,390 in payment of the balance of the accrued dividend, assuming this offering closes on September 30, 2000. Venkol Trust holds all 2,000,000 shares of our class A preferred stock and will receive 874,087 shares of common stock on conversion of those shares, 776,177 shares of common stock in partial payment of accumulated dividends and a cash dividend of \$221,997 in payment of the balance of the accrued dividend, assuming this offering closes on September 30, 2000. Frank Mancuso, Jr. and Venkol Trust own 19,608 and 117,650 shares of our class B shares of preferred stock and will receive 8,570 and 51,418 shares of common stock, upon conversion of those shares, 4,426 shares and 26,557 shares of common stock in payment of \$25,825 and \$154,952 of accumulated dividends and cash dividends of approximately \$12,912 and \$77,476, in payment of the balance of the accrued dividends, assuming this offering closes on September 30, 2000.

In June 1999, we sold an aggregate of 59,514 shares of common stock and three-year warrants to purchase an aggregate of 6,609 shares of common stock at \$11.74 per share for aggregate proceeds of \$776,192. Mr. Mancuso made a \$75,000 investment for which he received 5,750 shares of common stock and warrants to purchase 639 shares of common stock.

In April 2000, we issued 292,426 shares of common stock to existing security holders and their designees for proceeds of \$501,825 in a rights offering. Each of M.S. Koly, Samuel Herschkowitz, our Chairman and Chief Technical Officer, and James Sorrentino, a director of Delcath, purchased 14,859 shares for \$25,500, and William Bergman, a director of Delcath, purchased 8,741 shares for \$15,000.

In August and September 2000, Delcath borrowed an aggregate of \$230,000 for which it issued promissory notes due on May 27, 2001. The promissory notes bear interest at an annual rate of 22%. Of these loans, \$205,000 was borrowed from existing stockholders or relatives of existing stockholders of Delcath. M.S. Koly, Chief Executive Officer, President and a director of Delcath, and Mary Herschkowitz, the mother of Samuel Herschkowitz, M.D., Chairman and Chief Technical Officer of Delcath, provided \$50,000 and \$40,000 of the loans.

We believe that each of the transactions with our officers, directors and principal stockholders and their affiliates were on terms no less favorable than could have been obtained from unaffiliated third parties. All future transactions, including loans between us and our officers, directors and stockholders beneficially owning 5% or more of our outstanding voting securities, or their affiliates, will be on terms no less favorable to us than could be obtained in arm's length transactions from unaffiliated third parties. Further, all transactions and loans and any forgiveness of indebtedness owed by any of our officers, directors and stockholders beneficially owning 5% or more of our outstanding voting securities, or their affiliates, to us, must be approved by a majority of our independent directors who do not have an interest in the transactions and who have access, at our expense, to either our legal counsel or independent legal counsel.

## DESCRIPTION OF SECURITIES

Upon the closing of this offering, the authorized capital stock of Delcath will consist of 15,000,000 shares of common stock, \$.01 par value per share, and 10,000,000 shares of preferred stock, \$.01 par value per share, whose rights and designation have not yet been established. There will be no preferred stock outstanding immediately after the closing of this offering. The description in the sections below of Delcath's certificate of incorporation and by-laws refers to Delcath's Amended and Restated Certificate of Incorporation and Amended and Restated By-Laws, respectively, as they will be in effect upon the closing of this offering.

### Common Stock

Immediately prior to the closing of this offering, there will be 3,437,185 shares of common stock outstanding. After giving effect to the issuance of the 2,000,000 shares of common stock offered by this prospectus, assuming the underwriters do not exercise their overallotment option, there will be 5,437,185 shares of common stock outstanding upon the closing of this offering. As of the date of this prospectus, we have approximately 70 stockholders of record, assuming the conversion of all of our preferred stock into common stock. There is currently no public market for our common stock.

Holders of common stock are entitled to one vote for each share on all matters submitted to a stockholder vote. Holders of common stock do not have cumulative voting rights. Therefore, holders of a majority of the shares of common stock voting for the election of directors can elect all of the directors. Holders of common stock are entitled to share in all dividends that the board of directors, in its discretion, declares from legally available funds. In any liquidation, dissolution or winding up of Delcath, each outstanding share entitles its holder to participate pro rata in all assets that remain after payment of liabilities and after providing for each class of stock, if any, having preference over the common stock.

Holders of common stock have no conversion, preemptive or other subscription rights, and there are no redemption provisions applicable to the common stock. The rights of the holders of common stock are subject to any rights that may be fixed for holders of preferred stock, when and if any preferred stock is issued. All outstanding shares of common stock are, and the shares underlying all options and warrants will be, duly authorized, validly issued, fully paid and non-assessable upon our issuance of these shares.

### Preferred Stock

Under Delcath's certificate of incorporation, Delcath's board of directors is authorized, subject to limitations prescribed by law, without further stockholder approval, from time to time to issue up to an aggregate of 10,000,000 shares of preferred stock. The preferred stock may be issued in one or more series. Each series may have different rights, preferences and designations and qualifications, limitations and restrictions that may be established by Delcath's board of directors without approval from the stockholders. These rights, designations and preferences include:

- o number of shares to be issued;
- o dividend rights;
- o right to convert the preferred stock into a different type of security;
- o voting rights attributable to the preferred stock;
- o right to set aside assets for payments relating to the preferred stock; and
- o prices to be paid upon redemption of the preferred stock or a bankruptcy type event.

If Delcath's board of directors decides to issue any preferred stock, it could have the effect of delaying or preventing a third-party from taking control of Delcath. This is because the terms of the preferred stock could be designed to make it prohibitively expensive for any unwanted third party to make a bid for the shares of Delcath. In addition, the issuance of preferred stock with voting or conversion rights could adversely affect the voting power or other rights of the holders of our common stock. We have no present plans to issue any new shares of preferred stock.

There are currently 2,000,000 shares of Class A preferred stock and 416,675 shares of Class B preferred stock outstanding which will all be converted into shares of common stock immediately prior to the closing of this offering. The holders of the Class A preferred stock and Class B preferred stock are entitled to receive dividends on a cumulative basis at a rate of 11% and 8%, per share per year, as and when declared by the Board of Directors. Upon the conversion of the currently outstanding shares of Class A preferred stock and Class B preferred stock, the holders of these shares will receive an additional 870,234 shares of common stock and payment in cash of \$496,390 as accumulated dividends as of the date of this prospectus, assuming this offering closes on September 30, 2000. The holders of the Class A preferred stock have a liquidation preference over the holders of the Class B preferred stock and the common stockholders and the holders of the Class B preferred stock have a liquidation preference over the common stockholders. In addition to special voting rights to elect directors to the Board of Directors, each Class A preferred stockholder is entitled to ten times the number of votes per share of common stock into which the Class A preferred stock is convertible and each Class B preferred stockholder is entitled to the number of votes per share of common stock into which the Class B preferred stock is convertible.

Upon the closing of this offering and the payment of all accrued dividends, all of the shares of the Class A preferred stock and the Class B preferred stock will automatically convert into shares of common stock.

#### Options and Warrants

We have reserved 21,852 shares of common stock for issuance upon exercise of non-plan options. These options are exercisable at any time on or prior to February 4, 2002 at a price of \$2.29 per share. We have also reserved for issuance 21,468 shares of common stock for issuance upon outstanding warrants to purchase common stock at \$8.58 and \$11.74 per share which expire, respectively, on January 16, 2001 and March 2, 2002. Also, the representative of the underwriters will receive five-year warrants to purchase 200,000 shares. The exercise of any of these options and warrants will dilute the percentage ownership of our other stockholders.

#### Anti-Takeover Effects of Delaware Law and Delcath's Amended and Restated Certificate of Incorporation and By-Laws

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. That section provides, with exceptions, that a Delaware corporation may not engage in any of a broad range of business combinations with a person or his affiliate or associate who is an owner of 15% or more of the outstanding voting stock of the corporation for a period of three years from the date that this person became an interested stockholder.

Our board of directors is divided into three classes of directors serving staggered three-year terms. As a result, approximately one-third of the board of directors will be elected each year. These provisions, when coupled with the provisions of our amended and restated certificate of incorporation authorizing the board of directors to fill vacant directorships or increase the size of the board of directors, may deter a stockholder from removing incumbent directors and simultaneously gaining control of the board of directors by filling the vacancies created by that removal with its own nominees.

#### Transfer Agent and Warrant Agent

The transfer agent for our common stock and warrants is American Stock Transfer & Trust Company, 40 Wall Street, New York, New York 10005.

## SHARES ELIGIBLE FOR FUTURE SALE

After the closing of this offering, we will have 5,437,185 shares of common stock issued and outstanding of which the 2,000,000 shares offered by this prospectus will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by any affiliate of us. An affiliate of us is generally a person who has a controlling position with regard to us. Any shares purchased by our affiliates will be subject to the resale limitations of Rule 144 promulgated under the Securities Act.

All of the approximately 3,437,185 remaining shares of common stock that will be outstanding, are restricted securities as that term is defined under Rule 144.

Approximately 2,010,574 of these shares are immediately eligible for sale and the remaining 1,426,611 shares will become eligible, at various times, beginning 90 days following the date of this prospectus, in each case, subject to the contracted provisions below.

The holders of all of our common stock, including each of our officers, directors and principal stockholders, have agreed not to sell or dispose of any of the shares of common stock held by them, including in accordance with Rule 144, for a period of twelve months following the date of this prospectus without the prior written consent of the representative of the underwriters. For the second year following the closing, our officers, directors and principal shareholders have agreed that, without the representative's written consent, they will not sell any shares of common stock during any three-month period in excess of the amount they would be allowed to sell if they were deemed an affiliate of ours and the shares were deemed restricted as defined under Rule 144 of the Securities Act. This volume is the greater of:

- o 1% of the then outstanding common stock; and
- o the average weekly trading volume of the common stock during the four calendar weeks preceding a sale.

In general, under Rule 144, as currently in effect, beginning 90 days after the date of this prospectus, a person or group of persons whose shares are aggregated, who has beneficially owned restricted shares for at least one year, including the holding period of any prior owner except an affiliate of us, would be entitled to sell, within any three month period, a number of shares that does not exceed the greater of:

- o 1% of the then outstanding common stock; or
- o The average weekly trading volume of our common stock during the four calendar weeks preceding the sale, provided, that, public information about us as required by Rule 144 is available and the seller complies with manner of sale provisions and notice requirements.

The volume limitations described above, but not the one-year holding period, also apply to sales of our non-restricted securities by affiliates of us.

A person who is not an affiliate, has not been an affiliate within three months before the sale and has beneficially owned the restricted securities for at least two years, is entitled to sell the restricted shares under Rule 144 without regard to any of the limitations described above.

Before this offering, there was no public market for our common stock. We cannot predict the effect, if any, that sales of, or the availability for sale of, our common stock will have on the market price of our common stock prevailing from time to time. Nevertheless, the possibility that substantial amounts of common stock in the public market, including shares issuable upon the exercise of outstanding warrants or options, could adversely affect the prevailing market price of our common stock and could impair our ability to raise capital in the future through the sale of securities.

UNDERWRITING

Whale Securities Co., L.P. is acting as representative of the several underwriters named below. The underwriters have agreed, jointly and severally, subject to the terms and conditions contained in the underwriting agreement relating to this offering, to purchase the 2,000,000 shares of common stock offered by us. The number of shares of common stock that each underwriter has agreed to purchase appears opposite its name below:

Underwriter	Number of Shares
Whale Securities Co., L.P. ....	
Total .....	2,000,000 =====

The underwriting agreement provides that the obligations of the underwriters are subject to the delivery of an opinion of our counsel and to various other conditions. The underwriters are committed to purchase and pay for all of the shares offered by this prospectus if any of those shares are purchased.

The representative has advised us that the underwriters propose to offer our shares to the public at the public offering price indicated on the cover page of this prospectus. The underwriters may allow selected dealers who are members of the National Association of Securities Dealers, Inc., known as the NASD, concessions, not in excess of \$\_\_\_ per share, of which not in excess of \$\_\_\_ per share may be reallocated to other dealers who are members of the NASD.

We have granted to the representative an option, exercisable not later than 45 days after the date of this prospectus, to purchase up to 300,000 shares at the public offering price indicated on the cover page of this prospectus, less the underwriting discounts and commissions. The representative may exercise this option only to cover over-allotments, if any, made in connection with the sale of the common shares offered by this prospectus. If the representative exercises its over-allotment in full, the total price to the public would be \$13,800,000, the total underwriting discounts and commissions would be \$1,380,000 and the total proceeds to us, before payment of the expenses of this offering, would be \$12,420,000.

We have agreed to pay to the representative a non-accountable expense allowance equal to 3% of the gross proceeds from the sale of the shares offered by us, including any securities sold pursuant to the representative's over-allotment option, of which \$50,000 has been paid as of the date of this prospectus. We have also agreed to pay all expenses in connection with qualifying the shares offered under the laws of the states as the representative may designate, including expenses of counsel retained for this purpose by the underwriters. We estimate our expenses of this offering to be \$2,000,000, including the underwriters' discounts and commission, or \$2,234,000 if the representative's over-allotment option is completely exercised.

At the closing of this offering, we will sell to the representative and its designees, for an aggregate of \$100, representative's warrants to purchase up to 200,000 shares. The representative's warrants are exercisable at any time, in whole or in part, during the five-year period commencing on the date of this prospectus at an exercise price of \$9.90 per share, 165% of the public offering price per share. During the first year following the date of this prospectus, the representative's warrants may not be sold, transferred, pledged or hypothecated, except that the representative's warrants may be assigned or transferred only to officers and partners of the representative, or the underwriters and members of the selling group. During the exercise period, the holders of the representative's warrants will have the opportunity to profit from a rise in the market price of the shares, which will dilute the interests of our stockholders. We expect that the representative's warrants will be exercised when we would, in all likelihood be able to obtain any needed capital on terms more favorable to us than those provided in the representative's warrants. Any profit realized

by the representative on the sale of the representative's warrants or the underlying shares of common stock may be deemed additional underwriting compensation. The representative's warrants contain a cashless exercise provision. We have agreed that, upon the request of the holders of the majority of the representative's warrants, we will, at our own expense, on one occasion during the exercise period register the representative's warrants and the shares underlying the representative's warrants under the Securities Act. We have also agreed to include the representative's warrants and all underlying shares in any appropriate registration statement which is filed by us under the Securities Act during the seven years following the date of this prospectus.

We have agreed, for a period of three years from the date of this prospectus, if so requested by the representative, to nominate and use our best efforts to elect a designee of the representative as a director of Delcath or, at the representative's option, as a non-voting advisor to our board of directors. Our officers, directors and current stockholders have agreed to vote their shares in favor of the representative's designee. The representative has not yet exercised its right to designate a person.

The holders of all of our outstanding shares of common stock, options and warrants have agreed not to sell or dispose in another manner any of those securities in the public markets for a period of twelve months from the date of this prospectus without the representative's prior written consent. For the second year following the closing, our officers, directors and principal stockholders have agreed that without the representative's written consent they will not sell any shares of common stock during any three-month period in excess of the amount they would be allowed to sell if they were deemed an affiliate of ours and the shares were deemed restricted as defined under Rule 144 of the Securities Act. This amount is the greater of:

- o 1% of the then outstanding common stock; and
- o the average weekly trading volume of the common stock during the four calendar weeks preceding the sale.

We have agreed to indemnify the underwriters against civil liabilities, including liabilities under the Securities Act.

The representative has informed us that it does not expect sales of the securities offered to discretionary accounts to exceed 1% of the shares offered by this prospectus.

Before this offering, there has been no public market for our common stock. Accordingly, the initial public offering price of the common stock has been determined by negotiation between us and the representative and may not necessarily be related to our asset value, net worth or other established criteria of value. Factors considered in determining this price include our financial condition and prospects, an assessment of our management, market prices of similar securities of comparable publicly-traded companies, financial and operating information of companies engaged in activities similar to our business and the general condition of the securities market. Additionally, the initial public offering price of our common stock may not be indicative of the prices that may prevail in the public market.

In connection with this offering, the underwriters may engage in passive market making transactions in the shares on Nasdaq in accordance with Rule 103 of Regulation M promulgated under the Exchange Act.

In connection with this offering, the underwriters may engage in transactions that stabilize, maintain or affect in another manner the price of our common stock. These transactions may include stabilization transactions permitted by Rule 104 of Regulation M, under which persons may bid for or purchase shares to stabilize the market price. Specifically, the underwriters may over-allot in connection with this offering, creating a short position in our common stock for its own account. In addition, to cover over-allotments or to stabilize the price of our common stock, the underwriters may bid for, and purchase, shares in the open market. The underwriters may also reclaim selling concessions allowed to a dealer for distributing the common stock in this offering, if the underwriters repurchased previously distributed shares in transactions to cover short positions, in stabilization transactions or in another manner. Any of these activities may stabilize or maintain the market price of our common stock above independent market levels. The underwriters are not required to engage in these activities, and may end any of these activities at any time.



## LEGAL MATTERS

The validity of the common stock and warrants offered hereby will be passed upon for Delcath by Morse, Zelnick, Rose & Lander, LLP, New York, New York. Morse, Zelnick, Rose & Lander, LLP owns an aggregate 125,000 shares of our common stock. Blank Rome Tenzer Greenblatt LLP, New York, New York, has served as counsel to the underwriters in connection with this offering.

## EXPERTS

The financial statements of Delcath Systems, Inc. as of December 31, 1999 and for each of the years in the two year period ended December 31, 1999 and for the period from August 5, 1988 (inception) to December 31, 1999 included in this prospectus have been so included in reliance on the report of KPMG LLP, independent certified public accountants, given on the authority of such firm as experts in auditing and accounting.

## AVAILABLE INFORMATION

Delcath has filed with the Securities and Exchange Commission, a registration statement on Form SB-2, including exhibits and schedules thereto, under the Securities Act with respect to the shares to be sold in this offering. This prospectus which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement and the exhibits filed with it, portions of which have been omitted as permitted by the rules and regulations of the SEC. For further information with respect to Delcath and the shares to be sold in this offering, reference is made to the registration statement and to the exhibits filed with it. Statements contained in this prospectus as to the contents of any contract, agreement or other document referred to, are not necessarily complete. In each instance we refer you to the copy of the contracts, agreements and or other documents filed as exhibits to the registration statement, and these statements are deemed qualified in their entirety by reference to the contract or document.

You may inspect, without charge, all or any portion of the registration statement or any reports, statements or other information Delcath files at the SEC's public reference room at Room 1024, Judiciary Plaza, 450 Fifth Street, N.W., Washington, D.C. 20549 and at the regional offices of the SEC located at Seven World Trade Center, 13th Floor, Suite 1300, New York, New York 10048 and Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661. Copies of these documents may also be obtained from the SEC's Public Reference Room at 450 Fifth Street, N.W., Room 1024, Washington, D.C. 20549 upon payment of the prescribed fees. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

In addition, registration statements and other filings made with the SEC through its electronic data gathering, analysis and retrieval systems are publicly available through the SEC's site located at [www.sec.gov](http://www.sec.gov). The registration statement, including all exhibits and schedules and amendments, has been filed with the commission through the Electronic Data Gathering, Analysis and Retrieval system.

On the date of this prospectus, we will become subject to the reporting requirements of the Exchange Act and in accordance with these requirements, will file reports, proxy statements and other information with the SEC. We intend to furnish our stockholders with annual reports containing audited financial statements and other periodic reports as we deem appropriate or as may be required by law.

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Independent Auditors' Report

(When the reverse stock split as described in Note 2 of the accompanying financial statements has been consummated, we will be in a position to render the following opinion.)

/s/ KPMG LLP

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KPMG LLP

The Board of Directors  
Delcath Systems, Inc.:

We have audited the accompanying balance sheet of Delcath Systems, Inc. (a development stage enterprise) as of December 31, 1999 and the related statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 1999 and for the period from August 5, 1988 (inception) to December 31, 1999. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with generally accepted auditing standards. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Delcath Systems, Inc. (a development stage enterprise) as of December 31, 1999 and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 1999 and for the period August 5, 1988 (inception) to December 31, 1999, in conformity with generally accepted accounting principles.

May 5, 2000  
New York, New York

DELCATH SYSTEMS, INC.  
(A DEVELOPMENT STAGE COMPANY)

Balance Sheets

Assets	December 31, 1999	June 30, 2000
	-----	----- (unaudited)
Current assets:		
Cash and cash equivalents .....	\$ 561,078	417,549
Interest receivable .....	3,326	975
Prepaid rent .....	--	43,689
Prepaid insurance .....	4,167	23,333
Deferred IPO costs .....	--	291,363
	-----	-----
Total current assets .....	568,571	776,909
Furniture and fixtures, net .....	8,250	6,750
Due from affiliate .....	24,000	24,000
	-----	-----
Total assets .....	\$ 600,821	807,659
	=====	=====
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses .....	\$ 112,748	209,532
	-----	-----
Total current liabilities .....	112,748	209,532
	-----	-----
Commitments and contingencies (note 4)		
Stockholders' equity (note 2):		
Class A preferred stock, \$.01 par value: 5,000,000 shares authorized; 2,000,000 shares issued and outstanding (liqui- dation preference of \$2,216,637 at December 31, 1999) .....	20,000	20,000
Class B preferred stock, \$.01 par value: 5,000,000 shares authorized; 416,675 shares issued and outstanding (liquida- tion preference of \$1,625,033 at December 31, 1999) .....	4,167	4,167
Common stock, \$.01 par value: 15,000,000 shares authorized; 1,093,333 and 1,385,759 shares issued and outstanding .....	10,933	13,857
Additional paid-in capital .....	11,764,935	12,263,836
Deficit accumulated during development stage .....	(11,311,962)	(11,703,733)
	-----	-----
Total stockholders' equity .....	488,073	598,127
	-----	-----
Total liabilities and stockholders' equity .....	\$ 600,821	807,659
	=====	=====

See accompanying notes to financial statements.

DELCATH SYSTEMS, INC.

(A DEVELOPMENT STAGE COMPANY)

Statements of Operations

	Years ended December 31,	
	1998	1999
Costs and expenses:		
Legal, consulting and accounting fees .....	\$ 574,299	626,366
Stock option compensation expense (reversal) .....	759,229	(456,185)
Compensation and related expenses .....	466,644	200,128
Other operating expenses ...	324,271	227,817
Total costs and expenses .....	2,124,443	598,126
Operating income (loss)	(2,124,443)	(598,126)
Interest income .....	74,463	43,470
Interest expense .....	--	(17,925)
Net income (loss) .....	\$ (2,049,980)	(572,581)
Common share data:		
Basic and diluted income (loss) per share .....	\$ (2.01)	(0.54)
Weighted average number of shares of common stock outstanding .....	1,021,437	1,062,605

	Cumulative from inception (August 5, 1988) to December 31, 1999	Six months ended June 30,		Cumulative from inception (August 5, 1988) to June 30, 2000
		1999	2000	
		(Unaudited)		(Unaudited)
Costs and expenses:				
Legal, consulting and accounting fees .....	4,517,169	389,253	172,926	4,690,095
Stock option compensation expense (reversal) .....	2,520,170	(456,185)	--	2,520,170
Compensation and related expenses .....	2,488,170	123,733	104,765	2,592,935
Other operating expenses ...	2,191,276	149,381	127,116	2,318,392
Total costs and expenses .....	11,716,785	206,182	404,807	12,121,592
Operating income (loss)	(11,716,785)	(206,182)	(404,807)	(12,121,592)
Interest income .....	537,696	23,697	13,036	550,732
Interest expense .....	(132,873)	(17,925)	--	(132,873)
Net income (loss) .....	(11,311,962)	(200,410)	(391,771)	(11,703,733)
Common share data:				
Basic and diluted income (loss) per share .....		(0.19)	(0.32)	
Weighted average number of shares of common stock outstanding .....		1,042,283	1,239,547	

See accompanying notes to financial statements.

DELCATH SYSTEMS, INC.  
(A DEVELOPMENT STAGE COMPANY)

Statements of Stockholders' Equity

Six months ended June 30, 2000 (unaudited) and years ended December 31, 1999  
and 1998 and  
cumulative from inception (August 5, 1988) to December 31, 1999 and June 30,  
2000 (unaudited)

	Common stock \$.01 par value			
	Issued		In treasury	
	No. of shares	Amount	No. of shares	Amount
Shares issued in connection with the formation of the Company as of August 22, 1988 .....	786,678	\$ 7,867	--	--
Sale of preferred stock, August 22, 1988 .....	--	--	--	--
Shares returned as of March 9, 1990 .....	--	--	(524,451)	(5,245)
Sale of stock, October 2, 1990 .....	--	--	21,852	219
Sale of stock, January 23, 1991 .....	--	--	58,924	589
Sale of stock, August 30, 1991 .....	--	--	1,714	17
Sale of stock, December 31, 1992 .....	--	--	131,113	1,311
Sale of stock, July 15, 1994 .....	--	--	130,763	1,308
Sale of stock, December 19, 1996 .....	--	--	50,046	500
Shares issued in connection with conversion of short-term borrowings as of December 22, 1996 .....	74,086	741	124,619	1,246
Sale of stock, December 31, 1997 .....	67,742	677	--	--
Exercise of stock options .....	17,482	175	4,370	44
Shares issued as compensation .....	2,970	30	1,050	11
Amortization of compensatory stock options granted .....	--	--	--	--
Forfeiture of stock options .....	--	--	--	--
Shares issued in connection with exercise of warrants .....	27,318	273	--	--
Deficit accumulated from inception to December 31, 1997 .....	--	--	--	--
Balance at December 31, 1997 .....	976,276	9,763	--	--
Sale of stock, January 16, 1998 .....	43,704	437	--	--
Sale of stock, September 24, 1998 .....	4,370	44	--	--
Shares returned, April 17, 1998 .....	(4,370)	(44)	--	--
Amortization of compensatory stock options granted .....	--	--	--	--
Forfeiture of stock options .....	--	--	--	--
Exercise of stock options .....	10,926	109	--	--
Net loss for year ended December 31, 1998 .....	--	--	--	--
Balance at December 31, 1998 .....	1,030,906	10,309	--	--
Sale of stock, June 30, 1999 .....	59,514	595	--	--
Amortization of compensatory stock options granted .....	--	--	--	--
Forfeiture of stock options .....	--	--	--	--
Shares issued in connection with exercise of warrants .....	2,913	29	--	--
Net loss for year ended December 31, 1999 .....	--	--	--	--
Balance at December 31, 1999 .....	1,093,333	10,933	--	--
Sale of stock, April 14, 2000 .....	292,426	2,924	--	--
Net loss for six months ended June 30, 2000 (unaudited) .....	--	--	--	--
Balance at June 30, 2000 .....	1,385,759	\$13,857	--	--

	Common stock \$.01 par value		Class A preferred stock		Class B preferred stock	
	Outstanding		\$.01 par value		\$.01 par value	
	No. of shares	Amount	No. of shares	Amount	No. of shares	Amount
Shares issued in connection with the formation of the Company as of August 22, 1988 .....	786,678	\$ 7,867	--	--	--	--
Sale of preferred stock, August 22, 1988 .....	--	--	2,000,000	20,000	--	--
Shares returned as of March 9, 1990 .....	(524,451)	(5,245)	--	--	--	--
Sale of stock, October 2, 1990 .....	21,852	219	--	--	--	--
Sale of stock, January 23, 1991 .....	58,924	589	--	--	416,675	4,167
Sale of stock, August 30, 1991 .....	1,714	17	--	--	--	--
Sale of stock, December 31, 1992 .....	131,113	1,311	--	--	--	--
Sale of stock, July 15, 1994 .....	130,763	1,308	--	--	--	--
Sale of stock, December 19, 1996 .....	50,046	500	--	--	--	--
Shares issued in connection with conversion of short-term borrowings as of December 22, 1996 .....	198,705	1,987	--	--	--	--
Sale of stock, December 31, 1997 .....	67,742	677	--	--	--	--
Exercise of stock options .....	21,852	219	--	--	--	--
Shares issued as compensation .....	4,020	41	--	--	--	--
Amortization of compensatory stock options granted .....	--	--	--	--	--	--
Forfeiture of stock options .....	--	--	--	--	--	--
Shares issued in connection with exercise of warrants .....	27,318	273	--	--	--	--
Deficit accumulated from inception to December 31, 1997 .....	--	--	--	--	--	--
Balance at December 31, 1997 .....	976,276	9,763	2,000,000	20,000	416,675	4,167
Sale of stock, January 16, 1998 .....	43,704	437	--	--	--	--
Sale of stock, September 24, 1998 .....	4,370	44	--	--	--	--
Shares returned, April 17, 1998 .....	(4,370)	(44)	--	--	--	--
Amortization of compensatory stock options granted .....	--	--	--	--	--	--
Forfeiture of stock options .....	--	--	--	--	--	--
Exercise of stock options .....	10,926	109	--	--	--	--
Net loss for year ended December 31, 1998 .....	--	--	--	--	--	--
Balance at December 31, 1998 .....	1,030,906	10,309	2,000,000	20,000	416,675	4,167
Sale of stock, June 30, 1999 .....	59,514	595	--	--	--	--
Amortization of compensatory stock options granted .....	--	--	--	--	--	--
Forfeiture of stock options .....	--	--	--	--	--	--
Shares issued in connection with exercise of warrants .....	2,913	29	--	--	--	--
Net loss for year ended December 31, 1999 .....	--	--	--	--	--	--
Balance at December 31, 1999 .....	1,093,333	10,933	2,000,000	20,000	416,675	4,167
Sale of stock, April 14, 2000 .....	292,426	2,924	--	--	--	--
Net loss for six months ended June 30, 2000 (unaudited) .....	--	--	--	--	--	--
Balance at June 30, 2000 .....	1,385,759	\$ 13,857	2,000,000	\$20,000	416,675	\$4,167

	Additional paid-in capital	Deficit accumulated during development stage	Total
	-----	-----	-----
Shares issued in connection with the formation of the Company as of August 22, 1988 .....	\$ (6,867)	\$ --	\$ 1,000
Sale of preferred stock, August 22, 1988 .....	480,000	--	500,000
Shares returned as of March 9, 1990 .....	5,245	--	--
Sale of stock, October 2, 1990 .....	24,781	--	25,000
Sale of stock, January 23, 1991 .....	1,401,566	--	1,406,322
Sale of stock, August 30, 1991 .....	9,984	--	10,001
Sale of stock, December 31, 1992 .....	1,013,693	--	1,015,004
Sale of stock, July 15, 1994 .....	1,120,692	--	1,122,000
Sale of stock, December 19, 1996 .....	999,500	--	1,000,000
Shares issued in connection with conversion of short-term borrowings as of December 22, 1996 .....	1,702,977	--	1,704,964
Sale of stock, December 31, 1997 .....	774,323	--	775,000
Exercise of stock options .....	30,781	--	31,000
Shares issued as compensation .....	34,444	--	34,485
Amortization of compensatory stock options granted .....	2,496,347	--	2,496,347
Forfeiture of stock options .....	(279,220)	--	(279,220)
Shares issued in connection with exercise of warrants .....	234,125	--	234,398
Deficit accumulated from inception to December 31, 1997 .....	--	(8,689,401)	(8,689,401)
	-----	-----	-----
Balance at December 31, 1997 .....	10,042,371	(8,689,401)	1,386,900
Sale of stock, January 16, 1998 .....	499,563	--	500,000
Sale of stock, September 24, 1998 .....	56,956	--	57,000
Shares returned, April 17, 1998 .....	(4,956)	--	(5,000)
Amortization of compensatory stock options granted .....	1,166,418	--	1,166,418
Forfeiture of stock options .....	(407,189)	--	(407,189)
Exercise of stock options .....	67,391	--	67,500
Net loss for year ended December 31, 1998 .....	--	(2,049,980)	(2,049,980)
	-----	-----	-----
Balance at December 31, 1998 .....	11,420,554	(10,739,381)	715,649
Sale of stock, June 30, 1999 .....	775,597	--	776,192
Amortization of compensatory stock options granted .....	98,186	--	98,186
Forfeiture of stock options .....	(554,371)	--	(554,371)
Shares issued in connection with exercise of warrants .....	24,969	--	24,998
Net loss for year ended December 31, 1999 .....	--	(572,581)	(572,581)
	-----	-----	-----
Balance at December 31, 1999 .....	11,764,935	(11,311,962)	488,073
Sale of stock, April 14, 2000 .....	498,901	--	501,825
Net loss for six months ended June 30, 2000 (unaudited) .....	--	(391,771)	(391,771)
	-----	-----	-----
Balance at June 30, 2000 .....	\$12,263,836	\$ (11,703,733)	\$ 598,127
	=====	=====	=====

See accompanying notes to financial statements.



DELCATH SYSTEMS, INC.

(A DEVELOPMENT STAGE COMPANY)

Statement of Cash Flows

	Years ended December 31,	
	----- 1998 -----	----- 1999 -----
Cash flows from operating activities:		
Net income (loss) .....	\$ (2,049,980)	(572,581)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock option compensation expense (reversal) .....	759,229	(456,185)
Stock compensation expense .....	--	--
Depreciation expense .....	3,000	3,000
Amortization of organization costs .....	--	--
(Increase) decrease in prepaid expenses .....	7,966	867
(Increase) decrease in interest receivable .....	32,932	1,797
Due from affiliate .....	--	--
(Decrease) increase in accounts payable and accrued expenses .....	(174,369)	(69,323)
	-----	-----
Net cash used in operating activities .....	(1,421,222)	(1,092,425)
	-----	-----
Cash flows from investing activities:		
Purchase of furniture and fixtures .....	--	--
Purchase of short-term investments .....	--	--
Proceeds from maturities of short-term investments .....	--	--
Organization costs .....	--	--
	-----	-----
Net cash provided by (used in) investing activities .....	--	--
	-----	-----
Cash flows from financing activities:		
Net proceeds from sale of stock and exercise of stock options and warrants	624,500	801,190
Deposits .....	(304,991)	--
Deferred IPO costs .....	--	--
Proceeds from short-term borrowings .....	--	--
	-----	-----
Net cash provided by financing activities .....	319,509	801,190
	-----	-----
Increase (decrease) in cash and cash equivalents .....	(1,101,713)	(291,235)
Cash and cash equivalents at beginning of period .....	1,954,026	852,313
	-----	-----
Cash and cash equivalents at end of period	\$ 852,313	561,078
	=====	=====
Supplemental cash flow activities:		
Conversion of debt to common stock .....	\$ --	--
	=====	=====
Cash paid for interest .....	\$ --	17,925
	=====	=====

	Cumulative from inception (August 5, 1988) to December 31, 1999	Six months ended		Cumulative from inception (August 5, 1988) to June 30, 2000
		June 30, 1999	June 30, 2000	
		(Unaudited)		(Unaudited)
<b>Cash flows from operating activities:</b>				
Net income (loss) .....	(11,311,962)	(200,410)	(391,771)	(11,703,733)
Adjustments to reconcile net income (loss) to net cash used in operating activities:				
Stock option compensation expense (reversal) .....	2,520,171	(456,185)	--	2,520,171
Stock compensation expense .....	34,485	--	--	34,485
Depreciation expense .....	6,750	1,500	1,500	8,250
Amortization of organization costs .....	42,165	--	--	42,165
(Increase) decrease in prepaid expenses .....	(4,167)	(11,633)	(62,855)	(67,022)
(Increase) decrease in interest receivable .....	(3,326)	3,900	2,351	(975)
Due from affiliate .....	(24,000)	--	--	(24,000)
(Decrease) increase in accounts payable and accrued expenses .....	112,748	61,580	96,784	209,532
Net cash used in operating activities .....	(8,627,136)	(601,248)	(353,991)	(8,981,127)
<b>Cash flows from investing activities:</b>				
Purchase of furniture and fixtures .....	(15,000)	--	--	(15,000)
Purchase of short-term investments .....	(1,030,000)	--	--	(1,030,000)
Proceeds from maturities of short-term investments .....	1,030,000	--	--	1,030,000
Organization costs .....	(42,165)	--	--	(42,165)
Net cash provided by (used in) investing activities .....	(57,165)	--	--	(57,165)
<b>Cash flows from financing activities:</b>				
Net proceeds from sale of stock and exercise of stock options and warrants	7,540,415	801,190	501,825	8,042,240
Deposits .....	--	--	--	--
Deferred IPO costs .....	--	--	(291,363)	(291,363)
Proceeds from short-term borrowings .....	1,704,964	--	--	1,704,964
Net cash provided by financing activities .....	9,245,379	801,190	210,462	9,455,841
Increase (decrease) in cash and cash equivalents .....	561,078	199,942	(143,529)	417,549
Cash and cash equivalents at beginning of period .....	--	852,313	561,078	--
Cash and cash equivalents at end of period	561,078	1,052,255	417,549	417,549
<b>Supplemental cash flow activities:</b>				
Conversion of debt to common stock .....	1,704,964	--	--	1,704,964
Cash paid for interest .....	114,948	--	--	114,948

See accompanying notes to financial statements.

DELCATH SYSTEMS, INC.  
(A Development Stage Company)  
Notes to Financial Statements

December 31, 1999 and 1998

(1) Description of Business and Summary of Significant Accounting Policies

(a) 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. It is hoped that the procedure will result in a meaningful treatment for cancer. In November 1989, the Company was granted an IDE (Investigational Device Exemption) and an IND status (Investigational New Drug) for its product by the FDA (Food and Drug Administration).

(b) Basis of Financial Statement Presentation

The accounting and financial reporting policies of the Company conform to generally accepted accounting principles. The preparation of financial statements in conformity with generally accepted accounting principles requires management to make assumptions and estimates that impact the amounts reported in those statements. Such assumptions and estimates are subject to change in the future as additional information becomes available or as circumstances are modified. Actual results could differ from these estimates.

(c) Furniture and Fixtures

Furniture and fixtures are recorded at cost and are being depreciated over the estimated useful lives of the assets.

(d) Income Taxes

The Company accounts for income taxes following the asset and liability method in accordance with Statement of Financial Accounting Standards (SFAS) No. 109, "Accounting for Income Taxes." Under such method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The Company's income tax returns are prepared on the cash basis of accounting. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years that the asset is expected to be recovered or the liability settled.

(e) Stock Option Plan

The Company has historically accounted for its employee stock option plans in accordance with the provisions of Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. As such, compensation expense is recorded on the date of grant only if the current fair market value of the underlying stock exceeds the exercise price. Fair market values of the Company's common stock at the dates options were granted were based on third party sales of stock at or around the dates options were granted, or in the absence of such transactions, based on a determination by the board of directors based on current available information. In 1996, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock-Based Compensation," which permits entities to recognize as expense over the vesting period the fair value of all stock-based awards on the date of grant. Alternatively, SFAS No. 123 also allows entities to continue to apply the provisions of APB Opinion No. 25 and provide pro forma net income and pro forma earnings per share disclosures for employee stock option grants made in 1995 and future years as if the fair-value-based method defined in SFAS No. 123 had been applied. The Company has elected to continue to apply the provisions of APB Opinion No. 25 and provide the pro forma disclosure provisions of SFAS No. 123 (see note 2(e)).

DELCATH SYSTEMS, INC.  
(A Development Stage Company)  
Notes to Financial Statements

December 31, 1999 and 1998 -- (Continued)

(1) Description of Business and Summary of Significant Accounting Policies --  
(Continued)

(f) Earnings Per Share

Basic earnings per share is computed using the weighted average number of shares of common stock outstanding during the period. Diluted earnings per share reflect the dilutive effect of common stock equivalents using the treasury stock method.

(g) Statements of Cash Flows

For purposes of the statements of cash flows, the Company considers highly liquid debt instruments with original maturities of three months or less to be cash equivalents. At December 31, 1999 cash equivalents included commercial paper of \$557,000.

(h) Interim Financial Information

The financial statements and notes related thereto as of June 30, 2000 and for the six months ended June 30, 1999 and 2000 are unaudited, but in the opinion of management, include all normal recurring adjustments necessary for a fair presentation of financial position and results of operations. The operating results for the interim periods are not necessarily indicative of a full year's operations.

(2) Stockholders' Equity

The common stock and per share data for all periods gives effect to a reverse stock split of 1 for 2.2881 shares which is to occur immediately before the date of the Company's initial public offering described in note 5.

(a) Stock Issuances

BGH Medical Products, Inc. (name later changed to Delcath Systems, Inc.), a Delaware corporation (BGH - Delaware), was formed on August 5, 1988. As of August 22, 1988, BGH Medical Products, Inc., a Connecticut corporation (BGH - Conn.), was merged into BGH - Delaware, the surviving corporation. As of the merger date, the authorized capital stock of BGH - Conn. consisted of 5,000 shares of common stock, par value \$.01 per share, of which 1,000 shares were issued and outstanding. Upon the merger, each BGH - Conn. common share outstanding was exchanged into 786.678 shares of BGH - Delaware common stock. As a result of the conversion, BGH - Delaware issued 786,678 shares of common stock at \$.01 par value. The aggregate amount of the par value of all shares of common stock issued as a result of the exchange, \$7,867, was credited as the common stock capital of BGH - Delaware, and the difference in respect to the capital account deficiency was charged to additional paid-in capital.

On August 22, 1988, BGH - Delaware then sold in a private placement 2,000,000 shares of class A preferred stock, with a par value of \$.01, to two affiliated venture capital funds for an aggregate amount of \$500,000 in cash.

On March 8, 1990, 524,451 shares of common stock were returned to the Company as treasury stock due to relevant technology milestones not being fully achieved within the specified time period, in accordance with provisions of a stockholders' agreement.

Effective May 7, 1990, the Company changed its name to Delcath Systems, Inc.

On October 2, 1990, the Company sold 21,852 shares of common stock held in its treasury, at \$.01 par value, for an aggregate amount of \$25,000.

On January 23, 1991, the Company offered in a private placement shares of common stock and/or class B preferred stock at \$5.83 and \$2.55 per share, respectively, for an aggregate maximum amount of

DELCATH SYSTEMS, INC.  
(A Development Stage Company)  
Notes to Financial Statements

December 31, 1999 and 1998 -- (Continued)

(2) Stockholders' Equity -- (Continued)

\$2,000,000. Under the terms of the private placement, 58,924 shares of common stock held in its treasury and 416,675 shares of class B preferred stock were sold, yielding net proceeds to the Company of \$1,406,322. The common stock and class B preferred stock sold each has a par value of \$.01, resulting in an increase in additional paid-in capital of \$1,401,566. The two affiliated venture capital funds that owned the class A preferred stock purchased 117,650 of the class B preferred stock sold in the private placement.

On August 30, 1991, the Company sold an additional 1,714 shares of common stock held in its treasury at \$5.83 per share, yielding proceeds to the Company of \$10,001. The shares have a par value of \$.01, resulting in an additional paid-in capital amount of \$9,984.

In a December 1992 private placement, the Company sold 131,113 shares of common stock held in our treasury at \$8.01 per share for a total placement of \$1,050,000 (\$1,015,004 after expenses). The shares issued have a par value of \$.01, resulting in an additional paid-in capital amount of \$1,048,689 (\$1,013,693 after expenses). The two affiliated venture capital funds that owned the class A preferred stock purchased 34,963 of the shares of common stock in its treasury which were sold.

Effective January 1, 1994, the Company issued 2,185 shares of common stock held in its treasury at \$1.14 per share for a total price of \$2,500 upon the exercise of stock options by an employee of the Company.

During the first quarter of 1994, the Company increased its authorized number of shares of common stock from 5,000,000 to 15,000,000.

On July 15, 1994, the Company sold through a private placement offering, units at a price of \$51,000 per unit. Each unit consisted of 5,944 common shares and 594 warrants, each of which entitled the holder to purchase one share of common stock for \$8.58. In connection therewith, the Company sold twenty-two (22) units (130,763 common shares and 13,076 warrants expiring August 30, 1997) for total proceeds of \$1,122,000. The two affiliated venture capital funds that owned the class A preferred stock purchased six (6) of the units sold. During August 1997, the holders of warrants exercised 11,293 warrants to purchase 11,293 shares of common stock at \$8.58 each for total proceeds of \$96,900. The remaining warrants expired unexercised.

Effective January 1, 1995, the Company issued 2,185 shares of common stock held in its treasury at \$1.14 per share for a total price of \$2,500 upon the exercise of stock options by an employee of the Company.

Effective January 1, 1996, the Company issued 1,049 shares of common stock, valued at \$8.58 per share for a total of \$9,000, as compensation for consulting services.

On December 19, 1996, the Company sold through a private transaction 50,046 shares of common stock for total proceeds of \$1,000,000. In connection with the offering, the purchaser obtained sole distribution rights for the Company's products for a limited period of time in Japan, Korea, China, Taiwan, and Hong Kong. No value was attributed to the distribution rights. In addition, the purchaser will be required to buy certain products from the Company.

On April 26, 1996, the Company entered into short-term borrowing agreements with 26 investors under which it borrowed \$1,704,964 bearing interest at 10.25% per annum. Under the terms of the agreements, on December 22, 1996, the short-term borrowings were converted into 198,705 shares of common stock, based on a conversion price of \$8.58 per share, and 99,350 warrants, expiring April 25, 1999, entitling the holders to purchase 99,350 additional shares of common stock at \$8.58 per share. The two affiliated venture capital funds discussed above provided \$250,000 of the short-term loan, converting that debt into 29,136 shares and 14,568

DELCATH SYSTEMS, INC.  
(A Development Stage Company)  
Notes to Financial Statements

December 31, 1999 and 1998 -- (Continued)

(2) Stockholders' Equity -- (Continued)

warrants. From April 26, 1996 through December 22, 1996, interest of \$114,948 accrued on the borrowings. Such interest was paid in January 1997. During September 1997, the holders of warrants exercised 1,457 warrants to purchase 1,457 shares of common stock at \$8.58 each for total proceeds of \$12,499. During December 1997, the two affiliated venture capital funds exercised their 14,568 warrants to purchase 14,568 common shares at \$8.58 each for total proceeds of \$124,999. During April 1999, the holders of warrants exercised 2,913 warrants to purchase 2,913 common shares at \$8.58 each for total proceeds of \$24,998. The remaining warrants expired unexercised.

In 1997, the Company issued 2,970 shares of common stock, valued at \$8.58 per share based on a 1996 agreement, for a total cost of \$25,485, as compensation for consulting services.

From September 1997, through December 31, 1997, the Company issued 67,742 shares of common stock. During January 1998, the Company received an additional \$500,000 and issued another 43,704 shares. In April 1998, under the terms of the restricted stock sales agreements, the Company issued to the purchasers of the 111,446 shares of common stock 14,859 three year warrants entitling the holders to purchase 14,859 shares of common stock at \$8.58 per share.

In December 1997, the holder of non-incentive stock options exercised 17,482 options to purchase 17,482 shares of common stock at \$1.49 each for total proceeds of \$26,000.

At the end of December 1997, the holders of 35,545 shares of common stock agreed to sell those shares to the two affiliated venture capital funds discussed above at \$8.58 per share. The venture capital funds deposited \$304,991 with the Company pending transfer of the shares. At the time of transfer, the Company paid the funds to the sellers.

In April 1998, a venture capital firm exercised 10,926 non-incentive stock options to purchase 10,926 restricted common shares at \$6.18 each for total proceeds of \$67,500.

In April 1998, in connection with the settlement of a dispute with a former director, the Company cancelled 4,370 shares of common stock previously held by the former director in return for \$1.14 per share, the price originally paid by the former director.

In September 1998, the Company sold 4,370 shares of common stock to an individual for \$13.04 per share, yielding proceeds to the Company of \$57,000.

In June 1999, the Company sold 59,514 shares of common stock to individual investors for \$13.04 per share and warrants entitling the holders to purchase 6,609 common shares at \$11.74 per share (which warrants expire April 30, 2002), yielding proceeds to the Company of \$776,192.

In April 2000, the Company sold 292,426 shares at \$1.72 per share to existing stockholders in a rights offering yielding proceeds to the Company of \$501,825.

The two affiliated venture capital firms discussed above were liquidated in 1998 and the shares of the Company then owned by the funds were distributed to the individual investors of the funds, or their nominee, if so directed.

(b) Voting Rights

Each holder of common stock is entitled to one vote. Each share of class A preferred stock and each share of class B preferred stock is convertible into shares of common stock on a one for .4370 basis, subject to antidilution adjustments. In addition to special voting rights to elect directors to the Board of Directors,

DELCATH SYSTEMS, INC.  
(A Development Stage Company)  
Notes to Financial Statements

December 31, 1999 and 1998 -- (Continued)

(2) Stockholders' Equity -- (Continued)

each class A preferred stockholder is entitled to ten times the number of votes per share of common stock into which the class A preferred stock is convertible and each class B preferred stockholder is entitled to the number of votes per share of Common Stock into which the class B preferred stock is convertible.

(c) Liquidation Preference

In the event of any liquidation, dissolution or winding up of the Company, after provision for payment of debts and other liabilities, the holders of the class A preferred stock shall be entitled to receive, prior to any distribution of any of the assets or surplus funds of the Company to the holders of class B preferred stock and common stock, an amount equal to the sum of (a) 150% of the issue price (as adjusted for any combinations, consolidations, stock distributions or stock dividends with respect to such shares) plus (b) a sum equal to that amount of interest that would have accrued if a sum equal to 150% of the issue price had been invested at a compounded annual interest rate of 10% at the original issue date. After the satisfaction of the class A preferred stockholders, the holders of class B preferred stock will be entitled to a liquidation sum, in preference to the common stockholders, of \$3.90 per share. Common stockholders will be entitled to share ratably with the class A and class B preferred stockholders (on an as-converted basis) in the remaining assets of the Company.

(d) Dividends

The holders of class A and class B preferred stock are entitled to receive dividends on a cumulative basis at the rate of 11% and 8%, respectively, per share per annum as and when declared by the Board of Directors, before any dividend or distribution is declared, set apart for, or paid upon the common stock of the Company. As of December 31, 1999, class A preferred stock and class B preferred stock had dividends in arrears of \$624,740 (\$.31 per share) and \$759,429 (\$1.82 per share), respectively. Dividends declared but unpaid, at the option of the holder, are payable in cash or may be converted into common stock subject to antidilution adjustments. The class A dividends may be converted at the rate of \$.57 per share, while the class B dividends may be converted at the rate of \$5.83 per share.

The Company has entered into agreements with the preferred shareholders providing that if the Company completes a public offering of its common stock prior to September 30, 2001, the Board will, immediately prior to the offering, declare as payable all dividends in arrears. In such event, the preferred shareholders have agreed to accept one-third of such dividends in cash and then immediately convert all of their outstanding preferred stock into common stock as well as convert the balance of their declared but unpaid preferred stock dividends into common stock at the applicable conversion price.

(e) Stock Option Plans

The Company established an Incentive Stock Option Plan and a Non-Incentive Stock Option Plan under which stock options may be granted. Additionally, the Company has entered into separate contracts apart from the Incentive Stock Option Plan and the Non-Incentive Stock Option Plan under which options to purchase common shares have been granted. A stock option granted allows the holder of the option to purchase a share of the Company's common stock in the future at a stated price. The Plans are administered by the Board of Directors which determines the individuals to whom the options shall be granted as well as the terms and conditions of each option grant, the option price and the duration of each option.

The Company's Incentive and Non-Incentive Stock Plans were approved and became effective on November 1, 1992. The Incentive Stock Options vest as determined by the Company and expire over varying terms, but not more than five years from the date of grant.

DEL CATH SYSTEMS, INC.  
(A Development Stage Company)  
Notes to Financial Statements

December 31, 1999 and 1998 -- (Continued)

(2) Stockholders' Equity -- (Continued)

Stock option activity for the period January 1, 1998 through December 31, 1999 is as follows:

Grants	Non-Incentive and Incentive Option Plans		Other Option	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at December 31, 1997	255,020	\$ 6.11	21,852	\$ 2.29
Granted during 1998	21,852	6.18	--	--
Forfeited during 1998	(52,445)	6.18	--	--
Expired during 1998	(119,750)	6.18	--	--
Exercised during 1998	(10,926)	6.18	--	--
Outstanding at December 31, 1998	93,751	5.97	21,852	2.29
Granted during 1999	559,416	3.27	21,852	2.29
Canceled during 1999	(43,704)	5.97	--	--
Forfeited during 1999	(50,047)	5.97	--	--
Expired during 1999	--	--	(21,852)	2.29
Outstanding at December 31, 1999	559,416	\$ 3.27	21,852	\$ 2.29

The following summarizes information about shares subject to option at December 31, 1999:

Options outstanding				Options exercisable	
Number outstanding	Range of exercise prices	Weighted average exercise price	Weighted average remaining life in years	Number exercisable	Weighted average exercise price
240,374	\$2.29	\$2.29	3.76	131,113	\$ 2.29
340,894	3.89	3.89	4.00	340,894	3.89
581,268	\$2.29 - \$3.89	\$3.23	3.90	472,007	\$ 3.46

The Company applies APB 25 and related interpretations in accounting for its plans. As such, compensation cost is measured at the date of grant as the excess, if any, of the fair market value of the underlying stock over the exercise price. Such cost is then recognized over the period the recipient is required to perform services to earn such compensation. If a stock option is not exercised because an employee fails to fulfill an obligation, the estimate of compensation expense recorded in previous periods is adjusted by decreasing compensation expense in the period of forfeiture. In 1998 and 1999, former employees of the Company resigned and forfeited all of their non vested options. As a result, the expense previously accrued for such option grants was reversed. Accordingly, stock option compensation expense/(reversal) associated with the Incentive and Non-Incentive Stock Plans for the years ended December 31, 1998 and 1999 was \$759,229 and (\$456,185), respectively, net of forfeitures of \$407,189 and \$554,371, respectively. Had compensation cost for the Company's stock option grants been determined based on the fair value at the grant dates consistent with the methodology of SFAS 123, the Company's net loss for the years ended December 31, 1998 and 1999 would have been increased to the pro forma amounts indicated as follows:



DELCATH SYSTEMS, INC.  
(A Development Stage Company)  
Notes to Financial Statements

December 31, 1999 and 1998 -- (Continued)

(2) Stockholders' Equity -- (Continued)

	1998	1999
Net loss:		
As reported	\$ (2,049,980)	(572,581)
Pro forma	(2,132,139)	(944,303)

The per share weighted average fair value of stock options granted during 1999 and 1998 was \$.73, estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for the grants for both years: no dividend yield, risk free interest rate of 5.5%, expected lives of five years and no volatility.

(3) Income Taxes

As of December 31, 1999, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$8,542,000 which are available to offset future federal taxable income, if any, through 2019. The net operating loss carryforwards resulted in a deferred tax asset of approximately \$2,904,000 at December 31, 1999. Management does not expect the Company to be taxable in the near future and has established a 100% valuation allowance against the deferred tax asset created by the net operating loss carryforwards.

(4) Prepaid Rent and Due From Affiliate

The Company occupies office space pursuant to an informal arrangement with the landlord according to which the Company prepaid its rent for the period through December 31, 2000. In addition, the landlord is holding a \$24,000 deposit provided by the Company.

(5) Initial Public Offering

In March 2000, the Company engaged an investment banker for the purpose of issuing its stock in an initial public offering. In connection therewith, the Company anticipates declaring and paying the preferred stock dividends as described in note 2(d); converting all the outstanding preferred stock to common stock as described in note 2(d) and effecting a reverse split of the common shares of 1 for 2.2881 shares.

The Delcath System Procedure  
Isolating the Liver For Chemotherapy Treatment

[Diagram of interior cross section of a human torso showing the liver, heart and major arteries and veins. The Delcath system is shown with the Delcath catheters fully inserted in place. Arrows with numbers keyed to text at the bottom trace the flow of chemotherapy through the liver as directed by the Delcath system.]

1. An infusion catheter is inserted into the artery through which blood normally flows to the liver.
2. A second catheter -- the Delcath double balloon catheter -- is inserted through the inferior vena cava. Blood normally flows from the liver into the inferior vena cava to the heart which circulates the blood throughout the body.
3. The balloons on the double balloon catheter are then inflated using the caudal and cephalad extensions. The balloons prevent the normal flow of blood from the liver to the heart because the inferior vena cava is blocked. Once the balloons are inflated, the activated charcoal filters are opened and the priming line, which is used during catheter positioning, is clamped.
4. A chemotherapeutic agent is infused into the liver through the infusion catheter.
5. The blood in the liver, which is now infused with a chemotherapeutic agent, cannot flow to the heart. Blood exits the liver through perforations on the double balloon catheter and flows into this catheter out of the body. During the procedure, samples of the isolated blood can be obtained through the sampling extension.
6. Once out of the body, the infused blood is circulated through activated charcoal filters to remove most of the chemotherapeutic agent.
7. The filtered blood is returned to the patient through the jugular vein which leads to the superior vena cava and the heart. The heart restores the cleansed blood to normal circulation.

This diagram illustrates normal  
blood flow.

Blood normally travels from the  
hepatic (liver) veins into the inferior vena cava and towards the heart.

This diagram illustrates the blood flow  
using the Delcath system.

During drug delivery, the Delcath double balloon catheter isolates the hepatic  
blood for 60 minutes. The two balloons obstruct the normal flow and divert the  
hepatic blood through openings in the catheter. This blood travels through the  
catheter to the filtration system outside the patient's body.

CT scans showing the results of  
treatment using the Delcath system  
on a single patient.

[CT scan of liver of patient before treatment, with the tumors marked in red]

Pre-Treatment. Two large metastatic tumors in the liver.

[CT scan of same patient after treatment showing the reduction of tumors]

Post-Treatment. Significant reduction in size of tumors.

The above CT scans show the results of treatment using the Delcath System on a single patient, as reported in "Percutaneous hepatic vein isolation and high-dose hepatic arterial infusion chemotherapy for unresectable liver tumors," by Dr. T.S. Ravikumar and associates in the Journal of Clinical Oncology, December 1994. The scans should not be viewed as evidence that the Delcath system will generally shrink tumors in patients, but are presented because they highlight the reason Delcath is sponsoring Phase III clinical trials designed to demonstrate whether results seen in some Phase I/II patients will be repeated in a statistically relevant number of new patients.

=====  
We have not authorized any dealer, salesperson or any other person to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information. This prospectus does not constitute an offer to sell or buy any shares in any jurisdiction where it is unlawful.  
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Until \_\_\_\_\_, 2000 (25 days after the date of this prospectus), all dealers effecting transactions in the registered securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.  
=====

2,000,000 Shares

[GRAPHIC OMITTED]

Common Stock

-----  
PROSPECTUS  
-----

Whale Securities Co., L.P.

, 2000  
=====

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 24. Indemnification of Directors and Officers

Section 145 of the General Corporation Law of the State of Delaware provides for the indemnification of officers and directors under certain circumstances against expenses incurred in successfully defending against a claim and authorizes a Delaware corporation to indemnify its officers and directors under certain circumstances against expenses and liabilities incurred in legal proceedings involving such persons because of their being or having been an officer or director.

Section 102(b) of the Delaware General corporation Law permits a corporation, by so providing in its certificate of incorporation, to eliminate or limit a director's liability to the corporation and its stockholders for monetary damages arising out of certain alleged breaches of their fiduciary duty. Section 102(b)(7) provides that no such limitation of liability may affect a director's liability with respect to any of the following:

- o breaches of the director's duty of loyalty to the corporation or its stockholders;
- o acts or omissions not made in good faith or which involve intentional misconduct of knowing violations of law;
- o liability for dividends paid or stock repurchased or redeemed in violation of the Delaware General Corporation law; or
- o any transaction from which the director derived an improper personal benefit. Section 102(b)(7) does not authorize any limitation on the ability of the company or its stockholders to obtain injunctive relief, specific performance or other equitable relief against directors.

Article Seventh of the Registrant's Certificate of Incorporation provides that the personal liability of the directors of the Registrant be eliminated to the fullest extent permitted under Section 102(b) of the Delaware General Corporation law.

Article Eighth of the Registrant's Certificate of Incorporation and the Registrant's By-laws provides that all persons whom the Registrant is empowered to indemnify pursuant to the provisions of Section 145 of the Delaware General Corporation law (or any similar provision or provisions of applicable law at the time in effect), shall be indemnified by the Registrant to the full extent permitted thereby. The foregoing right of indemnification shall not be deemed to be exclusive of any other rights to which those seeking indemnification may be entitled under any by-law, agreement, vote of stockholders or disinterested directors, or otherwise.

Insofar as indemnification for liabilities under the Securities Act of 1933, as amended (the "Securities Act") may be permitted to directors, officers or persons controlling the Registrant pursuant to the foregoing provisions, the Registrant has been informed that in the opinion of the Commission, such indemnification is against public policy as expressed in the Securities Act and is therefor unenforceable.

Reference is made to the Underwriting Agreement, the proposed form of which is filed as Exhibit 1.1, pursuant to which the underwriters agree to indemnify the directors and certain officers of the Registrant and certain other persons against certain civil liabilities.

Item 25. Other Expenses of Issuance and Distribution

The following table sets forth the expenses (other than the underwriting discounts and commissions and the representative's non-accountable expense allowance) expected to be incurred in connection with the issuance and distribution of the securities being registered. All of such expenses are estimates, other than the filing fees payable to the Securities and Exchange Commission and the National Association of Securities Dealers, Inc.

Filing Fee - Securities and Exchange Commission .....	\$ 4,165.92
Filing Fee - National Association of Securities Dealers, Inc. ....	\$ 2,078.00
Fees and Expenses of Accountants .....	\$ 75,000.00
Fees and Expenses of Counsel .....	\$ 225,000.00*
Printing and Engraving Expenses .....	\$ 50,000.00
Blue Sky Fees and Expenses .....	\$ 75,000.00
Transfer Agent Fees .....	\$ 5,000.00
Miscellaneous Expenses .....	\$ 3,756.08
	-----
Total: .....	\$ 440,000.00
	=====

\* In addition, counsel will receive 125,000 common shares at the consummation of this offering.

#### Item 26. Recent Sales of Unregistered Securities

Since January 1997, the Registrant has issued securities without registration under the Securities Act in the following transactions:

1. From September 1997 through January 1998, the Registrant issued an aggregate of 114,446 shares of common stock to eleven investors, including Venkol Ventures LP, Venkol Ventures Ltd. and a director of the Registrant for aggregate proceeds of \$1,275,000. In April 1998, the eleven investors also received three-year warrants to purchase 14,859 shares of common stock at \$8.58 per share.

2. In December 1997, the Registrant issued an aggregate of 17,482 shares of common stock to an employee upon the exercise of non-incentive stock options for aggregate proceeds of \$26,000.

3. In December 1997, the Registrant issued an aggregate of 2,970 shares of common stock valued at \$25,485 to a consultant as compensation for consulting services.

4. In April 1998, the Registrant issued an aggregate of 10,926 shares of common stock to a venture capital firm upon the exercise of non-incentive stock options for aggregate proceeds of \$67,500.

5. In September 1998, the Registrant issued an aggregate of 4,370 shares of common stock to an investor for aggregate proceeds of \$57,000.

6. In April 1999, the Registrant issued an aggregate of 2,913 shares of common stock to a venture capital firm upon the exercise of warrants for aggregate proceeds of \$24,998.

7. In June 1999, the Registrant issued an aggregate of 59,514 shares of common stock and warrants entitling the holders thereof to purchase an aggregate of 6,609 shares of common stock to twelve investors, at \$11.74 per share, including a director of the Registrant, for aggregate proceeds of \$776,192.

8. In April 2000, the Registrant issued an aggregate of 292,426 shares of common stock to 14 security holders and their designees for aggregate proceeds of \$501,825

The sales and issuances of the common stock, options and warrants in each transaction described above were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(2) of the Securities Act as transactions not involving a public offering. The issuance of common stock and warrants described in item 6 were exempt from registration under Section 4(6) of the Securities Act. In addition, the issuance of common stock and warrants described in items 7 and 8 were exempt from registration under Regulation D Rules 506 and 504, respectively. The Registrant made a determination that each of the purchasers was a sophisticated investor who had access to the same type of information typically available in a registration statement. The purchasers in such private offerings represented their intention to acquire the securities for investment only and not with a view to the distribution thereof. Appropriate legends were affixed to the stock certificates and warrants issued in each transaction. All purchasers had adequate access, through their employment or other relationships, to sufficient information about the Registrant to make an informed investment decision. None of the securities was sold through an underwriter and, accordingly, there were no underwriting discounts or commissions involved.

Item 27. Exhibits

Exhibit No.	Description
1.1	Form of Underwriting Agreement*
3.1	Revised form of Amended and Restated Certificate of Incorporation of the Registrant*
3.2	Revised form of By-Laws of the Registrant*
4.1	Specimen Stock Certificate*
4.2	Form of Representative's Warrant Agreement*
5.1	Opinion of Morse, Zelnick, Rose & Lander, LLP*
10.1	1992 Incentive Stock Option Plan*
10.2	1992 Non-Incentive Stock Option Plan*
10.3	2000 Stock Option Plan*
10.4	Employment Agreement between the Registrant and M.S Koly, as amended*
10.5	Employment Agreement between the Registrant and Samuel Herschkowitz, M.D., as amended*
10.6	Distributorship Agreement with Nissho Corporation*
10.7	Form of Lock-up Agreement
10.8	Form of Promissory Note
23.1	Consent of KPMG LLP
23.2	Consent of Morse, Zelnick, Rose & Lander, LLP (included in Exhibit 5.1).*
23.3	Consents from the following scientific advisors and consultants: Morton G. Glickman, William N. Hait, M.D., Ph.D., T.S. Ravikumar, M.D., Anil R. Diwan, Ph.D., Harvey J. Ellis, C.C.P., Durmus Koch, James H. Muchmore, M.D., Gabriela Nicolau, Ph.D., and John Quiring, Ph.D.*
24	Power of Attorney (included in signature page).*
27.1	Financial Data Schedule

\* previously filed

Item 28. Undertakings.

The undersigned Registrant hereby undertakes to:

(1) file, during any period in which it offers or sells securities, a post effective amendment to this Registration Statement to:

- o include any prospectus required by Section 10(a)(3) of the Securities Act;
- o reflect in the prospectus any facts or events which, individually or together, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective Registration Statement; and
- o include any additional or changed material information on the plan of distribution;

(2) for determining liability under the Securities Act, treat each post-effective amendment as a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) file a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering.

Insofar as indemnification for liabilities arising under the Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

The undersigned Registrant hereby undertakes (1) to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by



the underwriters to permit prompt delivery to each purchaser; (2) that for the purpose of determining any liability under the Securities Act, treat the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act as part of this Registration Statement as of the time the Securities and Exchange Commission declares it effective; and (3) that for the purpose of determining any liability under the Securities Act, treat each post-effective amendment that contains a form of prospectus as a new registration statement for the securities offered in the registration statement herein, and treat the offering of the securities at that time as the initial bona fide offering of those securities.

SIGNATURES

In accordance with the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form SB-2 and authorized this Registration Statement to be signed on its behalf by the undersigned, in the City of New York, State of New York on September 19, 2000.

DELCATH SYSTEMS, INC.

By: /s/ M. S. Koly

-----  
M. S. Koly, President

ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints M. S. Koly and Stephen A. Zelnick, or any one of them, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all pre- or post-effective amendments to this Registration Statement, and to file the same with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any one of them, or their or his substitutes, may lawfully do or cause to be done by virtue hereof.

In accordance with the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed below by the following persons in the capacities indicated on September 19, 2000.

Signature	Title
M. S. Koly*	
M. S. Koly	President, Chief Executive Officer and Director
Joseph P. Milana*	
Joseph P. Milana	Chief Financial Officer
Samuel Herschkowitz*	
Samuel Herschkowitz	Director
William I. Bergman*	
William I. Bergman	Director
Frank G. Mancuso, Jr.*	
Frank G. Mancuso, Jr.	Director
James V. Sorrentino*	
James V. Sorrentino	Director

\*By: /s/ M.S. Koly  
M.S. Koly, attorney-in-fact

EXHIBIT INDEX

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27.1	Financial Data Schedule

\* previously filed

April \_\_, 2000

Whale Securities Co., L.P.  
650 Fifth Avenue  
New York, New York 10019

Re: Delcath Systems, Inc.

Dear Sir or Madam:

In order to induce Whale Securities Co., L.P. (the "Underwriter") to enter into an underwriting agreement with Delcath Systems, Inc. (the "Company") in connection with the proposed public offering of the common stock of the Company (the "Common Stock") contemplated by that certain letter of intent between the Company and the Underwriter dated March 8, 2000 (the "Proposed Offering"), and as described in a registration statement filed with the Securities and Exchange Commission (the "SEC") (such Registration Statement, as may be amended, is referred to herein as the "Registration Statement"), and as consideration for the Underwriter participating in the Proposed Offering, the undersigned hereby agrees that:

(1) Until twelve (12) months after the date the Registration Statement is declared effective by the SEC (the "Effective Date"), the undersigned will not[, without the prior written consent of the Underwriter,] [delete the bracketed language for any bridge financing lender] directly or indirectly, through an "affiliate", "associate" (as such terms are defined in the rules and regulations promulgated under the Securities Act of 1933, as amended (the "Act")), a family member or otherwise:

(i) offer, pledge, hypothecate, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant for the sale of, or otherwise dispose of or transfer any shares of the Company's Common Stock or any securities of the Company, including but not limited to, any securities convertible into or exchangeable or exercisable for Common Stock, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition, or file any registration statement under the Act with respect to any of the foregoing;

(ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Common Stock or other securities, whether any such swap or transaction is to be settled by delivery of Common Stock or other securities, in cash or otherwise; and

(iii) exercise any registration rights relating to any securities of the Company.

(2) [for those letters be signed by officers, directors and 5% or greater stockholders of Common Stock] During the twelve months following the end of the Lock-Up Period, the undersigned securityholder will not, without the Underwriter's prior written consent, sell, transfer, pledge, hypothecate or otherwise dispose of any of its shares of Common Stock during any three-month period in excess of the amount that the undersigned would be allowed to sell if it were deemed an "affiliate" of the Company and its shares were deemed "restricted," as those terms are defined in Rule 144 promulgated under the Act (i.e., in general, no more than the greater of (a) 1% of the then outstanding shares of Common Stock and (b) the average weekly trading volume of the Common Stock during the four calendar weeks preceding such sale);

(3) The undersigned agrees that an appropriate legend will be placed on any securities of the Company held by the undersigned to the effect that the securities may not be sold or otherwise disposed in accordance with this agreement without the prior written consent of the Underwriter.

(4) For a period of three (3) years following the Effective Date, the undersigned securityholder will vote all of the voting securities of the Company owned by the undersigned securityholder in favor of the election of a designee, if any, of the Underwriter (which designee may change from time to time) to the Company's Board of Directors.

Very truly yours,

SECURITYHOLDER:

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Date: \_\_\_\_\_

Number of Shares of Common  
Stock Beneficially Owned:

Other Securities of the Company  
Beneficially Owned (describe  
securities and state amount):

DELCATH SYSTEMS, INC.  
PROMISSORY NOTE

\$ \_\_\_\_\_

September \_\_, 2000

FOR VALUE RECEIVED, DELCATH SYSTEMS, INC., a Delaware corporation (the "Company") with its principal executive office at 1100 Summer Street, Stamford, Connecticut 06905, promises to pay to:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

(the "Payee") or permitted successors and assigns of the Payee, on or before June \_\_, 2001, the principal amount of \_\_\_\_\_ and 00/100 Dollars (\$\_\_\_\_\_) (the "Principal Amount"), together with interest thereon, at the rate of 22% per annum, at Payee's address set forth above, or at such other place as the Payee shall have notified the Company before any payment hereunder. The Note shall not be prepayable.

This Note is one of several notes (the "Bridge Notes") issued by the Company in the aggregate principal amount of \$230,000 to provide bridge financing pending the consummation of a proposed initial public offering by the Company of its common stock (the "IPO").

If the Company defaults in the payment of principal and interest on the Bridge Notes, and has not closed on an initial public offering within nine (9) months from the date of this Note then the Company, at its option, may satisfy the Bridge Notes by issuing that aggregate number of shares of the Company as equal to ten (10%) percent of the Company's then outstanding number of shares, after giving effect to the issuance of shares to all the Bridge Note holders. Each Payee shall be entitled to receive his pro rata portion of such aggregate number of shares. If the Company does not exercise its option to satisfy the Bridge Notes through issuance of shares then within 10 days of any such default then any Payee shall have the right to demand payment in shares as provided herein.

The Company further agrees:

(i) Upon the consummation of the IPO, it will segregate from the proceeds received therefrom the amount equal to the principal and interest payable through maturity of the Note in a Certificate of Deposit which it shall earmark for repayment of the Note.

(ii) It will make available to the Payee copies of any registration statement registering its stock with the Securities and Exchange Commission if and when requested by the Payee.

(iii) It will reimburse the Payee for expenses, including legal fees, incurred by Payee in connection with the loan evidenced by this Note provided such amount is submitted to the Company in advance of the loan and agreed to and accepted by the Company.

Anything above to the contrary notwithstanding, this Note shall become immediately due and payable if the Company shall: (i) apply for or consent to the appointment of a receiver, trustee, custodian or liquidator of it or any of its properties, (ii) admit in writing its inability to pay its debts as they

mature, (iii) make a general assignment for the benefit of creditors, (iv) be adjudicated a bankrupt or insolvent or be the subject of an order for relief under Title 11 of the United States Code, (v) file a voluntary petition in bankruptcy, or a petition or an answer seeking reorganization or an arrangement with creditors or to take advantage of any bankruptcy, reorganization, insolvency, readjustment of debt, dissolution or liquidation law or statute, or an answer admitting the material allegations of a petition filed against him or it in any proceeding under any such law, or (vi) take or permit to be taken any action in furtherance of or for the purpose of effecting any of the foregoing.

This Note shall be construed in accordance with the laws of New York and all legal proceedings to enforce payment shall be brought in the state or federal courts located in New York City.

The Company hereby waives diligence, presentment, demand, protest and notice of any kind whatsoever. The nonexercise by Payee of any of its rights hereunder in any particular instance shall not constitute a waiver thereof in that or any subsequent instance.

IN WITNESS WHEREOF, this Note has been executed and delivered on the date specified above by the duly authorized representative of the Company.

DELCATH SYSTEMS, INC.

By: \_\_\_\_\_  
Name:  
Title:



Consent of Independent Auditors

The Board of Directors  
Delcath Systems, Inc.

We consent to the use of our report included herein and to the references to our firm under the headings "Selected Financial Data" and "Experts" in the prospectus.

KPMG LLP

New York, New York  
September 19, 2000

1  
U.S. Dollars

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