

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Amendment No. 5

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 (Primary Standard Industrial (I.R.S. Employer  
Incorporation or organization) Classification Code Number) 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. / /

CALCULATION OF REGISTRATION FEE

Title of Each class of Securities to be Registered	Number of Units/Shares To Be Registered	Proposed Offering Price Per Security(1)	Proposed Aggregate Offering Price(1)	Amount of Registration Fee
Units, consisting of one share of common stock par value, \$.01 per share and one redeemable warrant to purchase one share of common stock (2) .....	1,380,000	\$ 6.00	\$ 8,280,000	\$ 2,185.92
Shares of common stock underlying the common stock purchase warrants included in the units (3) .....	1,380,000	\$ 6.60	\$ 9,108,000	\$ 2,405.51
Underwriter's warrants to purchase units (4) .....	120,000	\$ --	\$ --	\$ --
Units issuable upon exercise of the underwriter's warrants (4).....	120,000	\$ 7.20	\$ 864,000	\$ --
Shares of common stock underlying the warrants issuable upon exercise of the warrants underlying the underwriter's warrants (3)(4) .....	120,000	\$ 6.60	\$ 792,000	\$ --
Total Registration Fee .....			19,044,000	\$ 5,028.62
Amount previously paid .....				\$(4,165.92)
Amount Due .....				\$ 862.70

- (1) Estimated solely for purposes of determining the registration fee pursuant to Rule 457 under the Securities Act.
- (2) Includes 180,000 units issuable upon exercise of underwriters' over-allotment option.
- (3) Pursuant to Rule 416 under the Securities Act, there are also being registered hereby such additional indeterminate number of shares as may become issuable pursuant to the antidilution provisions of the warrants.
- (4) No registration fee required pursuant to Rule 457(g) under the Securities Act.

-----

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 OCTOBER 12, 2000

1,200,000 Units

[GRAPHIC OMITTED]

1,200,000 Shares of Common Stock and  
Redeemable Warrants to Purchase Shares of Common Stock

\$6.00 per Unit

Delcath Systems, Inc. is offering 1,200,000 units. Each unit consists of one share of common stock and one redeemable warrant. The units will trade until October , 2001, or an earlier date as to which the underwriter consents to the shares and warrants becoming separately tradable. After that date, the shares and the warrants will trade separately. Each warrant entitles the holder to purchase one share of common stock at a price of \$6.60, until October , 2005. Delcath may redeem some or all of the warrants at a price of \$.10 per warrant, upon 30 days notice, at any time after they become separately tradable, provided that the closing bid price of the common stock is at least \$9.90 and Delcath has received the underwriter's written consent for the redemption.

This is our initial public offering and there currently is no public market for the units, common stock or warrants. We expect that the initial public offering price will be \$6.00 per unit.

We anticipate that the units, common stock and warrants will be listed on the Nasdaq SmallCap Market under the symbols "DCTHU," "DCTH" and "DCTHW" and on the Boston Stock Exchange under the symbols "DCTU," "DCT" and "DCTW."

Investing in the common stock involves risks. See "Risk Factors" beginning on page 7.

	Public Offering Price	Underwriting Discounts and Commissions	Proceeds to Company
Per Unit .....	\$ 6.00	\$ .60	\$ 5.40
Total .....	\$7,200,000	\$720,000	\$6,480,000

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. a 45-day option to purchase up to an additional 180,000 units to cover over-allotments. The underwriter is offering the units on a firm commitment basis. The underwriter expects to deliver the units to purchasers against payment on \_\_\_\_\_, 2000.

Whale Securities Co., L.P.  
, 2000

Notice to California investors: Each purchaser of units 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 units 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.

### 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 is:

- o infused with the chemotherapy agents;
- o redirected out of the patient's body;
- o passed through filters which remove most of the chemotherapy agents; and
- o returned to the patient's general circulatory system.

Isolating the liver and cleansing the blood before it is returned to the patient's circulatory system protects other parts of the body from the harmful side effects of chemotherapy while allowing higher dosages of chemotherapy to be administered.

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 to demonstrate the safety and efficacy of the Delcath system in administering the chemotherapy agent, doxorubicin, to treat cancerous tumors in 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

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

### Securities offered

by Delcath..... 1,200,000 units, each unit consisting of one share of common stock and one redeemable warrant to purchase one share of common stock. The Units will trade until October , 2001, or an earlier date as to which underwriter consents to the shares and warrants becoming separately tradable.

### Common stock to be outstanding

after this offering..... 3,900,000 shares

The number of shares of common stock outstanding after this offering includes 1,520,931 shares to be issued immediately before the closing of this offering upon the conversion of all our outstanding convertible preferred stock, including 687,058 shares issued as payment of accumulated dividends, estimated through September 30, 2000;

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

- o 441,664 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 \$4.13 per share;
- o 17,252 shares reserved for issuance upon the exercise of non-plan options exercisable at a price of \$2.90 per share;
- o 16,950 shares reserved for issuance upon exercise of outstanding warrants with exercise prices of \$10.87 and \$14.87 per share;
- o 300,000 shares reserved for issuance upon exercise of options available for future grant under our 2000 stock option plan;
- o 240,000 shares reserved for issuance upon exercise of the underwriter's warrants and the warrants included in the units;
- o 360,000 shares reserved for issuance in this offering to cover over-allotments, if any, by the underwriter, and the exercise of warrants included in the units issued to cover over-allotments, if any; and
- o approximately 4,790 shares issuable as payment of accumulated dividends on our outstanding convertible preferred stock from October 1, 2000 through the closing of this offering.

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 effected in September 2000 and a one-for 1.26661 reverse stock split of our common stock effected in October 2000.

### Redeemable Warrants:

Number to be outstanding after this offering ... 1,200,000, redeemable warrants. The number of redeemable warrants outstanding after this offering does not include:

- o outstanding warrants to purchase 16,950 shares;

- o 120,000 warrants included in the underwriter's warrants; and
- o 180,000 warrants reserved for issuance in this offering to cover over-allotments, if any, by the underwriter.

Exercise terms..... Exercisable at any time after the warrants become separately tradable, each to purchase one share of common stock at a price of \$6.60, subject to adjustment.

Expiration date..... October , 2005

Redemption..... We may redeem some or all of the warrants at a price of \$.10 per warrant at any time after they become separately tradable, provided that the closing bid price of the common stock on all 20 days ending on the third day prior to the day on which we give notice has been at least 150% of the then effective exercise price of the warrants, we provide at least 30 days notice and we have received the underwriter's written consent for the redemption.

Nasdaq SmallCap Market  
symbols..... Units -- DCTHU  
Common stock -- DCTH  
Warrants -- DCTHW

Boston Stock  
Exchange symbols..... Units -- DCTU  
Common stock -- DCT  
Warrants -- DCTW

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 .....	(2.54)	(.68)	(.24)	(.40)
Weighted average number of shares of common stock outstanding .....	806,434	838,936	822,892	978,633

Balance Sheet Data:

The pro forma information gives effect to:

- o the payment in cash of \$496,390 in accumulated preferred stock dividends, estimated through September 30, 2000; and
- 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 1,200,000 units offered by this prospectus, including the receipt of estimated net proceeds of \$5,750,000 and the repayment of \$230,000 of indebtedness.

	As of December 31, 1999	As of June 30, 2000		
		Actual	Pro Forma	As Adjusted
Cash and cash equivalents .....	\$561,078	\$417,549	\$151,159	\$5,962,522
Total assets .....	600,821	807,659	541,269	6,061,269
Total liabilities .....	112,748	209,532	439,532	209,532
Stockholders' equity .....	488,073	598,127	101,737	5,851,737



## 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

Continuing losses may exhaust our capital resources and force us to terminate operations.

We expect to incur significant and increasing losses while generating minimal revenues over the next few years. 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.

We cannot assure you that the proceeds of this offering will be sufficient to enable us to complete our Phase III clinical trials and obtain FDA pre-marketing approval for the use of doxorubicin with our Delcath system 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 or 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 the FDA refuses to grant marketing approval or limits the circumstances under which the Delcath system may be used, our ability to market the Delcath system will be greatly reduced.

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. 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. If we fail to obtain FDA pre-marketing approval, we will not be able to market the Delcath system. Additionally, if we obtain FDA pre-marketing approval with substantial limitations on uses of the Delcath system, this would greatly reduce our ability to market the system. Either of these results 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 export the Delcath system to foreign markets, which will limit our sales opportunities.

If the FDA does not approve our pre-market application for 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.

Because of our limited experience, conduct of Phase III clinical trials and obtaining FDA pre-marketing approval could be delayed, which 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.

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

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 is not used in accordance with established payor protocols regarding cost effective treatment methods, or is 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. We must ensure that the components of the Delcath system are manufactured in accordance with manufacturing and performance specifications of the Delcath system on file with the FDA.

#### 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 \$5,750,000.

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 .....	\$4,000,000	69.6%
Research and development stage clinical trials for other chemotherapy agents .....	450,000	7.8
Repayment of indebtedness .....	270,000	4.7
Working capital and general corporate purposes .....	1,030,000	17.9
	-----	-----
Total .....	\$5,750,000	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 124 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.

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.

If the underwriter exercises the over-allotment option in full, we will realize additional net proceeds of \$939,600, 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 \$.28 per share. At June 30, 2000, our net tangible book value deficit would have been (\$189,626) or (\$.07) per share after giving pro forma effect to:

- o the conversion of all outstanding shares of our convertible preferred stock into 833,873 shares of common stock;
- o the payment of \$1,489,170 of estimated accumulated dividends through September 30, 2000 through the issuance of 687,058 shares of common stock and the payment of \$496,390 of estimated accumulated dividends in cash;
- o the issuance of 85,000 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 1,200,000 shares included in the units 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 \$5,851,737 or \$1.50 per share, representing an immediate increase in net tangible book value of \$1.57 per share to the existing stockholders and an immediate dilution of \$4.50 or 75.0% 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 .....	\$(.07)	
Increase in pro forma net tangible book value attributable to new investors .....	1.57	
	-----	
Adjusted pro forma net tangible book value after offering .....		1.50
		-----
Dilution to new investors .....		\$ 4.50
		=====

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 .....	2,700,000	69.2%	\$10,326,686	58.9%	\$ 3.82
New investors .....	1,200,000	30.8	7,200,000	41.1	6.00
Total .....	3,900,000	100.0%	\$17,526,686	100.0%	
	=====	=====	=====	=====	

The above table assumes no exercise of the underwriter's over-allotment option. If the underwriter exercises the over-allotment option in full, we estimate that the new investors will have paid \$8,280,000 for the 1,380,000 shares of common stock, representing approximately 44.5% of the total consideration for 33.8% 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 833,873 shares upon conversion of all of our preferred stock;
  - o the issuance of 687,058 shares as payment of \$992,780 of estimated accumulated dividends on our preferred stock, estimated through September 30, 2000;
  - o the payment of \$496,390 for the remaining accumulated dividends on our preferred stock, estimated through September 30, 2000;
  - o the issuance of 85,000 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 1,200,000 units, at an assumed initial public offering price of \$6.00 per unit, after deducting the underwriting discounts and estimated offering expenses payable by us.

The following table excludes from the common stock outstanding 475,866 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, 1,094,069 shares issued and outstanding (actual); 2,700,000 and 3,900,000 shares issued and outstanding (pro forma and as adjusted) .....	10,941	27,000	39,000
Additional paid-in capital .....	12,266,752	13,267,641	19,005,641
Accumulated deficit .....	(11,703,733)	(13,192,904)	(13,192,904)
Total stockholders' equity .....	\$ 598,127	\$ 101,737	\$ 5,851,737
Total capitalization .....	\$ 598,127	\$ 101,737	\$ 5,851,737

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 .....	\$ (2.54)	\$ (.68)
Weighted average number of shares of common stock outstanding .....	806,434	838,936

	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>\$ (.24)</b>	<b>\$ (.40)</b>	
<b>Weighted average number of shares of common stock outstanding .....</b>		<b>822,892</b>	<b>978,633</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 34,505 shares of common stock at a price of \$14.49 per share to Johnson & Johnson Development Corporation, and received proceeds of \$500,000.
- o In April 1998, we issued 8,626 shares of common stock upon exercise of options at a price of \$7.83 per share for proceeds of \$67,500.
- o In September 1998, we sold 3,450 shares of common stock to an individual at a price of \$16.52 per share and received proceeds of \$57,000.
- o In April 1999, we issued 2,300 shares of common stock upon exercise of warrants at a price of \$10.87 per share, and received proceeds of \$24,998.
- o In June 1999, we sold 46,987 shares of common stock at a price of \$16.52 per share and received proceeds of \$776,192.
- o In April 2000, we sold 230,873 shares of common stock at a price of \$2.17 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 \$50,000 in computer, laboratory and testing equipment. We also expect to hire approximately five additional employees in the areas of research and development, regulatory and clinical management, marketing and administrative functions at an estimated annual expense of \$325,000. The number and timing of such hiring will vary depending upon the success of the international marketing efforts and progress of the clinical trials.

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 687,058 shares of common stock and \$496,390 in cash as payment of accumulated dividends, estimated through September 30, 2000.

We believe that existing cash and cash equivalents, together with net proceeds of approximately \$5,750,000 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.

## BUSINESS

### 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 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 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, Greece, 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 and marketing medical devices in those markets and are willing to bear the cost of those activities.

### 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. With our initial Phase III clinical trials, we will seek to develop data on metastatic melanoma which has spread 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 1999 article in the Washington Post, 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.

#### 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, are 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

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 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 six medical centers and to involve approximately 124 test subjects who 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. 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 and we may not be able to prevent or correct their failures. Failure to perform as expected or required, including their failure to enroll a sufficient number of patients for our trials, could result in the failure of the clinical trials and the failure to obtain FDA pre-marketing approval.

We believe that we will acquire sufficient data to file a submission to seek FDA pre-marketing approval of the Delcath system within 12 to 18 months of the commencement of the clinical trials. 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 institutional 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. 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, 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 patients suffering from metastatic melanoma which has spread to the liver. 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, if we can establish foreign testing and marketing relationships, we plan to utilize one or more corporate 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 and quality system requirements. 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.

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.

#### 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, intravenous chemotherapy and chemotherapy through implanted infusion pumps, liver transplants, embolization, cryosurgery, radiowave ablation and the use of biological response modulators, monoclonal antibodies and liposomes. 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 effective or more affordable products or treatment methods, or achieve earlier product development or patent protection, in which case our chances to achieve meaningful revenues or profitability will be substantially limited.

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 strength which differ from those currently approved, we must obtain approval for revised labeling of a doxorubicin product permitting 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 concerning the device and its components, including the manufacturing and labeling of the device and 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 events 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 patients suffering from metastatic melanoma of the liver, 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 before approval, or that post-approval studies must be conducted.

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 methods 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 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 that may have been caused or contributed to by 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 design control, quality control and manufacturing procedures by requiring the manufacturer to demonstrate and maintain compliance with quality systems regulations including good manufacturing practices and other requirements. 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. The FDA-approved labeling for doxorubicin does not provide for its delivery with the Delcath system. We must obtain approval of a new drug application for that purpose or partner with the holder of an approved new drug application for doxorubicin to make this change to the labeling of doxorubicin. We are seeking to partner with a drug company for this purpose, but we have no assurance that we will find a partner or that the FDA will approve the application. If this approval is obtained, it 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 institutional 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 institutional 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 institutional 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 clinical 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 Nissho or any other foreign strategic partner to market our products in Asia, Europe, Latin America and other foreign jurisdictions, they 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 August 31, 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 and Directors

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
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.

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 underwriter, to nominate and use our best efforts to elect a designee of the underwriter as a director of Delcath or, at the underwriter's option, as a non-voting advisor to our board of directors. The underwriter 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 2002; 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 2003.

#### 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 34,505 shares of common stock at a price of \$4.93 per share, all of which are vested. Each non-employee director received a separate one-time grant in December 1999 of options to purchase 22,428 shares of common stock at a price of \$2.90 per share, half of which are vested, the remainder to vest in December 2000.

#### Key Employees

Jonathan A. Foltz, CFA, 38, 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.

#### 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	139,746
	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	60,867	22.5%	4.93	January 2004
M.S. Koly	25,396	9.4%	4.93	January 2004
M.S. Koly	53,483	19.7%	2.90	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	40,578	20,289	\$43,418	\$21,709
M.S. Koly	25,396	0	\$27,174	0
M.S. Koly	26,742	26,741	\$82,900	\$82,897

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 236,359 shares of common stock for issuance upon exercise of options granted from time to time under the 1992 incentive stock option plan, 205,305 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 236,359 shares of common stock under our 1992 incentive stock option plan at a weighted average price of \$4.02 and non-incentive stock options to purchase 205,305 shares of common stock under our 1992 non-incentive stock option plan at a weighted average price of \$4.26. 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 1,200,000 shares of common stock included in the units 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 dividing the number of shares beneficially owned by that person by the base number of outstanding shares, increased to reflect the shares underlying options, warrants or other convertible securities included in that person's holdings, but not those underlying shares held by any other person.

- o a base of 2,700,000 shares outstanding before this offering; and
- o a base of 3,900,000 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 .....	1,540,491	54.6%	38.3%
Venkol Trust .....	1,403,296	51.9	36.0
Samuel Herschkowitz, M.D. ....	281,012	10.1	7.1
Frank G. Mancuso, Jr. ....	111,779	4.1	2.8
James V. Sorrentino, Ph.D. ....	68,665	2.5	1.7
William I. Bergman .....	63,834	2.3	1.6
All directors and executive officers as a group (six persons) .....	1,870,507	60.8%	43.7%

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

- o 6,007 shares of the 12,015 shares held by Venkol Inc. as nominee for M.S. Koly;
- o 11,732 shares held by M. Ted Koly, M.S. Koly's minor son;
- o 119,456 shares issuable upon exercise of options; and
- o 1,400,536 shares and 2,760 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.

Mr. Koly's beneficially owned shares exclude 20,289 shares issuable upon exercise of options which become exercisable on January 28, 2001.

Samuel Herschkowitz's beneficially owned shares include;

- o 6,008 shares of the 12,015 shares held by Venkol Inc. as nominee for Dr. Herschkowitz;
- o 180,449 shares held by Venkol Trust and 356 shares issuable upon the exercise of warrants held by the Venkol Trust, as to which Dr. Herschkowitz has a beneficial remainder interest; and

- o 82,467 shares which are issuable upon exercise of options.

Dr. Herschkowitz's beneficially owned shares exclude 2,070 shares issuable upon exercise of options which become exercisable on January 28, 2001.

Frank G. Mancuso's beneficially owned shares include;

- o 14,441 shares held by Venkol Trust and 28 shares issuable upon the exercise of warrants held by the Venkol Trust, as to which Mr. Mancuso has a beneficial remainder interest;

- o 56,933 shares issuable upon exercise of options; and

- o 1,424 shares issuable upon exercise of warrants.

James V. Sorrentino's and William I. Bergman's beneficially owned shares include 56,933 shares issuable upon exercise of options.

The number of shares beneficially owned by all directors and executive officers as a group include 1,400,536 shares and 2,760 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 43.7% of our outstanding common stock, and 42.0% if the underwriter'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 87,988 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 20,703 shares of common stock for approximately \$300,000 and Mr. Mancuso, a director of Delcath, purchased 6,901 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 class A preferred stock, 117,650 shares of our class B preferred stock and 36,076 shares of common stock.

All of our preferred stockholders have agreed to convert their preferred stock into 833,873 shares of common stock. The preferred stockholders have also agreed to accept 687,058 shares of common stock as payment of \$992,780 of estimated accumulated dividends, and a cash dividend of \$496,390 as payment of the balance of the accrued dividend, estimated through September 30, 2000. Venkol Trust holds all 2,000,000 shares of our class A preferred stock and will receive 690,099 shares of common stock on conversion of those shares, 612,799 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 preferred stock and will receive 6,766 and 40,595 shares of common stock, upon conversion of those shares, 3,494 shares and 20,967 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, as payment of the balance of the accrued dividends, estimated through September 30, 2000.

In June 1999, we sold an aggregate of 46,987 shares of common stock and three-year warrants to purchase an aggregate of 5,218 shares of common stock at \$14.87 per share for aggregate proceeds of \$776,192. Mr. Mancuso made a \$75,000 investment for which he received 4,540 shares of common stock and warrants to purchase 504 shares of common stock.

In April 2000, we issued 230,873 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 11,732 shares for \$25,500, and William Bergman, a director of Delcath, purchased 6,901 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.

### Units

Each unit consists of one share of common stock and one redeemable warrant to purchase one share of common stock. The units will trade until October \_\_, 2001, or an earlier date as to which the underwriter consents to the shares and warrants becoming separately tradable.

### Common Stock

Immediately prior to the closing of this offering, there will be 2,700,000 shares of common stock outstanding. After giving effect to the issuance of the 1,200,000 shares of common stock included in the units offered by this prospectus, assuming the underwriter does not exercise its over-allotment option, there will be 3,900,000 shares of common stock outstanding upon the closing of this offering. As of the date of this prospectus, we have approximately 84 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.

### Redeemable Warrants

General. Each warrant will entitle the holder of the warrant to purchase one share of common stock at a price of \$6.60, subject to adjustment, at any time after the warrants become separately tradable until October \_\_, 2005.

The warrants will be issued in registered form under a warrant agreement by and among Delcath, American Stock Transfer & Trust Company, as warrant agent, and the underwriter. Reference is made to the warrant agreement, which has been filed as an exhibit to the registration statement in which this prospectus is included, for a complete description of the terms and conditions therein.

Redemption. We may redeem some or all of the warrants at a price of \$.10 per warrant, upon 30 days notice, at any time after they become separately tradable, provided that the closing bid quotation of our common stock on all 20 trading days ending on the third day prior to the day on which we give notice has been at least 150% of the then effective exercise price of the warrants and we have received the written consent of the underwriter for the redemption. The warrant holders shall have the right to exercise their warrants until the close of business on the date fixed for redemption. Redemption of the warrants could force



the holders to exercise the warrants and pay the exercise price at a time when it may be disadvantageous for the holders to do so, to sell the warrants at the then current market price when they might otherwise wish to hold the warrants or to accept the redemption price, which is likely to be substantially less than the market value of the warrants at the time of redemption.

Exercise. The warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price to the warrant agent for the number of warrants being exercised. The warrant holders do not have the rights or privileges of holders of common stock.

No warrant will be exercisable unless, at the time of exercise, Delcath has filed a current registration statement with the Securities and Exchange Commission covering the shares of common stock issuable upon exercise of the warrant and the shares have been registered or qualified or deemed to be exempt from registration or qualification under the securities laws of the state of residence of the holder of the warrant. Delcath will use its best efforts to have all the shares so registered or qualified on or before the exercise date and to maintain a current prospectus relating thereto until the expiration of the warrants, subject to the terms of the warrant agreement. We may not, however, be able to have a prospectus in effect when this prospectus is no longer current.

No fractional shares will be issued upon exercise of the warrants. However, if a warrant holder exercises all warrants then owned of record by him or her, we will pay to the warrant holder, in lieu of the issuance of any fractional share which is otherwise issuable, an amount in cash based on the market value of the common stock on the last trading day prior to the exercise date.

Adjustment of Exercise Price. The exercise price and number of shares of common stock or other securities issuable on exercise of the warrants are subject to adjustment in specified circumstances, including in the event of a stock dividend, recapitalization, reorganization, merger or consolidation of Delcath. However, the warrants are not subject to adjustment for issuances of common stock at prices below the exercise price of the warrants.

#### 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 687,058 shares of common stock and payment in cash of \$496,390 as accumulated dividends as of the date of this prospectus, based on an estimated closing date of 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 Other Outstanding Warrants

We have reserved 17,252 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 \$2.90 per share. We have also reserved for issuance 16,950 shares of common stock for issuance upon outstanding warrants to purchase common stock at \$10.87 and \$14.87 per share which expire, respectively, on January 16, 2001 and March 2, 2002. 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 3,900,000 shares of common stock issued and outstanding of which the 1,200,000 shares included in the units 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 2,700,000 remaining shares of common stock that will be outstanding, are restricted securities as that term is defined under Rule 144.

Approximately 1,587,366 of these shares are immediately eligible for sale and the remaining 1,112,634 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 approximately 2,650,000 shares 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 underwriter. For the second year following the closing, our officers, directors and principal stockholders have agreed that, without the underwriter'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., as underwriter, has agreed, subject to the terms and conditions contained in the underwriting agreement relating to this offering, to purchase the 1,200,000 units offered by us.

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

The underwriter has advised us that it proposes to offer the units to the public at the public offering price indicated on the cover page of this prospectus. The underwriter may allow selected dealers who are members of the National Association of Securities Dealers, Inc., known as the NASD, concessions, not in excess of \$.24 per unit, of which not in excess of \$.15 per unit may be reallocated to other dealers who are members of the NASD.

We have granted to the underwriter an option, exercisable not later than 45 days after the date of this prospectus, to purchase up to 180,000 additional units at the public offering price indicated on the cover page of this prospectus, less the underwriting discounts and commissions. The underwriter may exercise this option only to cover over-allotments, if any, made in connection with the sale of the units offered by this prospectus. If the underwriter exercises its over-allotment in full, the total price to the public would be \$8,280,000, the total underwriting discounts and commissions would be \$828,000 and the total proceeds to us, before payment of the expenses of this offering, would be \$7,452,000.

We have agreed to pay to the underwriter a non-accountable expense allowance equal to 3% of the gross proceeds from the sale of the units offered by us, including any securities sold pursuant to the underwriter'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 units offered under the laws of the states as the underwriter may designate, including expenses of counsel retained for this purpose by the underwriter. We estimate our expenses of this offering to be \$1,450,000, including the underwriter discounts and commission, or \$1,590,400 if the underwriter's over-allotment option is completely exercised.

At the closing of this offering, we will sell to the underwriter and its designees, for an aggregate of \$100, underwriter's warrants to purchase up to 120,000 units. The underwriter'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 \$6.60 per share, 110% of the public offering price per unit. The warrants included in the units issuable upon exercise of the underwriter's warrants are identical to the warrants included in the units offered by this prospectus but are exercisable at \$10.50 per share. During the first year following the date of this prospectus, underwriter's warrants may not be sold, transferred, pledged or hypothecated, except that the underwriter's warrants may be assigned or transferred only to officers and partners of the underwriter or members of the selling group. During the exercise period, the holders of the underwriter's warrants will have the opportunity to profit from a rise in the market price of our securities, which will dilute the interests of our stockholders. We expect that the underwriter'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 underwriter's warrants. Any profit realized by the underwriter on the sale of the underwriter's warrants or the underlying shares of common stock may be deemed additional underwriting compensation. The underwriter's warrants contain a cashless exercise provision. We have agreed that, upon the request of the holders of the majority of the underwriter's warrants, we will, at our own expense, on one occasion during the exercise period register the underwriter's warrants and the shares underlying the underwriter's warrants under the Securities Act. We have also agreed to include the underwriter'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.

Beginning one year from the date of this prospectus, we will pay to the underwriter a fee of 5% of the exercise price for each warrant exercised pursuant to a warrant solicitation, provided however, that the underwriter will not be entitled to receive this compensation in warrant exercise transactions in which (a) the market price of common stock at the time of the exercise is lower than the exercise price of the warrant; (b)

the warrants are held in any discretionary account; (c) disclosure of compensation arrangements is not made, in addition to the disclosure provided in this prospectus, in documents provided to holders of warrants at the time of exercise; (d) the exercise of the warrants is unsolicited; or (e) the transaction was in violation of Rule 10b-6 promulgated under the Exchange Act.

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

The holders of approximately 2,650,000 of our outstanding shares of common stock, and all of our outstanding 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 underwriter's prior written consent. For the second year following the closing, our officers, directors and principal stockholders have agreed that without the underwriter'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 underwriter against civil liabilities, including liabilities under the Securities Act.

The underwriter 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 units, common stock or warrants. Accordingly, the initial public offering price of the units and the exercise price of the warrants have been determined by negotiation between us and the underwriter and may not necessarily be related to our asset value, net worth or other established criteria of value. Factors considered in determining these prices 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 the units may not be indicative of the prices that may prevail in the public market.

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

#### LEGAL MATTERS

The validity of the units 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 85,000 shares of our common stock. Blank Rome Tenzer Greenblatt LLP, New York, New York, has served as counsel to the underwriter 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.

Index to Financial Statements

	Page
	-----
Independent Auditor's Report .....	F-2
Balance Sheets as of December 31, 1999 and June 30, 2000 (unaudited) .....	F-3
Statements of Operations for each of the years in the two-year period ended December 31, 1999, and cumulative from inception (August 5, 1988) to December 31, 1999, and for the six-month periods ended June 30, 1999 and 2000 (unaudited) and cumulative from inception (August 5, 1988) to June 30, 2000 (unaudited) .....	F-4
Statements of Stockholders' Equity for each of the years in the two-year period ended December 31, 1999 and cumulative from inception (August 5, 1988) to June 30, 2000 (unaudited) .....	F-5
Statements of Cash Flows for each of the years in the two-year period ended December 31, 1999, and cumulative from inception (August 5, 1988) to December 31, 1999, and the six-month periods ended June 30, 1999 and 2000 (unaudited) and cumulative from inception (August 5, 1988) to June 30, 2000 (unaudited) .....	F-6
Notes to Financial Statements .....	F-7

Independent Auditors' Report

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.

/s/ KPMG LLP

-----  
KPMG LLP

May 5, 2000 except as to Note 5  
which is as of September 28, 2000  
New York, New York



DEL CATH SYSTEMS, INC.  
(A DEVELOPMENT STAGE COMPANY)

Balance Sheets

Assets	December 31, 1999	June 30, 2000 <small>(unaudited)</small>
	-----	-----
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; 863,196 and 1,094,069 shares issued and outstanding .....	8,632	10,941
Additional paid-in capital .....	11,767,236	12,266,752
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.

DEL CATH 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
<b>Total costs and expenses .....</b>	<b>2,124,443</b>	<b>598,126</b>
Operating income (loss).....	(2,124,443)	(598,126)
Interest income .....	74,463	43,470
Interest expense .....	--	(17,925)
<b>Net income (loss) .....</b>	<b>\$(2,049,980)</b>	<b>(572,581)</b>
Common share data:		
Basic and diluted income (loss) per share .....	\$ (2.54)	(0.68)
Weighted average number of shares of common stock outstanding .....	806,434	838,936

[RESTUBED FOR ABOVE]

	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
<b>Total costs and expenses .....</b>	<b>11,716,785</b>	<b>206,182</b>	<b>404,807</b>	<b>12,121,592</b>
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)
<b>Net income (loss) .....</b>	<b>(11,311,962)</b>	<b>(200,410)</b>	<b>(391,771)</b>	<b>(11,703,733)</b>
Common share data:				
Basic and diluted income (loss) per share .....		(0.24)	(0.40)	
Weighted average number of shares of common stock outstanding .....		822,892	978,633	

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 .....	621,089	\$ 6,211	--	--
Sale of preferred stock, August 22, 1988 .....	--	--	--	--
Shares returned as of March 9, 1990 .....	--	--	(414,059)	(4,141)
Sale of stock, October 2, 1990 .....	--	--	17,252	173
Sale of stock, January 23, 1991 .....	--	--	46,522	465
Sale of stock, August 30, 1991 .....	--	--	1,353	14
Sale of stock, December 31, 1992 .....	--	--	103,515	1,035
Sale of stock, July 15, 1994 .....	--	--	103,239	1,032
Sale of stock, December 19, 1996 .....	--	--	39,512	395
Shares issued in connection with conversion of short-term borrowings as of December 22, 1996 .....	58,491	585	98,388	984
Sale of stock, December 31, 1997 .....	53,483	535	--	--
Exercise of stock options .....	13,802	138	3,450	35
Shares issued as compensation .....	2,345	23	828	8
Amortization of compensatory stock options granted .....	--	--	--	--
Forfeiture of stock options .....	--	--	--	--
Shares issued in connection with exercise of warrants .....	21,568	216	--	--
Deficit accumulated from inception to December 31, 1997 .....	--	--	--	--
Balance at December 31, 1997 .....	770,778	7,708	(0)	(0)
Sale of stock, January 16, 1998 .....	34,505	345	--	--
Sale of stock, September 24, 1998 .....	3,450	35	--	--
Shares returned, April 17, 1998 .....	(3,450)	(35)	--	--
Amortization of compensatory stock options granted .....	--	--	--	--
Forfeiture of stock options .....	--	--	--	--
Exercise of stock options .....	8,626	86	--	--
Net loss for year ended December 31, 1998 .....	--	--	--	--
Balance at December 31, 1998 .....	813,909	8,139	(0)	(0)
Sale of stock, June 30, 1999 .....	46,987	470	--	--
Amortization of compensatory stock options granted .....	--	--	--	--
Forfeiture of stock options .....	--	--	--	--
Shares issued in connection with exercise of warrants .....	2,300	23	--	--
Net loss for year ended December 31, 1999 .....	--	--	--	--
Balance at December 31, 1999 .....	863,196	8,632	(0)	(0)
Sale of stock, April 14, 2000 .....	230,873	2,309	--	--
Net loss for six months ended June 30, 2000 (unaudited) .....	--	--	--	--
Balance at June 30, 2000 .....	1,094,069	\$10,941	(0)	(0)

[RESTITUTION FOR ABOVE]

	Outstanding		Class A preferred stock \$ .01 par value		Class B preferred stock \$ .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 .....	621,089	\$ 6,211	--	--	--	--
Sale of preferred stock, August 22, 1988 .....	--	--	2,000,000	20,000	--	--
Shares returned as of March 9, 1990 .....	(414,059)	(4,141)	--	--	--	--
Sale of stock, October 2, 1990 .....	17,252	173	--	--	--	--
Sale of stock, January 23, 1991 .....	46,522	465	--	--	416,675	4,167
Sale of stock, August 30, 1991 .....	1,353	14	--	--	--	--
Sale of stock, December 31, 1992 .....	103,515	1,035	--	--	--	--
Sale of stock, July 15, 1994 .....	103,239	1,032	--	--	--	--
Sale of stock, December 19, 1996 .....	39,512	395	--	--	--	--
Shares issued in connection with conversion of short-term borrowings as of December 22, 1996 .....	156,879	1,569	--	--	--	--
Sale of stock, December 31, 1997 .....	53,483	535	--	--	--	--
Exercise of stock options .....	17,252	173	--	--	--	--
Shares issued as compensation .....	3,173	31	--	--	--	--
Amortization of compensatory stock options granted .....	--	--	--	--	--	--
Forfeiture of stock options .....	--	--	--	--	--	--
Shares issued in connection with exercise of warrants .....	21,568	216	--	--	--	--
Deficit accumulated from inception to December 31, 1997 .....	--	--	--	--	--	--
Balance at December 31, 1997 .....	770,778	7,708	2,000,000	20,000	416,675	4,167
Sale of stock, January 16, 1998 .....	34,505	345	--	--	--	--
Sale of stock, September 24, 1998 .....	3,450	35	--	--	--	--
Shares returned, April 17, 1998 .....	(3,450)	(35)	--	--	--	--
Amortization of compensatory stock options granted .....	--	--	--	--	--	--
Forfeiture of stock options .....	--	--	--	--	--	--
Exercise of stock options .....	8,626	86	--	--	--	--
Net loss for year ended December 31, 1998 .....	--	--	--	--	--	--
Balance at December 31, 1998 .....	813,909	8,139	2,000,000	20,000	416,675	4,167
Sale of stock, June 30, 1999 .....	46,987	470	--	--	--	--
Amortization of compensatory stock options granted .....	--	--	--	--	--	--
Forfeiture of stock options .....	--	--	--	--	--	--
Shares issued in connection with exercise of warrants .....	2,300	23	--	--	--	--
Net loss for year ended December 31, 1999 .....	--	--	--	--	--	--
Balance at December 31, 1999 .....	863,196	8,632	2,000,000	20,000	416,675	4,167
Sale of stock, April 14, 2000 .....	230,873	2,309	--	--	--	--
Net loss for six months ended June 30, 2000 (unaudited) .....	--	--	--	--	--	--
Balance at June 30, 2000 .....	1,094,069	\$10,941	2,000,000	\$20,000	416,675	\$4,167

[RESTUBBED FOR ABOVE]

	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 .....	\$ (5,211)	\$ --	\$ 1,000
Sale of preferred stock, August 22, 1988 .....	480,000	--	500,000
Shares returned as of March 9, 1990 .....	4,141	--	--
Sale of stock, October 2, 1990 .....	24,827	--	25,000
Sale of stock, January 23, 1991 .....	1,401,690	--	1,406,322
Sale of stock, August 30, 1991 .....	9,987	--	10,001
Sale of stock, December 31, 1992 .....	1,013,969	--	1,015,004
Sale of stock, July 15, 1994 .....	1,120,968	--	1,122,000
Sale of stock, December 19, 1996 .....	999,605	--	1,000,000
Shares issued in connection with conversion of short-term borrowings as of December 22, 1996 .....	1,703,395	--	1,704,964
Sale of stock, December 31, 1997 .....	774,465	--	775,000
Exercise of stock options .....	30,827	--	31,000
Shares issued as compensation .....	34,454	--	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 .....	234,182	--	234,398
Deficit accumulated from inception to December 31, 1997 .....	--	(8,689,401)	(8,689,401)
Balance at December 31, 1997 .....	10,044,426	(8,689,401)	1,386,900
Sale of stock, January 16, 1998 .....	499,655	--	500,000
Sale of stock, September 24, 1998 .....	56,965	--	57,000
Shares returned, April 17, 1998 .....	(4,965)	--	(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 .....	67,414	--	67,500
Net loss for year ended December 31, 1998 .....	--	(2,049,980)	(2,049,980)
Balance at December 31, 1998 .....	11,422,724	(10,739,381)	715,649
Sale of stock, June 30, 1999 .....	775,722	--	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 .....	24,975	--	24,998
Net loss for year ended December 31, 1999 .....	--	(572,581)	(572,581)
Balance at December 31, 1999 .....	11,767,236	(11,311,962)	488,073
Sale of stock, April 14, 2000 .....	499,516	--	501,825
Net loss for six months ended June 30, 2000 (unaudited) .....	--	(391,771)	(391,771)
Balance at June 30, 2000 .....	\$12,266,752	\$(11,703,733)	\$ 598,127
	=====	=====	=====

See accompanying notes to financial statements.

DELICATH 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

[RESTUBBED FOR TABLE ABOVE]

	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)
Cash flows from operating activities:				
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)
Cash flows from investing activities:				
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)
Cash flows from financing activities:				
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
Supplemental cash flow activities:				
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 reverse stock splits of 1 for 2.2881 shares on September 28, 2000 and 1 for 1.2666 shares on October 11, 2000 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 621.089 shares of BGH - Delaware common stock. As a result of the conversion, BGH - Delaware issued 621,089 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, \$6,211, 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, 414,059 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 17,252 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 \$7.39 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, 46,522 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 \$1,401,690. 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 1,353 shares of common stock held in its treasury at \$7.39 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 \$9,987.

In a December 1992 private placement, the Company sold 103,515 shares of common stock held in its treasury at \$10.14 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 \$1,048,965 (\$1,013,969 after expenses). The two affiliated venture capital funds that owned the class A preferred stock purchased 27,604 of the shares of common stock in its treasury which were sold.

Effective January 1, 1994, the Company issued 1,725 shares of common stock held in its treasury at \$1.45 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 approximately 4,693 common shares and 469 warrants, each of which entitled the holder to purchase one share of common stock for \$10.87. In connection therewith, the Company sold twenty-two (22) units (103,239 common shares and 10,324 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 8,916 warrants to purchase 8,916 shares of common stock at \$10.87 each for total proceeds of \$96,900. The remaining warrants expired unexercised.

Effective January 1, 1995, the Company issued 1,725 shares of common stock held in its treasury at \$1.45 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 828 shares of common stock, valued at \$10.87 per share for a total of \$9,000, as compensation for consulting services.

On December 19, 1996, the Company sold through a private transaction 39,512 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 156,879 shares of common stock, based on a conversion price of \$10.87 per share, and 78,438 warrants, expiring April 25, 1999, entitling the holders to purchase 78,438 additional shares of common stock at \$10.87 per share. The two affiliated venture capital funds discussed above provided \$250,000 of the short-term loan, converting that debt into approximately

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

December 31, 1999 and 1998 -- (Continued)

(2) Stockholders' Equity -- (Continued)

23,003 shares and 11,502 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 1,150 warrants to purchase 1,150 shares of common stock at \$10.87 each for total proceeds of \$12,499. During December 1997, the two affiliated venture capital funds exercised their 11,502 warrants to purchase 11,502 common shares at \$10.87 each for total proceeds of \$124,999. During April 1999, the holders of warrants exercised 2,300 warrants to purchase 2,300 common shares at \$10.87 each for total proceeds of \$24,998. The remaining warrants expired unexercised.

In 1997, the Company issued 2,345 shares of common stock, valued at \$10.87 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 53,483 shares of common stock. During January 1998, the Company received an additional \$500,000 and issued another 34,505 shares. In April 1998, under the terms of the restricted stock sales agreements, the Company issued to the purchasers of the 87,988 shares of common stock 11,732 three year warrants entitling the holders to purchase 11,732 shares of common stock at \$10.87 per share.

In December 1997, the holder of non-incentive stock options exercised 13,802 options to purchase 13,802 shares of common stock at \$1.88 each for total proceeds of \$26,000.

At the end of December 1997, the holders of 28,063 shares of common stock agreed to sell those shares to the two affiliated venture capital funds discussed above at \$10.87 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 8,626 non-incentive stock options to purchase 8,626 restricted common shares at \$7.83 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 3,450 shares of common stock previously held by the former director in return for \$1.45 per share, the price originally paid by the former director.

In September 1998, the Company sold 3,450 shares of common stock to an individual for \$16.52 per share, yielding proceeds to the Company of \$57,000.

In June 1999, the Company sold 46,987 shares of common stock to individual investors for \$16.52 per share and warrants entitling the holders to purchase 5,218 common shares at \$14.87 per share (which warrants expire April 30, 2002), yielding proceeds to the Company of \$776,192.

In April 2000, the Company sold 230,873 shares at \$2.17 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 .3450 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 \$.72 per share, while the class B dividends may be converted at the rate of \$.72 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.

DELCATH 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	201,341	\$ 7.74	17,252	\$ 2.90
Granted during 1998	17,252	7.83	--	--
Forfeited during 1998	(41,406)	7.83	--	--
Expired during 1998	(94,544)	7.83	--	--
Exercised during 1998	(8,626)	7.83	--	--
Outstanding at December 31, 1998	74,017	7.56	17,252	2.90
Granted during 1999	441,664	4.13	17,252	2.90
Canceled during 1999	(34,505)	7.56	--	--
Forfeited during 1999	(39,512)	7.56	--	--
Expired during 1999	--	--	(17,252)	2.90
Outstanding at December 31, 1999	441,664	\$ 4.13	17,252	\$ 2.90

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
189,777	\$2.90	\$2.90	3.76	103,515	\$2.90
269,139	4.93	4.93	4.00	269,139	4.93
458,916	\$2.90 - \$4.93	\$4.09	3.90	372,654	\$4.38

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 \$.92, 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, on September 28, 2000 the Company declared the preferred stock dividends as described in note 2(d), approved a resolution to convert the outstanding preferred stock to common stock as described in note 2(d) and effected a reverse split of the common shares of 1 for 2.2881 shares. On October 11, 2000, the Company effected an additional reverse split of the common shares of 1 for 1.2666.

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.  
=====

-----  
TABLE OF CONTENTS

	Page
Prospectus Summary .....	3
Risk Factors .....	7
Cautionary Statement Regarding Forward-Looking Statements .....	8
Use of Proceeds .....	9
Dilution .....	11
Dividend Policy .....	12
Capitalization .....	12
Selected Financial Data .....	13
Plan of Operation .....	14
Business .....	16
Management .....	31
Principal Stockholders .....	38
Certain Transactions .....	40
Description of Securities .....	41
Shares Eligible for Future Sale .....	44
Underwriting .....	45
Legal Matters .....	46
Experts .....	47
Available Information .....	47
Index to Financial Statements .....	F-1

-----  
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.  
=====

=====

1,200,000 Units

[GRAPHIC OMITTED]

1,200,000 Shares of Common Stock  
and  
Redeemable Warrants to Purchase  
1,200,000 Shares of 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 underwriter'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 .....	\$ 5,028.82
Filing Fee - National Association of Securities Dealers, Inc. ....	\$ 2,405.00
Fees and Expenses of Accountants .....	\$ 75,000.00
Fees and Expenses of Counsel .....	\$ 225,000.00*
Printing and Engraving Expenses .....	\$ 115,000.00
Blue Sky Fees and Expenses .....	\$ 85,000.00
Transfer Agent Fees .....	\$ 5,000.00
Miscellaneous Expenses .....	\$ 1,566.18
	-----
Total: .....	\$ 514,000.00
	=====

\* 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 87,988 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 11,732 shares of common stock at \$10.87 per share.
2. In December 1997, the Registrant issued an aggregate of 13,802 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 2,345 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 8,626 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 3,450 shares of common stock to an investor for aggregate proceeds of \$57,000.
6. In April 1999, the Registrant issued an aggregate of 2,300 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 46,987 shares of common stock and warrants entitling the holders thereof to purchase an aggregate of 5,218 shares of common stock to twelve investors, at \$14.87 per share, including a director of the Registrant, for aggregate proceeds of \$776,192.
8. In April 2000, the Registrant issued an aggregate of 230,873 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. 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 Underwriter's Warrant Agreement
4.3	Warrant Agreement among Registrant, Underwriter and Transfer Agent
4.4	Specimen Redeemable Warrant**
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

\*\* to be provided by amendment

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 October 12, 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 October 12, 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

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 Underwriter's Warrant Agreement
4.3	Warrant Agreement among Registrant, Underwriter and Transfer Agent
4.4	Specimen Redeemable Warrant**
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

\*\* to be provided by amendment



Delcath Systems, Inc.  
1,200,000 Units consisting of  
1,200,000 Shares of Common Stock  
(Par Value \$.01 Per Share)  
and  
Redeemable Warrants to Purchase  
1,200,000 Shares of Common Stock

UNDERWRITING AGREEMENT  
-----

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

New York, New York  
October , 2000

Dear Sirs:

Delcath Systems, Inc., a Delaware corporation (the "Company"), proposes to issue and sell to Whale Securities Co., L.P. (the "Underwriter") an aggregate of one million two hundred thousand (1,200,000) units (the "Offered Units") at a price of \$6.00 per Offered Unit, consisting of an aggregate of one million two hundred thousand (1,200,000) shares of common stock of the Company, par value \$.01 per share (the "Offered Shares"), which Offered Shares are presently authorized but unissued shares of the common stock, par value \$.01 per share (individually, a "Common Share" and collectively the "Common Shares"), of the Company, and one million two hundred thousand (1,200,000) Common Share purchase warrants (the "Offered Warrants"), entitling the holder of each Offered Warrant to purchase, at any time commencing on the Separation Date (as hereinafter defined) until October , 2005, one (1) Common Share, at an exercise price of Six Dollars Sixty Cents (\$6.60) (subject to adjustment in certain circumstances). The Offered Shares and the Offered Warrants will be offered to the public in Offered Units consisting of one Offered Share and one Offered Warrant at a public offering price of Six Dollars (\$6.00) per Offered Unit. The securities comprising the Offered Units will become detachable and separately transferable commencing one year from the Effective Date (as hereinafter defined) or such earlier date as to which the Underwriter consents (the "Separation Date"). The Company shall have the right to call each Offered Warrant for redemption upon not less than thirty (30) days' written notice at any time commencing on the Separation Date at a redemption price of Ten Cents (\$.10) per Offered Warrant; provided, that the closing bid quotation of the Common Stock on all twenty (20) of the trading days ending on the third trading day prior to the day on which the Company gives notice (the "Call Date") of redemption has been at least 150% (currently \$9.90, subject to adjustment) of the then effective exercise price of the Warrants and the Company obtains the written consent of the Underwriter with respect to such redemption prior to the Call Date. In addition, the Underwriter, in order to cover over-allotments in the sale of the Offered Units, may purchase up to an aggregate of one hundred eighty thousand (180,000) Units (the "Optional Units"), each Optional Unit consisting of one Common Share (collectively, the "Optional Shares") and one Common Share purchase warrant identical to the Offered Warrants (collectively, the "Optional Warrants"). The Offered Units and the Optional Units are sometimes collectively referred to as the "Units"; the Offered Shares and the Optional Shares are hereinafter sometimes collectively referred to as the "Shares"; and the Offered Warrants and the Optional Warrants are hereinafter sometimes collectively referred to as

the "Warrants." The Warrants will be issued pursuant to a Warrant Agreement filed as Exhibit 4.3 to the Registration Statement (the "Warrant Agreement") to be dated as of the Closing Date (as hereinafter defined) by and among the Company, the Underwriter and American Stock Transfer & Trust Company, as warrant agent (the "Warrant Agent").

The Company also proposes to issue and sell to the Underwriter, for its own account and the accounts of its designees, warrants (the "Underwriter's Warrants") to purchase up to an aggregate of one hundred twenty thousand (120,000) units (the "Underlying Units"), the Underlying Unit consisting of one Common Share (collectively, the "Underlying Shares") and/or one warrant similar but not identical to the warrants (collectively, the "Underlying Warrants"), which sale will be consummated in accordance with the terms and conditions of the form of Underwriter's Warrant Agreement filed as an exhibit to the Registration Statement (as hereinafter defined). The Underlying Shares, the Underlying Warrants and the Common Shares issuable upon exercise of the Underlying Warrants (the "Underlying Warrant Shares") are hereinafter sometimes referred to as the "Underlying Securities". The Units, Shares, the Warrants, the Common Shares issuable upon exercise of the Warrants (the "Warrant Shares"), the Underwriter's Warrants, the Underlying Securities (collectively, the "Securities") are more fully described in the Registration Statement and the Prospectus, as defined below.

The Company hereby confirms its agreement with the Underwriter as follows:

1. Purchase and Sale of Offered Units. On the basis of the representations and warranties herein contained, but subject to the terms and conditions herein set forth, the Company hereby agrees to sell the Offered Units to the Underwriter, and the Underwriter agrees to purchase the Offered Units from the Company, at a purchase price of \$5.40 per Offered Unit. The Underwriter plans to offer the Offered Units to the public at a public offering price of \$6.00 per Offered Unit.

2. Payment and Delivery.

(a) Payment for the Offered Units will be made to the Company by wire transfer or certified or official bank check or checks payable to its order in New York Clearing House funds, at the offices of the Underwriter, 650 Fifth Avenue, New York, New York 10019, against delivery of the Offered Units to the Underwriter. Such payment and delivery will be made at 10:00 A.M., New York City time, on the third business day following the Effective Date (as hereinafter defined) (the fourth business day following the Effective Date in the event that trading of the Offered Units commences on the day following the Effective Date), the date and time of such payment and delivery being herein called the "Closing Date." The certificates representing the Offered Units to be delivered will be in such denominations and registered in such names as the Underwriter may request not less than two full business days prior to the Closing Date, and will be made available to the Underwriter for inspection, checking and packaging at the office of the Company's transfer agent or correspondent in New York City, American Stock Transfer & Trust Company, 40 Wall Street, New York, New York 10005 not less than one full business day prior to the Closing Date.

(b) On the Closing Date, the Company will sell the Underwriter's Warrants to the Underwriter or to the Underwriter's designees limited to officers and partners of the Underwriter, members of the selling group and/or their officers or partners (collectively, the

"Underwriter's Designees"). The Underwriter's Warrants will be in the form of, and in accordance with, the provisions of the Underwriter's Warrant attached as an exhibit to the Registration Statement. The aggregate purchase price for the Underwriter's Warrants is One Hundred Dollars (\$100.00). The Underwriter's Warrants will be restricted from sale, transfer, assignment or hypothecation for a period of one (1) year from the Effective Date, except to the Underwriter's Designees. Payment for the Underwriter's Warrants will be made to the Company by check or checks payable to its order on the Closing Date against delivery of the certificates representing the Underwriter's Warrants. The certificates representing the Underwriter's Warrants will be in such denominations and such names as the Underwriter may request prior to the Closing Date.

### 3. Option to Purchase Optional Units.

(a) For the purposes of covering any over-allotments in connection with the distribution and sale of the Offered Units as contemplated by the Prospectus, the Underwriter is hereby granted an option to purchase all or any part of the Optional Shares from the Company. The purchase price to be paid for the Optional Units will be the same price per Optional Unit as the price per Offered Unit set forth in Section 1 hereof. The option granted hereby may be exercised by the Underwriter as to all or any part of the Optional Units at any time within 45 days after the Effective Date. The Underwriter will not be under any obligation to purchase any Optional Units prior to the exercise of such option.

(b) The option granted hereby may be exercised by the Underwriter by giving oral notice to the Company, which must be confirmed by a letter, telex or telegraph setting forth the number of Optional Units to be purchased, the date and time for delivery of and payment for the Optional Units to be purchased and stating that the Optional Units referred to therein are to be used for the purpose of covering over-allotments in connection with the distribution and sale of the Offered Units. If such notice is given prior to the Closing Date, the date set forth therein for such delivery and payment will not be earlier than either two full business days thereafter or the Closing Date, whichever occurs later. If such notice is given on or after the Closing Date, the date set forth therein for such delivery and payment will not be earlier than two full business days thereafter. In either event, the date so set forth will not be more than 15 full business days after the date of such notice. The date and time set forth in such notice is herein called the "Option Closing Date." Upon exercise of such option, through the Underwriter's delivery of the aforementioned notice, the Company will become obligated to convey to the Underwriter, and, subject to the terms and conditions set forth in Section 3(d) hereof, the Underwriter will become obligated to purchase, the number of Optional Units specified in such notice.

(c) Payment for any Optional Units purchased will be made to the Company by wire transfer or certified or official bank check or checks payable to its order in New York Clearing House funds, at the office of the Underwriter, against delivery of the Optional Units purchased to the Underwriter. The certificates representing the Optional Units to be delivered will be in such denominations and registered in such names as the Underwriter requests not less than two full business days prior to the Option Closing Date, and will be made available to the Underwriter for inspection, checking and packaging at the aforesaid office of the Company's transfer agent or correspondent not less than one full business day prior to the Option Closing Date.

(d) The obligation of the Underwriter to purchase and pay for any of the Optional Units is subject to the accuracy and completeness (as of the date hereof and as of the Option Closing Date) of and compliance in all material respects with the representations and warranties of the Company herein, to the accuracy and completeness of the statements of the Company or its officers made in any certificate or other document to be delivered by the Company pursuant to this Agreement, to the performance in all material respects by the Company of its obligations hereunder, to the satisfaction by the Company of the conditions, as of the date hereof and as of the Option Closing Date, set forth in Section 3(b) hereof, and to the delivery to the Underwriter of opinions, certificates and letters dated the Option Closing Date substantially similar in scope to those specified in Section 5, 6(b), (c), (d) and (e) hereof, but with each reference to "Offered Units" and "Closing Date" to be, respectively, to the Optional Units and the Option Closing Date.

4. Representations and Warranties of the Company. The Company represents and warrants to, and agrees with, the Underwriter that:

(a) The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware, with full power and authority, corporate and other, to own or lease, as the case may be, and operate its properties, whether tangible or intangible, and to conduct its business as described in the Registration Statement and to execute, deliver and perform this Agreement, the Underwriter's Warrant Agreement, the Warrant Agreement and the Consulting Agreement described in Section 5(r) hereof (the "Consulting Agreement") and to consummate the transactions contemplated hereby and thereby. The Company has no subsidiaries. The Company is duly qualified to do business as a foreign corporation and is in good standing in all jurisdictions wherein such qualification is necessary and where failure so to qualify could have a material adverse effect on the financial condition, results of operations, business or properties of the Company. The Company has no equity interests in any entity.

(b) This Agreement has been duly executed and delivered by the Company and constitutes the valid and binding obligation of the Company, and each of the Underwriter's Warrant Agreement, the Warrant Agreement and the Consulting Agreement, when executed and delivered by the Company on the Closing Date, will be the valid and binding obligations of the Company, enforceable against the Company in accordance with their respective terms. The execution, delivery and performance of this Agreement, the Underwriter's Warrant Agreement, the Warrant Agreement and the Consulting Agreement by the Company, the consummation by the Company of the transactions herein and therein contemplated and the compliance by the Company with the terms of this Agreement, the Consulting Agreement, the Underwriter's Warrant Agreement and the Warrant Agreement have been duly authorized by all necessary corporate action and do not and will not, with or without the giving of notice or the lapse of time, or both, (i) result in any violation of the Certificate of Incorporation or By-Laws, each as amended, of the Company; (ii) result in a breach of or conflict with any of the terms or provisions of, or constitute a default under, or result in the modification or termination of, or result in the creation or imposition of any lien, security interest, charge or encumbrance upon any of the properties or assets of the Company pursuant to any indenture, mortgage, note, contract, commitment or other agreement or instrument to which the Company is a party or by which the

Company or any of its properties or assets is or may be bound or affected; (iii) violate any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company, or any of its properties or business; or (iv) have any effect on any permit, certification, registration, approval, consent order, license, franchise or other authorization (collectively, the "Permits") necessary for the Company to own or lease and operate any of its properties and to conduct its business.

(c) No Permits of any court or governmental agency or body, other than under the Securities Act of 1933, as amended (the "Act"), the Regulations (as hereinafter defined) and applicable state securities or Blue Sky laws, are required (i) for the valid authorization, issuance, sale and delivery of the Shares to the Underwriter, and (ii) the consummation by the Company of the transactions contemplated by this Agreement, the Consulting Agreement, the Underwriter's Warrant Agreement or the Warrant Agreement.

(d) The conditions for use of a registration statement on Form SB-2 set forth in the General Instructions to Form SB-2 have been satisfied with respect to the Company, the transactions contemplated herein and in the Registration Statement. The Company has prepared in conformity with the requirements of the Act and the rules and regulations (the "Regulations") of the Securities and Exchange Commission (the "Commission") and filed with the Commission a registration statement (File No. 333-39470) on Form SB-2 and has filed one or more amendments thereto, covering the registration of the Shares under the Act, including the related preliminary prospectus or preliminary prospectuses (each thereof being herein called a "Preliminary Prospectus") and a proposed final prospectus. Each Preliminary Prospectus was endorsed with the legend required by Item 501(a)(5) of Regulation S-B of the Regulations and, if applicable, Rule 430A of the Regulations. Such registration statement including any documents incorporated by reference therein and all financial schedules and exhibits thereto, as amended at the time it becomes effective, and the final prospectus included therein are herein, respectively, called the "Registration Statement" and the "Prospectus," except that, (i) if the prospectus filed by the Company pursuant to Rule 424(b) of the Regulations differs from the Prospectus, the term "Prospectus" will also include the prospectus filed pursuant to Rule 424(b), and (ii) if the Registration Statement is amended or such Prospectus is supplemented after the date the Registration Statement is declared effective by the Commission (the "Effective Date") and prior to the Option Closing Date, the terms "Registration Statement" and "Prospectus" shall include the Registration Statement as amended or supplemented.

(e) Neither the Commission nor, to the best of the Company's knowledge after due investigation, any state regulatory authority has issued any order preventing or suspending the use of any Preliminary Prospectus or has instituted or, to the best of the Company's knowledge after due investigation, threatened to institute any proceedings with respect to such an order.

(f) The Registration Statement when it becomes effective, the Prospectus (and any amendment or supplement thereto) when it is filed with the Commission pursuant to Rule 424(b), and both documents as of the Closing Date and the Option Closing Date, referred to below, will contain all statements which are required to be stated therein in accordance with the Act and the Regulations and will in all material respects conform to the requirements of the Act and the Regulations, and neither the Registration Statement nor the Prospectus, nor any amendment or supplement thereto, on such dates, will contain any untrue

statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, except that this representation and warranty does not apply to statements or omissions made in reliance upon and in conformity with information furnished in writing to the Company in connection with the Registration Statement or Prospectus or any amendment or supplement thereto by the Underwriter expressly for use therein.

(g) The Company had at the date or dates indicated in the Prospectus a duly authorized and outstanding capitalization as set forth in the Registration Statement and the Prospectus. Based on the assumptions stated in the Registration Statement and the Prospectus, the Company will have on the Closing Date the adjusted stock capitalization set forth therein. Except as set forth in the Registration Statement or the Prospectus, on the Effective Date and on the Closing Date, there will be no options to purchase, warrants or other rights to subscribe for, or any securities or obligations convertible into, or any contracts or commitments to issue or sell shares of the Company's capital stock or any such warrants, convertible securities or obligations. Except as set forth in the Prospectus, no holders of any of the Company's securities has any rights, "demand," "piggyback" or otherwise, to have such securities registered under the Act.

(h) The descriptions in the Registration Statement and the Prospectus of contracts and other documents are accurate and present fairly the information required to be disclosed, and there are no contracts or other documents required to be described in the Registration Statement or the Prospectus or to be filed as exhibits to the Registration Statement under the Act or the Regulations which have not been so described or filed as required.

(i) KPMG LLP, the accountants who have certified certain of the financial statements filed and to be filed with the Commission as part of the Registration Statement and the Prospectus, are independent public accountants within the meaning of the Act and Regulations. The financial statements and schedules and the notes thereto filed as part of the Registration Statement and included in the Prospectus are complete, correct and present fairly the financial position of the Company as of the dates thereof, and the results of operations and changes in financial position of the Company for the periods indicated therein, all in conformity with generally accepted accounting principles applied on a consistent basis throughout the periods involved except as otherwise stated in the Registration Statement and the Prospectus. The selected financial data set forth in the Registration Statement and the Prospectus present fairly the information shown therein and have been compiled on a basis consistent with that of the audited and unaudited financial statements included in the Registration Statement and the Prospectus.

(j) The Company has filed with the appropriate federal, state and local governmental agencies, and all appropriate foreign countries and political subdivisions thereof, all tax returns, including franchise tax returns, which are required to be filed or has duly obtained extensions of time for the filing thereof and has paid all taxes shown on such returns and all assessments received by it to the extent that the same have become due; and the provisions for income taxes payable, if any, shown on the financial statements filed with or as part of the Registration Statement are sufficient for all accrued and unpaid foreign and domestic taxes, whether or not disputed, and for all periods to and including the dates of such financial statements. Except as disclosed in writing to the Underwriter, the Company has not executed or filed with any taxing authority, foreign or domestic, any agreement extending the period for

assessment or collection of any income taxes and is not a party to any pending action or proceeding by any foreign or domestic governmental agency for assessment or collection of taxes; and no claims for assessment or collection of taxes have been asserted against the Company.

(k) The outstanding Common Shares and outstanding options and warrants to purchase Common Shares have been duly authorized and validly issued. The outstanding Common Shares are fully paid and nonassessable. The outstanding options and warrants to purchase Common Shares constitute the valid and binding obligations of the Company, enforceable in accordance with their terms. The Company has duly reserved a sufficient number of Common Shares from its authorized but unissued Common Shares for issuance upon exercise of the outstanding options and warrants. None of the outstanding Common Shares or options or warrants to purchase Common Shares has been issued in violation of the preemptive rights of any stockholder of the Company. None of the holders of the outstanding Common Shares is subject to personal liability solely by reason of being such a holder. The offers and sales of the outstanding Common Shares and outstanding options and warrants to purchase Common Shares were at all relevant times either registered under the Act and the applicable state securities or Blue Sky laws or exempt from such registration requirements. The authorized Common Shares and outstanding options and warrants to purchase Common Shares conform to the descriptions thereof contained in the Registration Statement and Prospectus. Except as set forth in the Registration Statement and the Prospectus, on the Effective Date and the Closing Date, there will be no outstanding options or warrants for the purchase of, or other outstanding rights to purchase or acquire, Common Shares or securities convertible into Common Shares.

(l) No securities of the Company have been sold by the Company or by or on behalf of, or for the benefit of, any person or persons controlling, controlled by, or under common control with the Company within the three years prior to the date hereof, except as disclosed in the Registration Statement.

(m) The issuance and sale of the Units have been duly authorized. When the Units have been issued and duly delivered against payment therefor as contemplated by this Agreement. The Units and the Shares will be validly issued, fully paid and nonassessable, and the holders thereof will not be subject to personal liability solely by reason of being such holders. None of the Units, Shares, Warrants or Warrant Shares will be subject to preemptive rights of any stockholder of the Company.

(n) The issuance and sale of the Underlying Shares and Underlying Warrant Shares have been duly authorized and, when such Common Shares have been duly delivered against payment therefor, as contemplated by the Underwriter's Warrant Agreement, such Common Shares will be validly issued, fully paid and nonassessable. Holders of Underlying Shares and Underlying Warrant Shares issuable upon the exercise of the Underwriter's Warrants will not be subject to personal liability solely by reason of being such holders. Neither the Underwriter's Warrants nor the Underlying Shares or Underlying Warrant Shares issuable upon exercise thereof will be subject to preemptive rights of any stockholder of the Company. The Company has reserved a sufficient number of Common Shares from its authorized but unissued Common Shares for issuance upon exercise of the Underwriter's Warrants and the Underlying Warrants in accordance with the provisions of the Underwriter's Warrant Agreement and the Underlying Warrants. The Underwriter's Warrants conform to the

descriptions thereof contained in the Registration Statement and the Prospectus.

(o) The Company is not in violation of, or in default under, (i) any term or provision of its Certificate of Incorporation or By-Laws, each as amended; (ii) any material term or provision or any financial covenants of any indenture, mortgage, contract, commitment or other agreement or instrument to which it is a party or by which it or any of its property or business is or may be bound or affected; or (iii) any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company or any of the Company's properties or businesses. The Company owns, possesses or has obtained all governmental and other (including those obtain-able from third parties) Permits, necessary to own or lease, as the case may be, and to operate its properties, whether tangible or intangible, and to conduct its respective business and operations as presently conducted and all such Permits are outstanding and in good standing, and there are no proceedings pending or, to the best of the Company's knowledge after due investigation, threatened, or any basis therefor, seeking to cancel, terminate or limit such Permits.

(p) Except as set forth in the Prospectus, there are no claims, actions, suits, proceedings, arbitrations, investigations or inquiries before any governmental agency, court or tribunal, domestic or foreign, or before any private arbitration tribunal, pending, or, to the best of the Company's knowledge after due investigation, threatened against the Company or involving the Company's properties or business which, if determined adversely to the Company, would, individually or in the aggregate, result in any material adverse change in the financial position, stockholders' equity, results of operations, properties, business, management or affairs or business prospects of the Company or which question the validity of the capital stock of the Company or this Agreement or of any action taken or to be taken by the Company pursuant to, or in connection with, this Agreement; nor, to the best of the Company's knowledge after due investigation, is there any basis for any such claim, action, suit, proceeding, arbitration, investigation or inquiry. There are no outstanding orders, judgments or decrees of any court, governmental agency or other tribunal naming the Company and enjoining the Company from taking, or requiring the Company to take, any action, or to which the Company, or the Company's properties or business is bound or subject.

(q) Neither the Company nor any of its affiliates has incurred any liability for any finder's fees or similar payments in connection with the transactions herein contemplated.

(r) The Company owns or possesses adequate and enforceable rights to use all patents, patent applications, trademarks, service marks, copyrights, rights, trade secrets, confidential information, processes and formulations used or proposed to be used in the conduct of its business as described in the Prospectus (collectively the "Intangibles"); to the best of the Company's knowledge, after due investigation the Company has not infringed nor is infringing upon the rights of others with respect to the Intangibles; and the Company has not received any notice of conflict with the asserted rights of others with respect to the Intangibles which could, singly or in the aggregate, materially adversely affect its business as presently conducted or the prospects, financial condition or results of operations of the Company, and the Company knows of no basis therefor; and, to the best of the Company's knowledge, no others have infringed upon the Intangibles of the Company.



(s) Since the respective dates as of which information is given in the Registration Statement and the Prospectus and the Company's latest financial statements, the Company has not incurred any material liability or obligation, direct or contingent, or entered into any material transaction, whether or not incurred in the ordinary course of business, and has not sustained any material loss or interference with its business from fire, storm, explosion, flood or other casualty, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree; and since the respective dates as of which information is given in the Registration Statement and the Prospectus, there have not been, and prior to the Closing Date referred to below there will not be, any changes in the capital stock or any material increases in the long-term debt of the Company or any material adverse change in or affecting the general affairs, management, financial condition, stockholders' equity, results of operations or prospects of the Company, otherwise than as set forth or contemplated in the Prospectus.

(t) The Company does not own any real property. The Company has good title to all personal property (tangible and intangible) owned by it, free and clear of all security interests, charges, mortgages, liens, encumbrances and defects, except such as are described in the Registration Statement and Prospectus or such as do not materially affect the value or transferability of such property and do not interfere with the use of such property made, or proposed to be made, by the Company. The leases, licenses or other contracts or instruments under which the Company leases, holds or is entitled to use with respect to any property, real or personal, are valid, subsisting and enforceable only with such exceptions as are not material and do not interfere with the use of such property made, or proposed to be made, by the Company, and all rentals, royalties or other payments accruing thereunder which became due prior to the date of this Agreement have been duly paid, and the Company, to the best of the Company's knowledge after due investigation, is not aware of any other party in default thereunder and, to the best of the Company's knowledge after due investigation, no event has occurred which, with the passage of time or the giving of notice, or both, would constitute a default thereunder. The Company has not received notice of any violation of any applicable law, ordinance, regulation, order or requirement relating to its owned or leased properties. The Company has adequately insured its properties against loss or damage by fire or other casualty and maintains, in adequate amounts, such other insurance as is usually maintained by companies engaged in the same or similar businesses located in its geographic area.

(u) Each contract or other instrument (however characterized or described) to which the Company is a party or by which its properties or businesses is or may be bound or affected and to which reference is made in the Prospectus has been duly and validly executed, is in full force and effect in all material respects and is enforceable against the parties thereto in accordance with its terms, and none of such contracts or instruments has been assigned by the Company, and the Company, to the best of the Company's knowledge after due investigation is not, and any other party is not, in default thereunder and, to the best of the Company's knowledge after due investigation, no event has occurred which, with the lapse of time or the giving of notice, or both, would constitute a default thereunder.

None of the material provisions of such contracts or instruments violates any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court having jurisdiction over the Company or any of its respective assets or businesses, including, without limitation, the United States Food and Drug Administration (the "FDA") and the United States Federal Trade Commission (the "FTC"), and comparable foreign state

and local regulatory authorities.

(v) The employment, consulting, confidentiality and non-competition agreements between the Company and its officers, employees, consultants and any other third parties described in the Registration Statement, are binding and enforceable obligations upon the respective parties thereto in accordance with their respective terms, except as such enforce-ability may be limited by applicable bankruptcy, insolvency, moratorium or other similar laws or arrangements affecting creditors' rights generally and subject to principles of equity.

(w) Except as set forth in the Prospectus, the Company does not have employee benefit plans (including, without limitation, profit sharing and welfare benefit plans) or deferred compensation arrangements that are subject to the provisions of the Employee Retirement Income Security Act of 1974.

(x) To the best of the Company's knowledge after due investigation, no labor problem exists with any of the Company's employees or is imminent which could adversely affect the Company.

(y) The Company has not directly or indirectly, at any time (i) made any contributions to any candidate for political office, or failed to disclose fully any such contribution in violation of law or (ii) made any payment to any state, federal or foreign governmental officer or official, or other person charged with similar public or quasi-public duties, other than payments or contributions required or allowed by applicable law. The Company's internal accounting controls and procedures are sufficient to cause the Company to comply in all material respects with the Foreign Corrupt Practices Act of 1977, as amended.

(z) The Shares have been approved for listing on the Nasdaq SmallCap Market and the Boston Stock Exchange.

(aa) Neither the Company nor any of its officers or directors has distributed, and will not distribute prior to the later of (i) the Closing Date or any date on which Optional Shares are to be purchased, as the case may be, or (ii) the expiration of the period during which dealers effecting transactions in the Shares may be required to deliver a Prospectus, any offering material in connection with the offering and sale of the Shares, other than any Preliminary Prospectus, the Prospectus, the Registration Statement and other materials, if any, permitted by the Act.

(ab) The Preliminary Prospectus and the Prospectus delivered to the Underwriters for use in connection with the offering of the Shares were identical to the versions of the Preliminary Prospectus and Prospectus filed with the Commission via the Commission's Electronic Data Gathering Analysis and Retrieval System, except to the extent permitted by Regulation S-T.

(ac) The Company has provided to Blank Rome Tenzer Greenblatt LLP, counsel to the Underwriter ("Underwriter's Counsel"), all agreements, certificates, correspondence and other items, documents and information in its possession and/or available to it requested by such counsel's Corporate Review Memorandum dated April 3, 2000 (the "Memorandum") and the Company's response to such Memorandum is accurate and complete in all material respects.

Any certificate or questionnaire signed by an officer of the Company and delivered to the Underwriter or to Underwriter's Counsel shall be deemed to be a representation and warranty by the Company to the Underwriter as to the matters covered thereby.

5. Certain Covenants of the Company. The Company covenants with the Underwriter as follows:

(a) The Company will not at any time, whether before the Effective Date or thereafter during such period as the Prospectus is required by law to be delivered in connection with the sales of the Units, Shares and Warrants by the Underwriter or a dealer, file or publish any amendment or supplement to the Registration Statement or Prospectus of which the Underwriter has not been previously advised and furnished a copy, or to which the Underwriter shall object in writing.

(b) The Company will use its best efforts to cause the Registration Statement to become effective and will advise the Underwriter immediately, and, if requested by the Underwriter, confirm such advice in writing, (i) when the Registration Statement, or any post-effective amendment to the Registration Statement or any supplemented Prospectus is filed with the Commission; (ii) of the receipt of any comments from the Commission; (iii) of any request of the Commission for amendment or supplementation of the Registration Statement or Prospectus or for additional information; and (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or of any order preventing or suspending the use of any Preliminary Prospectus, or of the suspension of the qualification of the Units, Shares and/or Warrants for offering or sale in any jurisdiction, or of the initiation of any proceedings for any of such purposes. The Company will use its best efforts to prevent the issuance of any such stop order or of any order preventing or suspending such use and to obtain as soon as possible the lifting thereof, if any such order is issued.

(c) The Company will deliver to the Underwriter, without charge, from time to time until the Effective Date, as many copies of each Preliminary Prospectus as the Underwriter may reasonably request, and the Company hereby consents to the use of such copies for purposes permitted by the Act. The Company will deliver to the Underwriter, without charge, as soon as the Registration Statement becomes effective, and thereafter from time to time as requested, such number of copies of the Prospectus (as supplemented, if the Company makes any supplements to the Prospectus) as the Underwriter may reasonably request. The Company has furnished or will furnish to the Underwriter a signed copy of the Registration Statement as originally filed and of all amendments thereto, whether filed before or after the Registration Statement becomes effective, a copy of all exhibits filed therewith and a signed copy of all consents and certificates of experts.

(d) The Company will comply with the Act, the Regulations, the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations thereunder so as to permit the continuance of sales of and dealings in the Offered Shares and in any Optional Shares which may be issued and sold. If, at any time when a prospectus relating to the Shares is required to be delivered under the Act, any event occurs as a result of which the Registration Statement and Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to

make the statements therein, in light of the circumstances under which they were made, not misleading, or if it shall be necessary to amend or supplement the Registration Statement and Prospectus to comply with the Act or the regulations thereunder, the Company will promptly file with the Commission, subject to Section 5(a) hereof, an amendment or supplement which will correct such statement or omission or which will effect such compliance.

(e) The Company will furnish such proper information as may be required and otherwise cooperate in qualifying the Shares for offering and sale under the securities or Blue Sky laws relating to the offering in such jurisdictions as the Underwriter may reasonably designate, provided that no such qualification will be required in any jurisdiction where, solely as a result thereof, the Company would be subject to service of general process or to taxation or qualification as a foreign corporation doing business in such jurisdiction.

(f) The Company will make generally available to its securityholders, in the manner specified in Rule 158(b) under the Act, and deliver to the Underwriter and Underwriter's Counsel as soon as practicable and in any event not later than 45 days after the end of its fiscal quarter in which the first anniversary date of the effective date of the Registration Statement occurs, an earning statement meeting the requirements of Rule 158(a) under the Act covering a period of at least 12 consecutive months beginning after the effective date of the Registration Statement.

(g) For a period of five years from the Effective Date, the Company will deliver to the Underwriter and to Underwriter's Counsel on a timely basis (i) a copy of each report or document, including, without limitation, reports on Forms 8-K, 10-K (or 10-KSB), 10-Q (or 10-QSB) and exhibits thereto, filed or furnished to the Commission, any securities exchange or the National Association of Securities Dealers, Inc. (the "NASD") on the date each such report or document is so filed or furnished; (ii) as soon as practicable, copies of any reports or communications (financial or other) of the Company mailed to its securityholders; (iii) as soon as practicable, a copy of any Schedule 13D, 13G, 14D-1 or 13E-3 received or prepared by the Company from time to time; (iv) monthly statements setting forth such information regarding the Company's results of operations and financial position (including balance sheet, profit and loss statements and data regarding outstanding purchase orders) as is regularly prepared by management of the Company; and (v) such additional information concerning the business and financial condition of the Company as the Underwriter may from time to time reasonably request and which can be prepared or obtained by the Company without unreasonable effort or expense. The Company will furnish to its stockholders annual reports containing audited financial statements and such other periodic reports as it may determine to be appropriate or as may be required by law.

(h) Neither the Company nor any person that controls, is controlled by or is under common control with the Company will take any action designed to or which might be reasonably expected to cause or result in the stabilization or manipulation of the price of the Units, Common Shares or Warrants.

(i) If the transactions contemplated by this Agreement are consummated, the Underwriter shall retain the \$50,000 previously paid to it, and the Company will pay or cause to be paid the following: all costs and expenses incident to the performance of the obligations of the Company under this Agreement, including, but not limited to, the fees and

expenses of accountants and counsel for the Company; the preparation, printing, mailing and filing of the Registration Statement (including financial statements and exhibits), Preliminary Prospectuses and the Prospectus, and any amendments or supplements thereto; the printing and mailing of the Selected Dealer Agreement, the issuance and delivery of the Shares to the Underwriter; all taxes, if any, on the issuance of the Shares; the fees, expenses and other costs of qualifying the Shares for sale under the Blue Sky or securities laws of those states in which the Shares are to be offered or sold, including fees and disbursements of counsel in connection therewith, and including those of such local counsel as may have been retained for such purpose; the filing fees incident to securing any required review by the NASD and either the Boston Stock Exchange or Pacific Stock Exchange; the cost of printing and mailing the "Blue Sky Survey"; the cost of furnishing to the Underwriter copies of the Registration Statement, Preliminary Prospectuses and the Prospectus as herein provided; the costs of placing "tombstone advertisements" in any publications which may be selected by the Underwriter; and all other costs and expenses incident to the performance of the Company's obligations hereunder which are not otherwise specifically provided for in this Section 5(i).

In addition, at the Closing Date or the Option Closing Date, as the case may be, the Underwriter will deduct from the payment for the Offered Units or any Optional Units three percent (3%) of the gross proceeds of the offering (less the sum of \$50,000 previously paid to the Underwriter), as payment for the Underwriter's nonaccountable expense allowance relating to the transactions contemplated hereby, which amount will include the fees and expenses of Underwriter's Counsel (other than the fees and expenses of Underwriter's Counsel relating to Blue Sky qualifications and registrations, which, as provided for above, shall be in addition to the three percent (3%) nonaccountable expense allowance and shall be payable directly by the Company to Underwriter's Counsel on or prior to the Closing Date).

(j) If the transactions contemplated by this Agreement or related hereto are not consummated because the Company decides not to proceed with the offering for any reason or because the Underwriter decides not to proceed with the offering as a result of a breach by the Company of its representations, warranties or covenants in the Agreement or as a result of adverse changes in the affairs of the Company, then the Company will be obligated to reimburse the Underwriter for its accountable expenses up to the sum of \$75,000, inclusive of the \$50,000 previously paid to the Underwriter by the Company. In all cases other than those set forth in the preceding sentence, if the Company or the Underwriter decide not to proceed with the offering, the Company will only be obligated to reimburse the Underwriter for its accountable expenses up to \$25,000, and inclusive of the amounts previously paid to the Underwriter by the Company. In no event, however, will the Underwriter, in the event the offering is terminated, be entitled to retain or receive more than an amount equal to its actual accountable out-of-pocket expenses.

(k) The Company intends to apply the net proceeds from the sale of the Units for the purposes set forth in the Prospectus. Except as set forth in the Prospectus, no portion of the net proceeds from the sale of the Shares will be used to repay any indebtedness.

(l) During the period of twelve (12) months from the Effective Date hereof, neither the Company nor any of its officers, directors or securityholders will offer for sale or sell or otherwise dispose of, directly or indirectly, any securities of the Company, in any manner whatsoever, whether pursuant to Rule 144 of the Regulations or otherwise, and no holder

of registration rights relating to securities of the Company will exercise any such registration rights, in either case, without the prior written consent of the Underwriter. During the 12-month period commencing one year from the date hereof, no officer, director or securityholder who beneficially owns or holds 5% or more of the outstanding Common Shares (calculated in accordance with Rule 13d-3(d)(i) under the Exchange Act) may sell any Common Shares in excess of the amount that they would be allowed to sell if they were deemed "affiliates" of the Company and their shares were deemed "restricted," as those terms are defined in Rule 144 promulgated under the Securities Act, without the prior written consent of the Underwriter.

(m) The Company will not file any registration statement relating to the offer or sale of any of the Company's securities, including any registration statement on Form S-8, during the twelve (12) months from the Effective Date, without the Underwriter's prior written consent.

(n) The Company maintains and will continue to maintain a system of internal accounting controls sufficient to provide reasonable assurances that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary in order to permit preparation of financial statements in accordance with generally accepted accounting principles and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(o) The Company will use its best efforts to maintain the listing of the Units, Shares and Warrants on the Nasdaq SmallCap Market and will, if so qualified, list the Units, Shares and Warrants, and maintain such listing for so long as qualified, on the Nasdaq National Market System.

(p) The Company will, concurrently with the Effective Date, register the classes of equity securities of which the Units, Shares and Warrants are a part under Section 12(b) or 12(g) of the Exchange Act and the Company will maintain such registration for a minimum of five (5) years from the Effective Date.

(q) Subject to the sale of the Offered Units, the Underwriter and its successors will have the right to designate a nominee for election, at its or their option, either as a member of or a non-voting advisor to the Board of Directors of the Company (which board, during such period, shall meet at least quarterly, have no members who are related (by marriage or otherwise) to any of its Board members, and be comprised of members, a majority of which are not otherwise affiliated with the Company, its management or its founders), and the Company will use its best efforts to cause such nominee to be elected and continued in office as a director of the Company or as such advisor until the expiration of three (3) years from the Effective Date. Each of the Company's current officers, directors and stockholders agree to vote all of the Common Shares owned by such person or entity so as to elect and continue in office such nominee of the Underwriter. Following the election of such nominee as a director or advisor, such person shall receive no more or less compensation than is paid to other non-officer directors of the Company for attendance at meetings of the Board of Directors of the Company and shall be entitled to receive reimbursement for all reasonable costs incurred in attending such meetings including, but not limited to, food, lodging and transportation. The Company agrees to

indemnify and hold such director or advisor harmless, to the maximum extent permitted by law, against any and all claims, actions, awards and judgments arising out of his service as a director or advisor and, in the event the Company maintains a liability insurance policy affording coverage for the acts of its officers and directors, to include such director or advisor as an insured under such policy. The rights and benefits of such indemnification and the benefits of such insurance shall, to the extent possible, extend to the Underwriter insofar as it may be or may be alleged to be responsible for such director or advisor.

If the Underwriter does not exercise its option to designate a member of or advisor to the Company's Board of Directors, the Underwriter shall nonetheless have the right to send a representative (who need not be the same individual from meeting to meeting) to observe each meeting of the Board of Directors. The Company agrees to give the Underwriter notice of each such meeting and to provide the Underwriter with an agenda and minutes of the meeting no later than it gives such notice and provides such items to the directors.

(r) The Company agrees to employ the Underwriter or a designee of the Underwriter as a financial consultant for a period of two (2) years from the Closing Date, pursuant to a separate written consulting agreement between the Company and the Underwriter and/or such designee (the "Consulting Agreement"), which will provide that the Company will pay the Underwriter (exclusive of any accountable out-of-pocket expenses) a finder's fee in the event the Underwriter originates a financing, merger, acquisition, joint venture or other transaction to which the Company is a party. The Company further agrees to deliver a duly and validly executed copy of said Consulting Agreement, in form and substance acceptable to the Underwriter, on the Closing Date.

(s) Subject to the provisions of applicable law, the Underwriter shall be entitled to receive a warrant solicitation fee of five percent (5%) of the aggregate exercise price of the Warrants for each Warrant exercised during the period commencing one year after the Effective Date; provided, however, that the Underwriter will not be entitled to receive such compensation in Warrant exercise transactions in which (i) the market price of the Common Shares at the time of exercise is lower than the exercise price of the Warrants; (ii) the Warrants are held in any discretionary account; (iii) disclosure of compensation arrangements is not made in the Registration Statement and in documents provided to holders of Warrants at the time of exercise; (iv) the holder thereof has not confirmed in writing that the Underwriter solicited the exercise of the Warrants; or (v) the solicitation or exercise of the Warrants was in violation of Regulation M promulgated under the Exchange Act.

(t) The Company shall retain a transfer agent for the Units, Common Shares and Warrants, reasonably acceptable to the Underwriter, for a period of three (3) years from the Effective Date. In addition, for a period of three (3) years from the Effective Date, the Company, at its own expense, shall cause such transfer agent to provide the Underwriter, if so requested in writing, with copies of the Company's daily transfer sheets, and, when requested by the Underwriter, a current list of the Company's securityholders, including a list of the beneficial owners of securities held by a depository trust company and other nominees.

(u) The Company hereby agrees, at its sole cost and expense, to supply and deliver to the Underwriter and Underwriter's Counsel, within a reasonable period from the date hereof, four bound volumes, including the Registration Statement, as amended or supplemented, all exhibits to the Registration Statement, the Prospectus and all other underwriting documents.

(v) The Company shall, as of the date hereof, have applied for listing in Standard & Poor's Corporation Records Service (including annual report information) or Moody's Industrial Manual (Moody's OTC Industrial Manual not being sufficient for these purposes) and shall use its best efforts to have the Company listed in such manual and shall maintain such listing for a period of five (5) years from the Effective Date.

(w) For a period of five (5) years from the Effective Date, the Company shall provide the Underwriter, on a not less than annual basis, with internal forecasts setting forth projected results of operations for each quarterly and annual period in the two (2) fiscal years following the respective dates of such forecasts. Such forecasts shall be provided to the Underwriter more frequently than annually if prepared more frequently by management, and revised forecasts shall be prepared and provided to the Underwriter when required to reflect more current information, revised assumptions or actual results that differ materially from those set forth in the forecasts.

(x) For a period of three (3) years from the Effective Date, or until such earlier time as the Common Shares are listed on the New York Stock Exchange or the American Stock Exchange, the Company shall cause its legal counsel to provide the Underwriter with a list, to be updated at least annually, of those states in which the Common Shares may be traded in non-issuer transactions under the Blue Sky laws of the 50 states.

(y) For a period of three (3) years from the Effective Date, the Company shall continue to retain KPMG LLP (or such other nationally recognized accounting firm acceptable to the Underwriter) as the Company's independent public accountants.

(z) For a period of three (3) years from the Effective Date, the Company, at its expense, shall cause its then independent certified public accountants, as described in Section 5(y) above, to review (but not audit) the Company's financial statements for each of the first three fiscal quarters prior to the announcement of quarterly financial information, the filing of the Company's 10-Q (or 10-QSB) quarterly report (or other equivalent report) and the mailing of quarterly financial information to stockholders.

(aa) For a period of twenty-five (25) days from the Effective Date, the Company will not issue press releases or engage in any other publicity without the Underwriter's prior written consent, other than normal and customary releases issued in the ordinary course of the Company's business or those releases required by law.

(bb) The Company will not increase or authorize an increase in the compensation of its five (5) most highly paid employees greater than those increases provided for in their employment agreements with the Company in effect as of the Effective Date and disclosed in the Registration Statement, without the prior written consent of the Underwriter, for a period of three (3) years from the Effective Date.

(ab) For a period of three (3) years from the Effective Date, the Company will promptly submit to the Underwriter copies of accountant's management reports and similar correspondence between the Company's accountants and the Company.



(ac) For a period of two (2) years from the Effective Date, the Company will not offer or sell any of its securities (i) pursuant to Regulation S promulgated under the Act or (ii) at a discount to market or in a discounted transaction, without the prior written consent of the Underwriter, other than the issuance of Common Shares upon exercise of options and warrants outstanding on the Closing Date and described in the Prospectus.

(ad) For a period of three (3) years from the Effective Date, the Company will provide to the Underwriter ten (10) day's written notice prior to any issuance by the Company or its subsidiaries of any equity securities or securities exchangeable for or convertible into equity securities of the Company, except for (i) Common Shares issuable upon exercise of currently outstanding options and warrants or conversion of currently outstanding convertible securities and (ii) options available for future grant pursuant to any stock option plan in effect on the Effective Date and the issuance of shares of Common Shares upon the exercise of such options.

(ae) Prior to the Effective Date and for a period of two (2) years thereafter, the Company will retain a financial public relations firm reasonably acceptable to the Underwriter.

(af) For a period of five (5) years from the Effective Date, the Company will cause its Board of Directors to meet, either in person or telephonically, a minimum of four (4) times per year and will hold a stockholder's meeting at least once per annum.

(ag) Prior to the Effective Date, the Company shall have obtained Director's and Officer's insurance naming the Underwriter as an additional insured party, in an amount equal to twenty-five percent (25%) of the gross proceeds of the offering, and the Company will maintain such insurance for a period of at least three (3) years from the Closing Date.

6. Conditions of the Underwriter's Obligation to Purchase the Offered Units from the Company. The obligation of the Underwriter to purchase and pay for the Offered Units which it has agreed to purchase from the Company is subject (as of the date hereof and the Closing Date) to the accuracy of and compliance in all material respects with the representations and warranties of the Company herein, to the accuracy of the statements of the Company or its officers made pursuant hereto, to the performance in all material respects by the Company of its obligations hereunder, and to the following additional conditions:

(a) The Registration Statement will have become effective not later than 10:00 A.M., New York City time, on the day following the date of this Agreement, or at such later time or on such later date as the Underwriter may agree to in writing; prior to the Closing Date, no stop order suspending the effectiveness of the Registration Statement will have been issued and no proceedings for that purpose will have been initiated or will be pending or, to the best of the Underwriter's or the Company's knowledge, will be contemplated by the Commission; and any request on the part of the Commission for additional information will have been complied with to the satisfaction of Underwriter's Counsel.

(b) At the time that this Agreement is executed and at the Closing Date, there will have been delivered to the Underwriter a signed opinion of each of Morse, Zelnick, Rose & Lander LLP, Covington & Burling and Kirkpatrick & Lockhart LLP, counsels for the Company (individually and collectively, "Company Counsel"), dated as of the date hereof or the Closing Date, as the case may be (and any other opinions of counsel referred to in such opinion of Company Counsel or relied upon by Company Counsel in rendering their opinion), reasonably satisfactory to Underwriter's Counsel, to the effect that:

(i) The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware, with full power and authority, corporate and other, and with all Permits necessary to own or lease, as the case may be, and operate its properties, whether tangible or intangible, and to conduct its business as described in the Registration Statement. To the best of Company Counsel's knowledge, the Company has no subsidiaries. The Company is duly qualified to do business as a foreign corporation and is in good standing in all jurisdictions wherein such qualification is necessary and failure so to qualify could have a material adverse effect on the financial condition, results of operations, business or properties of the Company.

(ii) The Company has full power and authority, corporate and other, to execute, deliver and perform this Agreement, the Consulting Agreement, the Warrant Agreement, the Warrants and the Underwriter's Warrant Agreement and to consummate the transactions contemplated hereby and thereby. The execution, delivery and performance of this Agreement, the Consulting Agreement, the Warrant Agreement, the Warrants and the Underwriter's Warrant Agreement by the Company, the consummation by the Company of the transactions herein and therein contemplated and the compliance by the Company with the terms of this Agreement, the Consulting Agreement, the Warrant Agreement, the Warrants and the Underwriter's Warrant Agreement have been duly authorized by all necessary corporate action, and this Agreement has been duly executed and delivered by the Company. This Agreement is (assuming for the purposes of this opinion that it is valid and binding upon the other party thereto) and, when executed and delivered by the Company on the Closing Date, each of the Consulting Agreement, the Warrant Agreement, the Warrants and the Underwriter's Warrant Agreement will be, valid and binding obligations of the Company, enforceable in accordance with their respective terms, subject, as to enforcement of remedies, to applicable bankruptcy, insolvency, reorganization, moratorium and other laws affecting the rights of creditors generally and the discretion of courts in granting equitable remedies and except that enforceability of the indemnification provisions set forth in Section 7 hereof and the contribution provisions set forth in Section 8 hereof may be limited by the federal securities laws or public policy underlying such laws.

(iii) The execution, delivery and performance of this Agreement, the Consulting Agreement, the Warrant Agreement, the Warrants and the Underwriter's Warrant Agreement by the Company, the consummation by the Company of the transactions herein and therein contemplated and the compliance by the Company with the terms of this Agreement, the Consulting Agreement, the Warrant Agreement, the Warrants and the Underwriter's Warrant Agreement do not, and will not, with or without the giving of notice or the lapse of time, or both, (A) result in a violation of the Certificate of Incorporation or By-Laws, each as amended, of the Company, (B) result in a breach of or conflict with any terms or provisions of, or constitute a default under, or result in the modification or termination of, or

result in the creation or imposition of any lien, security interest, charge or encumbrance upon any of the properties or assets of the Company pursuant to any indenture, mortgage, note, contract, commitment or other material agreement or instrument to which the Company is a party or by which the Company, or any of the Company's properties or assets are or may be bound or affected; (C) violate any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company, or any of the Company's properties or business; or (D) have any effect on any Permit necessary for the Company to own or lease, as the case may be, and operate its properties or conduct its business or the ability of the Company to make use of its properties or business.

(iv) To the best of Company Counsel's knowledge, no Permits of any court or governmental agency or body (other than under the Act, the Regulations and applicable state securities or Blue Sky laws) are required for the valid authorization, issuance, sale and delivery of the Units or the Underwriter's Warrants to the Underwriter, and the consummation by the Company of the transactions contemplated by this Agreement, the Consulting Agreement, the Warrant Agreement, the Warrants or the Underwriter's Warrant Agreement.

(v) The Registration Statement has become effective under the Act; to the best of Company Counsel's knowledge, no stop order suspending the effectiveness of the Registration Statement has been issued, and no proceedings for that purpose have been instituted or are pending, threatened or contemplated under the Act or applicable state securities laws.

(vi) The Registration Statement and the Prospectus, as of the Effective Date, and each amendment or supplement thereto as of its effective or issue date (except for the financial statements and other financial data included therein or omitted therefrom, as to which Company Counsel need not express an opinion) comply as to form in all material respects with the requirements of the Act and Regulations and the conditions for use of a registration statement on Form SB-2 have been satisfied by the Company.

(vii) The descriptions in the Registration Statement and the Prospectus of statutes, regulations, government classifications, contracts and other documents (including opinions of such counsel); and the response to Item 13 of Form SB-2 have been reviewed by Company Counsel, and, based upon such review, are accurate in all material respects and present fairly the information required to be disclosed, and there are no material statutes, regulations or government classifications, or, to the best of Company Counsel's knowledge, material contracts or documents, of a character required to be described in the Registration Statement or the Prospectus or to be filed as exhibits to the Registration Statement, which are not so described or filed as required.

None of the material provisions of the contracts or instruments described above violates any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company, or any of its assets or businesses, including, without limitation, the FDA and FTC and comparable foreign, state and local regulatory authorities.

(viii) The outstanding Common Shares and outstanding options and warrants to purchase Common Shares have been duly authorized and validly issued. The outstanding Common Shares are fully paid and nonassessable. The outstanding options and warrants to purchase Common Shares constitute the valid and binding obligations of the Company, enforceable in accordance with their terms. None of the outstanding Common Shares or options or warrants to purchase Common Shares has been issued in violation of the preemptive rights of any stockholder of the Company. None of the holders of the outstanding Common Shares is subject to personal liability solely by reason of being such a holder. The offers and sales of the outstanding Common Shares and outstanding options and warrants to purchase Common Shares were at all relevant times either registered under the Act and the applicable state securities or Blue Sky laws or exempt from such registration requirements. The authorized Common Shares and outstanding options and warrants to purchase Common Shares conform to the descriptions thereof contained in the Registration Statement and Prospectus. To the best of Company Counsel's knowledge, except as set forth in the Prospectus, no holders of any of the Company's securities has any rights, "demand", "piggyback" or otherwise, to have such securities registered under the Act.

(ix) The issuance and sale of the Units, Shares and Warrants have been duly authorized and, when the Shares and Warrant Shares have been issued and duly delivered against payment therefor as contemplated by this Agreement, the Shares and Warrant Shares will be validly issued, fully paid and nonassessable, and the holders thereof will not be subject to personal liability solely by reason of being such holders. Neither the Shares nor the Warrant Shares are subject to preemptive rights of any stockholder of the Company. The Company has reserved a sufficient number of Common Shares from its authorized but unissued Common Shares for issuance upon exercise of the Warrants in accordance with the provisions of the Warrant Agreement. The certificates representing the Shares and the Warrants are in proper legal form.

(x) The issuance and sale of the Underlying Shares and Underlying Warrant Shares have been duly authorized and, when such Common Shares have been duly delivered against payment therefor, as contemplated by the Underwriter's Warrant Agreement, such Common Shares will be validly issued, fully paid and nonassessable. Holders of Underlying Shares and Underlying Warrant Shares will not be subject to personal liability solely by reason of being such holders. Neither the Underwriter's Warrants nor the Underlying Shares or Underlying Warrant Shares issuable upon exercise thereof will be subject to preemptive rights of any stockholder of the Company. The Company has reserved a sufficient number of Common Shares from its authorized, but unissued, Common Shares for issuance upon exercise of the Underwriter's Warrants and the Underlying Warrants in accordance with the provisions of the Underwriter's Warrant Agreement. The Underwriter's Warrants conform to the descriptions thereof in the Registration Statement and Prospectus.

(xi) Upon delivery of the Offered Units to the Underwriter against payment therefor as provided in this Agreement, the Underwriter (assuming it is a bona fide purchaser within the meaning of the Uniform Commercial Code) will acquire good title to the Offered Units, free and clear of all liens, encumbrances, equities, security interests and claims.

(xii) Assuming that the Underwriter exercises the over-allotment option to purchase any of the Optional Units and makes payment therefor in accordance with the terms of this Agreement, upon delivery of the Optional Units to the Underwriter hereunder, the Underwriter (assuming it is a bona fide purchaser within the meaning of the Uniform Commercial Code) will acquire good title to such Optional Units, free and clear of any liens, encumbrances, equities, security interests and claims.

(xiii) To the best of Company Counsel's knowledge, there are no claims, actions, suits, proceedings, arbitrations, investigations or inquiries before any governmental agency, court or tribunal, foreign or domestic, or before any private arbitration tribunal, pending or threatened against the Company, or involving the Company's properties or businesses, other than as described in the Prospectus, such description being accurate, and other than litigation incident to the kind of business conducted by the Company which, individually and in the aggregate, is not material.

(xiv) The Company owns or possesses adequate and enforceable rights to use all patents, patent applications, trademarks, service marks, copyrights, rights, trade secrets, confidential information, processes and formulations used or proposed to be used in the conduct of its business as described in the Prospectus (collectively the "Intangibles"); to the best of Company Counsel's knowledge, the Company has not infringed nor is infringing with the rights of others with respect to the Intangibles; and, to the best of Company Counsel's knowledge, the Company has not received any notice that it has or may have infringed, is infringing upon or is conflicting with the asserted rights of others with respect to the Intangibles which might, singly or in the aggregate, materially adversely affect its business, results of operations or financial condition and such counsel is not aware of any licenses with respect to the Intangibles which are required to be obtained by the Company other than those licenses which the Company has obtained. The opinions described in this Section 6(b)(xiv) may be given by Company Counsel in reliance on the opinion of an attorney, reasonably acceptable to Underwriter's Counsel, practicing in the patent area.

Company Counsel has participated in reviews and discussions in connection with the preparation of the Registration Statement and the Prospectus, and in the course of such reviews and discussions and such other investigation as Company Counsel deemed necessary, no facts came to its attention which lead it to believe that (A) the Registration Statement (except as to the financial statements and other financial data contained therein, as to which Company Counsel need not express an opinion), on the Effective Date, contained any untrue statement of a material fact required to be stated therein or omitted to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, or that (B) the Prospectus (except as to the financial statements and other financial data contained therein, as to which Company Counsel need not express an opinion) contains any untrue statement of a material fact or omits to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. Each counsel giving an opinion must give the opinion set forth in this paragraph as to such subject matter of its opinion.

In rendering its opinion pursuant to this Section 6(b), Company Counsel may rely upon the certificates of government officials and officers of the Company as to matters of fact, provided that Company Counsel shall state that they have no reason to believe, and do not believe, that they are not justified in relying upon such opinions or such certificates of government officials and officers of the Company as to matters of fact, as the case may be.

The opinion letters delivered pursuant to this Section 6(b) shall state that any opinion given therein qualified by the phrase "to the best of our knowledge" is being given by Company Counsel after due investigation of the matters therein discussed.

(c) At the Closing Date, there will have been delivered to the Underwriter a signed opinion of Underwriter's Counsel, dated as of the Closing Date, to the effect that the opinions delivered pursuant to Section 6(b) hereof appear on their face to be appropriately responsive to the requirements of this Agreement, except to the extent waived by the Underwriter, specifying the same, and with respect to such related matters as the Underwriter may require.

(d) At the Closing Date (i) the Registration Statement and the Prospectus and any amendments or supplements thereto will contain all material statements which are required to be stated therein in accordance with the Act and the Regulations and will conform in all material respects to the requirements of the Act and the Regulations, and neither the Registration Statement nor the Prospectus nor any amendment or supplement thereto will contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading; (ii) since the respective dates as of which information is given in the Registration Statement and the Prospectus, there will not have been any material adverse change in the financial condition, results of operations or general affairs of the Company from that set forth or contemplated in the Registration Statement and the Prospectus, except changes which the Registration Statement and the Prospectus indicate might occur after the Effective Date; (iii) since the respective dates as of which information is given in the Registration Statement and the Prospectus, there shall have been no material transaction, contract or agreement entered into by the Company, other than in the ordinary course of business, which would be required to be set forth in the Registration Statement and the Prospectus, other than as set forth therein; and (iv) no action, suit or proceeding at law or in equity will be pending or, to the best of the Company's knowledge, threatened against the Company which is required to be set forth in the Registration Statement and the Prospectus, other than as set forth therein, and no proceedings will be pending or, to the best of the Company's knowledge, threatened against the Company before or by any federal, state or other commission, board or administrative agency wherein an unfavorable decision, ruling or finding would materially adversely affect the business, property, financial condition or results of operations of the Company, other than as set forth in the Registration Statement and the Prospectus. At the Closing Date, there will be delivered to the Underwriter a certificate signed by the Chairman of the Board or the President or a Vice President of the Company, dated the Closing Date, evidencing compliance with the provisions of this Section 6(d) and stating that the representations and warranties of the Company set forth in Section 4 hereof were accurate and complete in all material respects when made on the date hereof and are accurate and complete in all material respects on the Closing Date as if then made; that the Company has performed all covenants and complied with all conditions required by this Agreement to be performed or complied with by the Company prior to or as of the Closing Date; and that, as of the Closing Date, no stop order suspending the effectiveness of the Registration Statement has been issued and no proceedings for that purpose have been initiated or, to the best of his knowledge, are contemplated or threatened. In addition, the Underwriter will have received such other and further certificates of officers of the Company as the Underwriter or Underwriter's Counsel may reasonably request.

(e) At the time that this Agreement is executed and at the Closing Date, the Underwriter will have received a signed letter from KPMG LLP, dated the date such letter is to be received by the Underwriter and addressed to it, confirming that it is a firm of independent public accountants within the meaning of the Act and Regulations and stating that: (i) insofar as reported on by them, in their opinion, the financial statements of the Company included in the Prospectus comply as to form in all material respects with the applicable accounting requirements of the Act and the applicable Regulations; (ii) on the basis of procedures and inquiries (not constituting an examination in accordance with generally accepted auditing standards) consisting of a reading of the unaudited interim financial statements of the Company, if any, appearing in the Registration Statement and the Prospectus and the latest available unaudited interim financial statements of the Company, if more recent than that appearing in the Registration Statement and Prospectus, inquiries of officers of the Company responsible for financial and accounting matters as to the transactions and events subsequent to the date of the latest audited financial statements of the Company, and a reading of the minutes of meetings of the stockholders, the Board of Directors of the Company and any committees of the Board of Directors, as set forth in the minute books of the Company, nothing has come to their attention which, in their judgment, would indicate that (A) during the period from the date of the latest financial statements of the Company appearing in the Registration Statement and Prospectus to a specified date not more than three business days prior to the date of such letter, there have been any decreases in net current assets or net assets as compared with amounts shown in such financial statements or decreases in net sales or decreases [increases] in total or per share net income [loss] compared with the corresponding period in the preceding year or any change in the capitalization or long-term debt of the Company, except in all cases as set forth in or contemplated by the Registration Statement and the Prospectus, and (B) the unaudited interim financial statements of the Company, if any, appearing in the Registration Statement and the Prospectus, do not comply as to form in all material respects with the applicable accounting requirements of the Act and the Regulations or are not fairly presented in conformity with generally accepted accounting principles and practices on a basis substantially consistent with the audited financial statements included in the Registration Statement or the Prospectus; and (iii) they have compared specific dollar amounts, numbers of shares, numerical data, percentages of revenues and earnings, and other financial information pertaining to the Company set forth in the Prospectus (with respect to all dollar amounts, numbers of shares, percentages and other financial information contained in the Prospectus, to the extent that such amounts, numbers, percentages and information may be derived from the general accounting records of the Company, and excluding any questions requiring an interpretation by legal counsel) with the results obtained from the application of specified readings, inquiries and other appropriate procedures (which procedures do not constitute an examination in accordance with generally accepted auditing standards) set forth in the letter, and found them to be in agreement.

(f) There shall have been duly tendered to the Underwriter certificates representing the Offered Units to be sold on the Closing Date.

(g) The NASD shall have indicated that it has no objection to the underwriting arrangements pertaining to the sale of the Units by the Underwriter.

(h) No action shall have been taken by the Commission or the NASD the effect of which would make it improper, at any time prior to the Closing Date or the Option Closing Date, as the case may be, for any member firm of the NASD to execute transactions (as principal or as agent) in the Units, Shares or Warrants, and no proceedings for the purpose of taking such action shall have been instituted or shall be pending, or, to the best of the Underwriter's or the Company's knowledge, shall be contemplated by the Commission or the NASD. The Company represents at the date hereof, and shall represent as of the Closing Date or Option Closing Date, as the case may be, that it has no knowledge that any such action is in fact contemplated by the Commission or the NASD.

(i) The Company meets the current and any existing and proposed criteria for inclusion of the Units, Shares and Warrants on Nasdaq SmallCap Market.

(j) All proceedings taken at or prior to the Closing Date or the Option Closing Date, as the case may be, in connection with the authorization, issuance and sale of the Units, Shares and Warrants shall be reasonably satisfactory in form and substance to the Underwriter and to Underwriter's Counsel, and such counsel shall have been furnished with all such documents, certificates and opinions as they may request for the purpose of enabling them to pass upon the matters referred to in Section 6(c) hereof and in order to evidence the accuracy and completeness of any of the representations, warranties or statements of the Company, the performance of any covenants of the Company, or the compliance by the Company with any of the conditions herein contained.

(k) As of the date hereof, the Company will have delivered to the Underwriter the written undertakings of its officers, directors and securityholders and/or registration rights holders, as the case may be, to the effect of the matters set forth in Sections 5(l) and (q).

If any of the conditions specified in this Section 6 have not been fulfilled, this Agreement may be terminated by the Underwriter on notice to the Company.

#### 7. Indemnification.

(a) The Company agrees to indemnify and hold harmless the Underwriter, each officer, director, partner, employee and agent of the Underwriter, and each person, if any, who controls the Underwriter within the meaning of Section 15 of the Act or Section 20(a) of the Exchange Act, from and against any and all losses, claims, damages, expenses or liabilities, joint or several (and actions in respect thereof), to which they or any of them may become subject under the Act or under any other statute or at common law or otherwise, and, except as hereinafter provided, will reimburse the Underwriter and each such person, if any, for any legal or other expenses reasonably incurred by them or any of them in connection with investigating or defending any actions, whether or not resulting in any liability, insofar as such losses, claims, damages, expenses, liabilities or actions arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained (i) in the Registration Statement, in any Preliminary Prospectus or in the Prospectus (or the Registration Statement or Prospectus as from time to time amended or



supplemented) or (ii) in any application or other document executed by the Company, or based upon written information furnished by or on behalf of the Company, filed in any jurisdiction in order to qualify the Units under the securities laws thereof (hereinafter "application"), or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary in order to make the statements therein not misleading, in light of the circumstances under which they were made, unless such untrue statement or omission was made in such Registration Statement, Preliminary Prospectus, Prospectus or application in reliance upon and in conformity with information furnished in writing to the Company in connection therewith by the Underwriter or any such person through the Underwriter expressly for use therein; provided, however, that the indemnity agreement contained in this Section 7(a) with respect to any Preliminary Prospectus will not inure to the benefit of the Underwriter (or to the benefit of any other person that may be indemnified pursuant to this Section 7(a)) if (A) the person asserting any such losses, claims, damages, expenses or liabilities purchased the Units which are the subject thereof from the Underwriter or other indemnified person; (B) the Underwriter or other indemnified person failed to send or give a copy of the Prospectus to such person at or prior to the written confirmation of the sale of such Units to such person; and (C) the Prospectus did not contain any untrue statement or alleged untrue statement or omission or alleged omission giving rise to such cause, claim, damage, expense or liability.

(b) The Underwriter agrees to indemnify and hold harmless the Company, each of its directors, each of its officers who have signed the Registration Statement and each person, if any, who controls the Company within the meaning of Section 15 of the Act or Section 20(a) of the Exchange Act, from and against any and all losses, claims, damages, expenses or liabilities, joint or several (and actions in respect thereof), to which they or any of them may become subject under the Act or under any other statute or at common law or otherwise, and, except as hereinafter provided, will reimburse the Company and each such director, officer or controlling person for any legal or other expenses reasonably incurred by them or any of them in connection with investigating or defending any actions, whether or not resulting in any liability, insofar as such losses, claims, damages, expenses, liabilities or actions arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained (i) in the Registration Statement, in any Preliminary Prospectus or in the Prospectus (or the Registration Statement or Prospectus as from time to time amended or supplemented) or (ii) in any application (including any application for registration of the Units under state securities or Blue Sky laws), or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary in order to make the statements therein not misleading, in light of the circumstances under which they were made, but only insofar as any such statement or omission was made in reliance upon and in conformity with information furnished in writing to the Company in connection therewith by the Underwriter expressly for use therein.

(c) Promptly after receipt of notice of the commencement of any action in respect of which indemnity may be sought against any indemnifying party under this Section 7, the indemnified party will notify the indemnifying party in writing of the commencement thereof, and the indemnifying party will, subject to the provisions hereinafter stated, assume the defense of such action (including the employment of counsel satisfactory to the indemnified party and the payment of expenses) insofar as such action relates to an alleged liability in respect of which indemnity may be sought against the indemnifying party. After notice from the indemnifying party of its election to assume the defense of such claim or action, the indemnifying party shall no longer be liable to the indemnified party under this Section 7 for any legal or other expenses subsequently incurred by the indemnified party in connection with the defense thereof other than reasonable costs of investigation; provided, however, that if, in the reasonable judgment of the indemnified party or parties, it is advisable for the

indemnified party or parties to be represented by separate counsel, the indemnified party or parties shall have the right to employ a single counsel to represent the indemnified parties who may be subject to liability arising out of any claim in respect of which indemnity may be sought by the indemnified parties thereof against the indemnifying party, in which event the fees and expenses of such separate counsel shall be borne by the indemnifying party. Any party against whom indemnification may be sought under this Section 7 shall not be liable to indemnify any person that might otherwise be indemnified pursuant hereto for any settlement of any action effected without such indemnifying party's consent, which consent shall not be unreasonably withheld.

8. Contribution. To provide for just and equitable contribution, if (i) an indemnified party makes a claim for indemnification pursuant to Section 7 hereof (subject to the limitations thereof) and it is finally determined, by a judgment, order or decree not subject to further appeal, that such claim for indemnification may not be enforced, even though this Agreement expressly provides for indemnification in such case; or (ii) any indemnified or indemnifying party seeks contribution under the Act, the Exchange Act, or otherwise, then the Company (including, for this purpose, any contribution made by or on behalf of any director of the Company, any officer of the Company who signed the Registration Statement and any controlling person of the Company) as one entity and the Underwriter (including, for this purpose, any contribution by or on behalf of each person, if any, who controls the Underwriter within the meaning of Section 15 of the Act or Section 20(a) of the Exchange Act and each officer, director, partner, employee and agent of the Underwriter) as a second entity, shall contribute to the losses, liabilities, claims, damages and expenses whatsoever to which any of them may be subject, so that the Underwriter is responsible for the proportion thereof equal to the percentage which the underwriting discount per Unit set forth on the cover page of the Prospectus represents of the initial public offering price per Unit set forth on the cover page of the Prospectus and the Company is responsible for the remaining portion; provided, however, that if applicable law does not permit such allocation, then, if applicable law permits, other relevant equitable considerations such as the relative fault of the Company and the Underwriter in connection with the facts which resulted in such losses, liabilities, claims, damages and expenses shall also be considered. The relative fault, in the case of an untrue statement, alleged untrue statement, omission or alleged omission, shall be determined by, among other things, whether such statement, alleged statement, omission or alleged omission relates to information supplied by the Company or by the Underwriter, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement, alleged statement, omission or alleged omission. The Company and the Underwriter agree that it would be unjust and inequitable if the respective obligations of the Company and the Underwriter for contribution were determined by pro rata or per capita allocation of the aggregate losses, liabilities, claims, damages and expenses or by any other method of allocation that does not reflect the equitable considerations referred to in this Section 8. No person guilty of a fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) will be entitled to contribution from any person who is not guilty of such fraudulent misrepresentation. For purposes of this Section 8, each person, if any, who controls the Underwriter within the meaning of Section 15 of the Act or Section 20(a) of the Exchange Act and each officer, director, partner, employee and agent of the Underwriter will have the same rights to contribution as the Underwriter, and each person, if any, who controls the Company within the meaning of Section 15 of the Act or Section 20(a) of the Exchange Act, each

officer of the Company who has signed the Registration Statement and each director of the Company will have the same rights to contribution as the Company, subject in each case to the provisions of this Section 8. Anything in this Section 8 to the contrary notwithstanding, no party will be liable for contribution with respect to the settlement of any claim or action effected without its written consent. This Section 8 is intended to supersede, to the extent permitted by law, any right to contribution under the Act or the Exchange Act or otherwise available.

9. Survival of Indemnities, Contribution, Warranties and Representations. The respective indemnity and contribution agreements of the Company and the Underwriter contained in Sections 7 and 8 hereof, and the representations and warranties of the Company contained herein shall remain operative and in full force and effect, regardless of any termination or cancellation of this Agreement or any investigation made by or on behalf of the Underwriter, the Company or any of its directors and officers, or any controlling person referred to in said Sections, and shall survive the delivery of, and payment for, the Units.

10. Termination of Agreement.

(a) The Company, by written or telegraphic notice to the Underwriter, or the Underwriter, by written or telegraphic notice to the Company, may terminate this Agreement prior to the earlier of (i) 11:00 A.M., New York City time, on the first full business day after the Effective Date; or (ii) the time when the Underwriter, after the Registration Statement becomes effective, releases the Offered Units for public offering. The time when the Underwriter "releases the Offered Units for public offering" for the purposes of this Section 10 means the time when the Underwriter releases for publication the first newspaper advertisement, which is subsequently published, relating to the Offered Units, or the time when the Underwriter releases for delivery to members of a selling group copies of the Prospectus and an offering letter or an offering telegram relating to the Offered Units, whichever will first occur.

(b) This Agreement, including without limitation, the obligation to purchase the Units and the obligation to purchase the Optional Units after exercise of the option referred to in Section 3 hereof, are subject to termination in the absolute discretion of the Underwriter, by notice given to the Company prior to delivery of and payment for all the Offered Units or such Optional Units, as the case may be, if, prior to such time, any of the following shall have occurred: (i) the Company withdraws the Registration Statement from the Commission or the Company does not or cannot expeditiously proceed with the public offering; (ii) the representations and warranties in Section 4 hereof are not materially correct or cannot be complied with; (iii) trading in securities generally on the New York Stock Exchange or the American Stock Exchange will have been suspended; (iv) limited or minimum prices will have been established on either such Exchange; (v) a banking moratorium will have been declared either by federal or New York State authorities; (vi) any other restrictions on transactions in securities materially affecting the free market for securities or the payment for such securities, including the Offered Units or the Optional Units, will be established by either of such Exchanges, by the Commission, by any other federal or state agency, by action of the Congress or by Executive Order; (vii) trading in any securities of the Company shall have been suspended or halted by any national securities exchange, the NASD or the Commission; (viii) there has been a materially adverse change in the condition (financial or otherwise), prospects or obligations of the Company; (ix) the Company will have sustained a material loss, whether or not insured, by reason of fire, flood, accident or other calamity; (x) any action has been taken by the government of the United States or any department or agency thereof which, in the judgment of the Underwriter, has had a material adverse effect upon the market or potential market for securities in general; or (xi) the market for securities in general or political, financial or economic conditions will have so materially adversely changed that, in the judgment of the Underwriter, it will be impracticable to offer for sale, or to enforce contracts made by the Underwriter for the resale of, the Offered Units or the Optional Units, as the case may be.

(c) If this Agreement is terminated pursuant to Section 6 hereof or this Section 10 or if the purchases provided for herein are not consummated because any condition of the Underwriter's obligations hereunder is not satisfied or because of any refusal, inability or failure on the part of the Company to comply with any of the terms or to fulfill any of the conditions of this Agreement, or if for any reason the Company shall be unable to or does not perform all of its obligations under this Agreement, the Company will not be liable to the Underwriter for damages on account of loss of anticipated profits arising out of the transactions covered by this Agreement, but the Company will remain liable to the extent provided in Sections 5(j), 7, 8 and 9 of this Agreement.

11. Information Furnished by the Underwriter to the Company. It is hereby acknowledged and agreed by the parties hereto that for the purposes of this Agreement, including, without limitation, Sections 4(f), 7(a), 7(b) and 8 hereof, the only information given by the Underwriter to the Company for use in the Prospectus are the statements set forth in the last sentence of the last paragraph on the cover page, the information in the third paragraph on page 44 with respect to concessions and reallowances, the information in the third sentence of the third paragraph on page 45 with respect to the determination of the public offering price and the statements appearing in the fifth and sixth paragraphs on page 45 with respect to stabilizing the market price of Units, as such information appears in any Preliminary Prospectus and in the Prospectus.

#### 12. Confidentiality.

(a) The Underwriter agrees to treat as confidential the information which is delivered to it by the Company pursuant to Section 5(v) hereof (the "Information"). All Information shall be kept in confidence and not disclosed to a third party or used by the Underwriter, except as required for the consummation of the transactions contemplated by this Agreement or as provided in Section 12(b) hereof. The Underwriter further agrees to reveal the Information only to those of its representatives who need to know the Information for the purposes of consummating the transactions contemplated by this Agreement and who are informed of and agree to be bound by the confidential nature of the Information.

(b) The restrictions set forth in Section 12(a) hereof do not apply to any Information which: (i) is or becomes generally available to the public; (ii) was known to the Underwriter prior to its receipt of Information from the Company; (iii) the Underwriter obtained from an independent third party who obtained such Information lawfully and was under no obligation of confidentiality; or (iv) is disclosed when such disclosure is compelled pursuant to legal, judicial or administrative proceedings, or otherwise required by law, subject to the Underwriter giving reasonable prior notice to the Company to allow the Company to participate in such proceedings.

13. Notices and Governing Law. All communications hereunder will be in writing and, except as otherwise provided, will be delivered at, or mailed by certified mail, return receipt requested, or telegraphed to, the following addresses: if to the Underwriter, to Whale Securities Co., L.P., Attention: William G. Walters, 650 Fifth Avenue, New York, New York 10019, with a copy to Blank Rome Tenzer Greenblatt LLP, Attention: Robert J. Mittman, Esq., 405 Lexington Avenue, New York, New York 10174; if to the Company, addressed to it at Delcath Systems, Inc., 1100 Summer Street, Stamford, Connecticut 06905, Attention: M.S. Koly, with a copy to Morse, Zelnick, Rose & Lander, LLP, 450 Park Avenue, New York, New York 10022, Attention: Stephen A. Zelnick, Esq.

This Agreement shall be deemed to have been made and delivered in New York City and shall be governed as to validity, interpretation, construction, effect and in all other respects by the internal laws of the State of New York. The Company (1) agrees that any legal suit, action or proceeding arising out of or relating to this Agreement shall be instituted exclusively in New York State Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, (2) waives any objection which the Company may have now or hereafter to the venue of any such suit, action or proceeding, and (3) irrevocably consents to the jurisdiction of the New York State Supreme Court, County of New York, and the United States District Court for the Southern District of New York in any such suit, action or proceeding. The Company further agrees to accept and acknowledge service of any and all process which may be served in any such suit, action or proceeding in the New York State Supreme Court, County of New York, or in the United States District Court for the Southern District of New York and agrees that service of process upon the Company mailed by certified mail to the Company's address shall be deemed in every respect effective service of process upon the Company, in any such suit, action or proceeding.

14. Parties in Interest. This Agreement is made solely for the benefit of the Underwriter, the Company and, to the extent expressed, any person controlling the Company or the Underwriter, each officer, director, partner, employee and agent of the Underwriter, the directors of the Company, its officers who have signed the Registration Statement, and their respective executors, administrators, successors and assigns, and, no other person will acquire or have any right under or by virtue of this Agreement. The term "successors and assigns" will not include any purchaser of the Units from the Underwriter, as such purchaser.

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to us the enclosed duplicates hereof, whereupon it will become a binding agreement between the Company and the Underwriter in accordance with its terms.

Very truly yours,

DELCATH SYSTEMS, INC.

By \_\_\_\_\_  
Name: M.S. Koly  
Title: Chief Executive Officer

Confirmed and accepted in  
New York, N.Y., as of the  
date first above written:

WHALE SECURITIES CO., L.P.

By: Whale Securities Corp.,  
General Partner

By \_\_\_\_\_  
Name: William G. Walters  
Title: Chairman

CERTIFICATE OF AMENDMENT  
TO  
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION  
OF  
DEL CATH SYSTEMS, INC.

Delcath Systems, Inc., a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware, DOES HEREBY CERTIFY:

FIRST: That, by written consent of all the Directors and the holders of a majority of the issued and outstanding capital stock of the Corporation, the following resolution proposing an amendment to the Amended and Restated Certificate of Incorporation of said Corporation was duly adopted. The resolution setting forth the amendment is as follows:

RESOLVED: That Article FOURTH of the Amended and Restated Certificate of Incorporation be amended by adding the following paragraph of Article FOURTH thereof so that, as amended, said article FOURTH shall be and read as follows:

"Each 1.26661011 shares of the Corporation's Common Stock, par value \$.01 per share, issued and outstanding as of the close of business on October 11, 2000 shall be converted and reclassified into one (1) share of the Corporation's Common Stock, par value \$.01 per share, so that each share of the Corporation's Common Stock \$.01 par value per share, issued and outstanding is hereby converted and reclassified. No fractional interests resulting from such conversion shall be issued, but in lieu thereof, the Corporation will pay cash for each currently issued and outstanding share of Common Stock, par value \$.01 per share, representing such fractional interest at a price equal to the per share price of the Corporation's Common Stock on October 11, 2000."

SECOND: That said amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, said Delcath Systems, Inc. has caused this certificate to be signed by M.S. Koly, its President and Chief Executive Officer, this 11th day of October, 2000.

DELCATH SYSTEMS, INC.

By: /s/ M.S. Koly

-----

M.S. Koly, President and  
Chief Executive Officer



WARRANT AGREEMENT dated as of \_\_\_\_\_, 2000 between Delcath Systems, Inc., a Delaware corporation (the "Company"), and Whale Securities Co., L.P. (hereinafter referred to as the "Underwriter").

W I T N E S S E T H:  
- - - - -

WHEREAS, the Company proposes to issue to the Underwriter warrants (the "Warrants") to purchase up to 120,000 (as such number may be adjusted from time to time pursuant to Article 8 of this Agreement) "Units" (as herewith defined in Article 1 hereof); and

WHEREAS, the Underwriter has agreed, pursuant to the underwriting agreement (the "Underwriting Agreement") dated \_\_\_\_\_, 2000 between the Underwriter and the Company, to act as the underwriter in connection with the Company's proposed public offering (the "Public Offering") of 1,200,000 Units at an initial public offering price of \$6.00 per Public Share; and

WHEREAS, the Warrants issued pursuant to this Agreement are being issued by the Company to the Underwriter or to its designees who are officers and partners of the Underwriter or to members of the selling group participating in the distribution of the Public Shares to the public in the Public Offering and/or their respective officers or partners (collectively, the "Designees"), in consideration for, and as part of the Underwriter's compensation in connection with, the Underwriter acting as the Underwriter pursuant to the Underwriting Agreement;

NOW, THEREFORE, in consideration of the premises, the payment by the Underwriter to the Company of ONE HUNDRED DOLLARS (\$100.00), the agreements herein set forth and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Grant.

The Underwriter and/or the Designees are hereby granted the right to purchase, at any time from \_\_\_\_\_, 2000 until 5:00 P.M., New York time, on \_\_\_\_\_, 2005 (the "Warrant Exercise Term"), up to 120,000 Units at an initial exercise price (subject to adjustment as provided in Article 8 hereof) of \$6.60 per Unit. Each Unit consists of 120,000 fully-paid and non-assessable shares (the "Shares") of the Company's Common stock, \$.01 par value ("Common Stock"), and 120,000 Common Stock Purchase Warrants (the "Unit Warrants"). The Unit Warrants are each exercisable to purchase one fully-paid and non-assessable share of Common Stock at a price of \$10.50 per share (the "Unit Warrant Shares"). The Unit Warrants are exercisable commencing October \_\_, 2001 (or such earlier date as to which the Underwriter consents to the Units becoming detachable and separately transferable) (the "Separation Date") until 5:00 P.M., New York City time on \_\_\_\_\_, 2005. Except as provided in Section 13 hereof, the Units and the Unit Warrants are in all respects identical to the units and warrants being sold to the public pursuant to the terms and provisions of the Underwriting Agreement.

2. Warrant Certificates.

The warrant certificates delivered and to be delivered pursuant to this Agreement (the "Warrant Certificates") shall be in the form set forth in Exhibit A attached hereto and made a part hereof, with such appropriate insertions, omissions, substitutions and other variations as required or permitted by this Agreement.

### 3. Exercise of Warrant.

3.1. Cash Exercise. The Warrants initially are exercisable at a price of \$6.60 per Unit, payable in cash or by check to the order of the Company, or any combination thereof, subject to adjustment as provided in Article 8 hereof. Upon surrender of the Warrant Certificate with the annexed Form of Election to Purchase duly executed, together with payment of the Exercise Price (as hereinafter defined) for the Shares purchased, at the Company's principal offices in New York (currently located at 1100 Summer Street, Stamford, Connecticut 06905) the registered holder of a Warrant Certificate ("Holder" or "Holders") shall be entitled to receive a certificate or certificates for the Shares so purchased and a certificate or certificates for the Unit Warrants so purchased. The purchase rights represented by each Warrant Certificate are exercisable at the option of the Holder thereof, in whole or in part (but not as to fractional Shares or fractional Unit Warrants). In the case of the purchase of less than all the Units purchasable under any Warrant Certificate, the Company shall cancel said Warrant Certificate upon the surrender thereof and shall execute and deliver a new Warrant Certificate of like tenor for the balance of the Units purchasable thereunder.

3.2. Cashless Exercise. At any time during the Warrant Exercise Term, the Holder may, at the Holder's option, exchange, in whole or in part, the Warrants represented by such Holder's Warrant Certificate (a "Warrant Exchange"), into the number of shares of Common Stock determined in accordance with this Section 3.2, by surrendering such Warrant Certificate at the principal office of the Company or at the office of its transfer agent, accompanied by a notice stating such Holder's intent to effect such exchange, the number of Units to be so exchanged and the date on which the Holder requests that such Warrant Exchange

occur (the "Notice of Exchange"). The Warrant Exchange shall take place on the date specified in the Notice of Exchange or, if later, the date the Notice of Exchange is received by the Company (the "Exchange Date"). Certificates for the shares of Common Stock issuable upon such Warrant Exchange and, if applicable, a new Warrant Certificate of like tenor representing the Warrants which were subject to the surrendered Warrant Certificate and not included in the Warrant Exchange, shall be issued as of the Exchange Date and delivered to the Holder within three (3) days following the Exchange Date. In connection with any Warrant Exchange, the Holder shall be entitled to subscribe for and acquire the number of shares of Common Stock (rounded to the next higher integer) equal to the sum of (i) (A) the number of Units specified by the Holder in its Notice of Exchange (the "Total Number") less (B) the number of Units equal to the quotient obtained by dividing (I) the product of the Total Number and the existing Exercise Price (as hereinafter defined) by (II) the Market Price (as hereinafter defined) of a share of Common Stock, plus (ii) the Total Number less (B) the number of Units equal to the quotient obtained by dividing (I) the product of the Total Number and the exercise price of the Unit Warrant by (II) the current Market Price (as hereinafter defined) of a share of Common Stock. "Market Price" at any date shall be deemed to be the last reported sale price, or, in case no such reported sales takes place on such day, the average of the last reported sale prices for the last three (3) trading days, in either case as officially reported by the principal securities exchange on which the Common Stock is listed or admitted to trading or as reported in the NASDAQ National Market System, or, if the Common Stock is not listed or admitted to trading on any national securities exchange or quoted on the NASDAQ National Market System, the closing bid

price as furnished by (i) the National Association of Securities Dealers, Inc. through Nasdaq or (ii) a similar organization if Nasdaq is no longer reporting such information.

#### 4. Issuance of Certificates.

Upon the exercise of the Warrants, the issuance of certificates for the Shares purchased and certificates for the Unit Warrants purchased, and upon exercise of the Unit Warrants, the issuance of certificates for the Unit Warrant Shares purchased shall be made forthwith (and in any event within three (3) business days thereafter) without charge to the Holder thereof including, without limitation, any tax which may be payable in respect of the issuance thereof, and such certificates shall (subject to the provisions of Article 5 hereof) be issued in the name of, or in such names as may be directed by, the Holder thereof; provided, however, that the Company shall not be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of any such certificates in a name other than that of the Holder and the Company shall not be required to issue or deliver such certificates unless or until the person or persons requesting the issuance thereof shall have paid to the Company the amount of such tax or shall have established to the satisfaction of the Company that such tax has been paid.

The Warrant Certificates and the certificates representing the Shares and the Unit Warrants shall be executed on behalf of the Company by the manual or facsimile signature of the present or any future Chairman or Vice Chairman of the Board of Directors, Chief Executive Officer or President or Vice President of the Company under its corporate seal reproduced thereon, attested to by the manual or facsimile signature of the present or any future Secretary or Assistant Secretary of the Company. Warrant Certificates shall be dated the date of execution by the Company upon initial issuance, division, exchange, substitution or transfer.

Upon exercise, in part or in whole, of the Warrants, certificates representing the Shares and the Unit Warrants purchased, and upon exercise, in whole or in part, of the Unit Warrants, certificates representing the Unit Warrant Shares purchased (collectively, the "Warrant Securities"), shall bear a legend substantially similar to the following:

"The securities represented by this certificate have not been registered for purposes of public distribution under the Securities Act of 1933, as amended (the "Act"), and may not be offered or sold except (i) pursuant to an effective registration statement under the Act, (ii) to the extent applicable, pursuant to Rule 144 under the Act (or any similar rule under such Act relating to the disposition of securities), or (iii) upon the delivery by the holder to the Company of an opinion of counsel, reasonably satisfactory to counsel to the Company, stating that an exemption from registration under such Act is available."

5. Restriction on Transfer of Warrants.

The Holder of a Warrant Certificate, by the Holder's acceptance thereof, covenants and agrees that the Warrants are being acquired as an investment and not with a view to the distribution thereof, and that the Warrants may not be sold, transferred, assigned, hypothecated or otherwise disposed of, in whole or in part, for a period of one (1) year from the date hereof, except to the Designees.

6. Price.

6.1. Initial and Adjusted Exercise Price. The initial exercise price of each Warrant shall be \$6.60 per Unit. The adjusted exercise price shall be the price which shall result from time to time from any and all adjustments of the initial exercise price in accordance with the provisions of Article 8 hereof.

6.2. Exercise Price. The term "Exercise Price" herein shall mean the initial exercise price or the adjusted exercise price, depending upon the context.

## 7. Registration Rights.

7.1. Registration Under the Securities Act of 1933. None of the Warrants, Shares, Unit Warrants or Unit Warrant Shares have been registered for purposes of public distribution under the Securities Act of 1933, as amended (the "Act").

7.2. Registrable Securities. As used herein the term "Registrable Security" means each of the Warrants, the Shares, the Unit Warrants, the Unit Warrant Shares and any shares of Common Stock issued upon any stock split or stock dividend in respect of such Shares or Unit Warrant Shares; provided, however, that with respect to any particular Registrable Security, such security shall cease to be a Registrable Security when, as of the date of determination, (i) it has been effectively registered under the Act and disposed of pursuant thereto, (ii) registration under the Act is no longer required for the subsequent public distribution of such security or (iii) it has ceased to be outstanding. The term "Registrable Securities" means any and/or all of the securities falling within the foregoing definition of a "Registrable Security." In the event of any merger, reorganization, consolidation, recapitalization or other change in corporate structure affecting the Common Stock, such adjustment shall be made in the definition of "Registrable Security" as is appropriate in order to prevent any dilution or enlargement of the rights granted pursuant to this Article 7.

7.3. Piggyback Registration. If, at any time during the seven (7) years following the effective date of the Public Offering, the Company proposes to prepare and file one or more post-effective amendments to the registration statement filed in connection with the Public Offering or any new registration statement or post-effective amendments thereto covering equity or debt securities of the Company, or any such securities of the Company held by its

stockholders (in any such case, other than in connection with a merger, acquisition or pursuant to Form S-8 or successor form), (for purposes of this Article 7, collectively, the "Registration Statement"), it will give written notice of its intention to do so by registered mail ("Notice"), at least thirty (30) business days prior to the filing of each such Registration Statement, to all holders of the Registrable Securities. Upon the written request of such a holder (a "Requesting Holder"), made within twenty (20) business days after receipt of the Notice, that the Company include any of the Requesting Holder's Registrable Securities in the proposed Registration Statement, the Company shall, as to each such Requesting Holder, use its best efforts to effect the registration under the Act of the Registrable Securities which it has been so requested to register ("Piggyback Registration"), at the Company's sole cost and expense and at no cost or expense to the Requesting Holders (except as provided in Section 7.5(b) hereof).

#### 7.4. Demand Registration.

(a) At any time during the Warrant Exercise Term, any "Majority Holder" (as such term is defined in Section 7.4(c) below) of the Registrable Securities shall have the right (which right is in addition to the piggyback registration rights provided for under Section 7.3 hereof), exercisable by written notice to the Company (the "Demand Registration Request"), to have the Company prepare and file with the Securities and Exchange Commission (the "Commission"), on one occasion, at the sole expense of the Company (except as provided in Section 7.5(b) hereof), a Registration Statement and such other documents, including a prospectus, as may be necessary (in the opinion of both counsel for the Company and counsel for such Majority Holder), in order to comply with the provisions of the Act, so as to permit a public offering and sale of the Registrable Securities by the holders thereof. The Company shall use its



best efforts to cause the Registration Statement to become effective under the Act, so as to permit a public offering and sale of the Registrable Securities by the holders thereof. Once effective, the Company will use its best efforts to maintain the effectiveness of the Registration Statement until the earlier of (i) the date that all of the Registrable Securities have been sold or (ii) the date that the holders of the Registrable Securities receive an opinion of counsel to the Company that all of the Registrable Securities may be freely traded (without limitation or restriction as to quantity or timing and without registration under the Act) under Rule 144(k) promulgated under the Act or otherwise.

(b) The Company covenants and agrees to give written notice of any Demand Registration Request to all holders of the Registrable Securities within ten (10) business days from the date of the Company's receipt of any such Demand Registration Request. After receiving notice from the Company as provided in this Section 7.4(b), holders of Registrable Securities may request the Company to include their Registrable Securities in the Registration Statement to be filed pursuant to Section 7.4(a) hereof by notifying the Company of their decision to have such securities included within ten (10) days of their receipt of the Company's notice.

(c) The term "Majority Holder" as used in Section 7.4 hereof shall mean any holder or any combination of holders of Registrable Securities, if included in such holders' Registrable Securities are that aggregate number of shares of Common Stock (including Shares already issued and Shares issuable pursuant to the exercise of outstanding Warrants, Unit Warrant Shares already issued and Unit Warrant Shares issuable pursuant to the exercise of outstanding Unit Warrants) as would constitute a majority of the aggregate number of Shares

(including Shares already issued and Shares issuable pursuant to the exercise of outstanding Warrants, Unit Warrant Shares already issued and Unit Warrant Shares issuable pursuant to the issue of outstanding Unit Warrants) included in all the Registrable Securities.

7.5. Covenants of the Company With Respect to Registration. The Company covenants and agrees as follows:

(a) In connection with any registration under Section 7.4 hereof, the Company shall file the Registration Statement as expeditiously as possible, but in any event no later than twenty (20) days following receipt of any demand therefor, shall use its best efforts to have any such Registration Statement declared effective at the earliest possible time, and shall furnish each holder of Registrable Securities such number of prospectuses as shall reasonably be requested.

(b) The Company shall pay all costs, fees and expenses (other than underwriting fees, discounts and nonaccountable expense allowance applicable to the Registrable Securities and the fees and expenses of counsel retained by the holders of Registrable Securities) in connection with all Registration Statements filed pursuant to Sections 7.3 and 7.4(a) hereof including, without limitation, the Company's legal and accounting fees, printing expenses, and blue sky fees and expenses.

(c) The Company will take all necessary action which may be required in qualifying or registering the Registrable Securities included in the Registration Statement for offering and sale under the securities or blue sky laws of such states as are reasonably requested by the holders of such securities.

(d) The Company shall indemnify any holder of the Registrable Securities to be sold pursuant to any Registration Statement and any underwriter or person deemed to be an underwriter under the Act and each person, if any, who controls such holder or underwriter or person deemed to be an underwriter within the meaning of Section 15 of the Act or Section 20(a) of the Securities Exchange Act of 1934, as amended ("Exchange Act"), against all loss, claim, damage, expense or liability (including all expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever) to which any of them may become subject under the Act, the Exchange Act or otherwise, arising from such Registration Statement to the same extent and with the same effect as the provisions pursuant to which the Company has agreed to indemnify the Underwriter as set forth in Section 7 of the Underwriting Agreement and to provide for just and equitable contribution as set forth in Section 8 of the Underwriting Agreement.

(e) Any holder of Registrable Securities to be sold pursuant to a Registration Statement, and such holder's successors and assigns, shall severally, and not jointly, indemnify, the Company, its officers and directors and each person, if any, who controls the Company within the meaning of Section 15 of the Act or Section 20(a) of the Exchange Act, against all loss, claim, damage or expense or liability (including all expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever) to which they may become subject under the Act, the Exchange Act or otherwise, arising from information furnished by or on behalf of such holder, or such holder's successors or assigns, for specific inclusion in such Registration Statement to the same extent and with the same effect as the provisions pursuant to which the Underwriter has agreed to indemnify the Company as set forth

in Section 7 of the Underwriting Agreement and to provide for just and equitable contribution as set forth in Section 8 of the Underwriting Agreement.

(f) Nothing contained in this Agreement shall be construed as requiring any Holder to exercise the Warrants or the Unit Warrants included in the Units underlying such Warrants prior to the initial filing of any Registration Statement or the effectiveness thereof.

(g) If the Company shall fail to comply with the provisions of this Article 7, the Company shall, in addition to any other equitable or other relief available to the holders of Registrable Securities, be liable for any or all incidental, special and consequential damages sustained by the holders of Registrable Securities, requesting registration of their Registrable Securities.

(h) The Company shall promptly deliver copies of all correspondence between the Commission and the Company, its counsel or auditors and all memoranda relating to discussions with the Commission or its staff with respect to the Registration Statement to each holder of Registrable Securities included for such registration in such Registration Statement pursuant to Section 7.3 hereof or Section 7.4 hereof requesting such correspondence and memoranda and to the managing underwriter, if any, of the offering in connection with which such holder's Registrable Securities are being registered and shall permit each holder of Registrable Securities and such underwriter to do such reasonable investigation, upon reasonable advance notice, with respect to information contained in or omitted from the Registration Statement as it deems reasonably necessary to comply with applicable securities laws or rules of the National Association of Securities Dealers, Inc. Such investigation shall include access to

books, records and properties and opportunities to discuss the business of the Company with its officers and independent auditors, all to such reasonable extent and at such reasonable times and as often as any such holder of Registrable Securities or underwriter shall reasonably request.

#### 8. Adjustments of Exercise Price and Number of Units.

8.1. Computation of Adjusted Price. In case the Company shall at any time after the date hereof pay a dividend in shares of Common Stock or make a distribution in shares of Common Stock, then upon such dividend or distribution the Exercise Price in effect immediately prior to such dividend or distribution shall forthwith be reduced to a price determined by dividing:

(a) an amount equal to the total number of shares of Common Stock outstanding immediately prior to such dividend or distribution multiplied by the Exercise Price in effect immediately prior to such dividend or distribution, by

(b) the total number of shares of Common Stock outstanding immediately after such issuance or sale.

For the purposes of any computation to be made in accordance with the provisions of this Section 8.1, the Common Stock issuable by way of dividend or other distribution on any stock of the Company shall be deemed to have been issued immediately after the opening of business on the date following the date fixed for the determination of stockholders entitled to receive such dividend or other distribution.

8.2. Subdivision and Combination. In case the Company shall at any time subdivide or combine the outstanding shares of Common Stock, the Exercise Price shall forthwith be proportionately decreased in the case of subdivision or increased in the case of combination.

8.3. Adjustment in Number of Units. Upon each adjustment of the Exercise Price pursuant to the provisions of this Article 8, the number of Units issuable upon the exercise of each Warrant shall be adjusted to the nearest full number of Units by multiplying a number equal to the Exercise Price in effect immediately prior to such adjustment by the number of Units issuable upon exercise of the Warrants immediately prior to such adjustment and dividing the product so obtained by the adjusted Exercise Price.

8.4. Reclassification, Consolidation, Merger, etc. In case of any reclassification or change of the outstanding shares of Common Stock (other than a change in par value to no par value, or from no par value to par value, or as a result of a subdivision or combination), or in the case of any consolidation of the Company with, or merger of the Company into, another corporation (other than a consolidation or merger in which the Company is the surviving corporation and which does not result in any reclassification or change of the outstanding shares of Common Stock, except a change as a result of a subdivision or combination of such shares or a change in par value, as aforesaid), or in the case of a sale or conveyance to another corporation of the property of the Company as an entirety, the Holders shall thereafter have the right to purchase the kind and number of shares of stock and other securities and property receivable upon such reclassification, change, consolidation, merger, sale or conveyance as if the Holders were the owners of the shares of Common Stock underlying the Warrants and the Unit Warrant Shares contained in the Unit Warrants underlying such Warrants immediately prior to any such events at a price equal to the product of (x) the number of shares of Common Stock issuable upon exercise of the Warrants and the Unit Warrants underlying such

Warrants and (y) the Exercise Price in effect immediately prior to the record date for such reclassification, change, consolidation, merger, sale or conveyance as if such Holders had exercised the Warrants and the Unit Warrants underlying such Warrants.

8.5. Adjustment of Unit Warrants Exercise Price and Securities on Exercise of Unit Warrant. With respect to any of the Unit Warrants underlying the Warrants, whether or not the Warrants have been exercised and whether or not the Warrants are issued and outstanding, the exercise price for, and the number of, shares of Common Stock issuable upon exercise of the Unit Warrants shall be automatically adjusted in accordance with Section 9 of the Unit Warrant Agreement, upon the occurrence of any of the events described therein. Thereafter, the underlying Unit Warrants shall be exercisable at such adjusted exercise price and for such adjustment number of underlying shares of Common Stock.

8.6. Determination of Outstanding Shares of Common Stock. The number of shares of Common Stock at any one time outstanding shall include the aggregate number of shares of Common Stock issued and the aggregate number of shares of Common Stock issuable upon the exercise of options, rights, warrants and upon the conversion or exchange of convertible or exchangeable securities.

8.7. Dividends and Other Distributions with Respect to Outstanding Securities. In the event that the Company shall at any time prior to the exercise of all warrants make any distribution of its assets to holders of its Common Stock as a liquidating or a partial liquidating dividend, then the holder of Warrants who exercises its Warrants after the record date for the determination of those holders of Common Stock entitled to such distribution of assets as a liquidating or partial liquidating dividend shall be entitled to receive for the Warrant Price per

Warrant, in addition to each share of Common Stock, the amount of such distribution (or, at the option of the Company, a sum equal to the value of any such assets at the time of such distribution as determined by the Board of Directors of the Company in good faith) which would have been payable to such holder had he been the holder of record of the Common Stock receivable upon exercise of his Warrant on the record date for the determination of those entitled to such distribution. At the time of any such dividend or distribution, the Company shall make appropriate reserves to ensure the timely performance of the provisions of this Subsection 8.6.

8.8. Subscription Rights for Shares of Common Stock or Other Securities. In the case that the Company or an affiliate of the Company shall at any time after the date hereof and prior to the exercise of all the Warrants issue any rights, warrants or options to subscribe for shares of Common Stock or any other securities of the Company or of such affiliate to all the stockholders of the Company, the Holders of unexercised Warrants on the record date set by the Company or such affiliate in connection with such issuance of rights, warrants or options shall be entitled, in addition to the shares of Common Stock or other securities receivable upon the exercise of the Warrants, to receive such rights, warrants or options that such Holders would have been entitled to receive had they been, on such record date, the holders of record of the number of whole shares of Common Stock then issuable upon exercise of their outstanding Warrants (assuming for purposes of this Section 8.8), that the exercise of the Warrants is permissible immediately upon issuance).

#### 9. Exchange and Replacement of Warrant Certificates.

Each Warrant Certificate is exchangeable without expense, upon the surrender thereof by the registered Holder at the principal executive office of the Company, for a new



Warrant Certificate of like tenor and date representing in the aggregate the right to purchase the same number of securities in such denominations as shall be designated by the Holder thereof at the time of such surrender.

Upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of any Warrant Certificate, and, in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it, and reimbursement to the Company of all reasonable expenses incidental thereto, and upon surrender and cancellation of the Warrant Certificate, if mutilated, the Company will make and deliver a new Warrant Certificate of like tenor, in lieu thereof.

10. Elimination of Fractional Interests.

The Company shall not be required to issue certificates representing fractions of Shares, nor shall it be required to issue scrip or pay cash in lieu of fractional interests, it being the intent of the parties that all fractional interests shall be eliminated by rounding any fraction up to the nearest whole number of Shares and Unit Warrants.

11. Reservation and Listing of Securities.

The Company shall at all times reserve and keep available out of its authorized shares of Common Stock, solely for the purpose of issuance upon the exercise of the Warrants and the Unit Warrants, such number of shares of Common Stock as shall be issuable upon the exercise thereof. The Company covenants and agrees that, upon exercise of the Warrants and payment of the Exercise Price therefor, all Shares issuable upon such exercise shall be duly and validly issued, fully paid, non-assessable and not subject to the preemptive rights of any stockholder. The Company further covenants and agrees that upon exercise of the Unit Warrants

underlying the Warrants and payment of the Unit Warrant exercise price therefor, all Unit Warrant Shares issuable upon such exercise shall be duly and validly issued, fully paid, non-assessable and not subject to the preemptive rights of any stockholder. As long as the Warrants shall be outstanding, the Company shall use its best efforts to cause all shares of Common Stock issuable upon the exercise of the Warrants and Unit Warrants underlying the Warrants to be listed on or quoted by Nasdaq or listed on such national securities exchange, in the event the Common Stock is listed on a national securities exchange.

12. Notices to Warrant Holders.

Nothing contained in this Agreement shall be construed as conferring upon the Holder or Holders the right to vote or to consent or to receive notice as a stockholder in respect of any meetings of stockholders for the election of directors or any other matter, or as having any rights whatsoever as a stockholder of the Company. If, however, at any time prior to the expiration of the Warrants and their exercise, any of the following events shall occur:

(a) the Company shall take a record of the holders of its shares of Common Stock for the purpose of entitling them to receive a dividend or distribution payable otherwise than in cash, or a cash dividend or distribution payable otherwise than out of current or retained earnings, as indicated by the accounting treatment of such dividend or distribution on the books of the Company; or

(b) the Company shall offer to all the holders of its Common Stock any additional shares of capital stock of the Company or securities convertible into or exchangeable for shares of capital stock of the Company, or any option, right or warrant to subscribe therefor; or

(c) a dissolution, liquidation or winding up of the Company (other than in connection with a consolidation or merger) or a sale of all or substantially all of its property, assets and business as an entirety shall be proposed; or

(d) reclassification or change of the outstanding shares of Common Stock (other than a change in par value to no par value, or from no par value to par value, or as a result of a subdivision or combination), consolidation of the Company with, or merger of the Company into, another corporation (other than a consolidation or merger in which the Company is the surviving corporation and which does not result in any reclassification or change of the outstanding shares of Common Stock, except a change as a result of a subdivision or combination of such shares or a change in par value, as aforesaid), or a sale or conveyance to another corporation of the property of the Company as an entirety is proposed; or

(e) The Company or an affiliate of the Company shall propose to issue any rights to subscribe for shares of Common Stock or any other securities of the Company or of such affiliate to all the shareholders of the Company;

then, in any one or more of said events, the Company shall give written notice to the Holder or Holders of such event at least fifteen (15) days prior to the date fixed as a record date or the date of closing the transfer books for the determination of the stockholders entitled to such dividend, distribution, convertible or exchangeable securities or subscription rights, options or warrants, or entitled to vote on such proposed dissolution, liquidation, winding up or sale. Such notice shall specify such record date or the date of closing the transfer books, as the case may be. Failure to

give such notice or any defect therein shall not affect the validity of any action taken in connection with the declaration or payment of any such dividend or distribution, or the issuance of any convertible or exchangeable securities or subscription rights, options or warrants, or any proposed dissolution, liquidation, winding up or sale.

### 13. Unit Warrants

The form of the certificates representing the Unit Warrants (and the form of election to purchase shares of Common Stock upon the exercise of the Unit Warrants and the form of assignment printed on the reverse thereof) shall be substantially as set forth in Exhibit "A" to the Unit Warrant Agreement; provided, however, (i) each Unit Warrant issuable upon exercise of the Warrants shall evidence the right to initially purchase one fully paid and non-assessable share of Common Stock in respect of the Unit Warrant at an initial purchase price of \$10.50 per share from the Separation Date until \_\_\_\_\_, 2005 and (ii) the Target Redemption Price (as defined in the Public Warrant Agreement) of the Unit Warrants is 150% of the then effective exercise price of the Unit Warrants. As set forth in Section 8.5 of this Agreement, the exercise price of the Unit Warrants and the number of shares of Common Stock issuable upon the exercise of the Unit Warrants are subject to adjustment, whether or not the Warrants have been exercised and the Unit Warrants have been issued, in the manner and upon the occurrence of the events set forth in Section 9 of the Unit Warrant Agreement, which is hereby incorporated herein by reference and made a part hereof as is set forth in its entirety herein. Subject to the provisions of this Agreement and upon issuance of the Unit Warrants underlying the Warrants, each registered holder of such Unit Warrants shall have the right to purchase from the Company (and the Company shall issue to such registered holders) up to the number of fully paid and non-assessable shares of Common Stock underlying such Unit Warrants (subject to adjustment as provided herein and in the Unit Warrant Agreement), free and

clear of all preemptive rights of shareholders, provided that such registered holder complies with the terms governing exercise of the Unit Warrants set forth in the Unit Warrant Agreement, and pays the applicable exercise price, determined in accordance with the terms of the Unit Warrant Agreement. Upon exercise of the Unit Warrants, the Company shall forthwith issue to the registered holder of any such Unit Warrant in his name or in such name as may be directed by him, certificates for the number of shares of Common Stock and the number of Unit Warrants so purchased. Except as otherwise provided in Section 8.5 hereof, the Unit Warrants underlying the Warrants shall be governed in all respects by the terms of the Unit Warrant Agreement. The Unit Warrants shall be transferable in the manner provided in the Unit Warrant Agreement, and upon any such transfer, a new Unit Warrant shall be issued promptly to the transferee. The Company covenants to, and agrees with, each Holder that without the prior written consent of all the Holders, the Unit Warrant Agreement will not be modified, amended, cancelled, altered or superseded, and that the Company will send to each Holder, irrespective of whether or not the Warrants have been exercised, any and all notices required by the Unit Warrant Agreement to be sent to holders of the Unit Warrants.

#### 14. Notices.

All notices, requests, consents and other communications hereunder shall be in writing and shall be deemed to have been duly made when delivered, or mailed by registered or certified mail, return receipt requested:

(a) If to a registered Holder of the Warrants, to the address of such Holder as shown on the books of the Company; or

(b) If to the Company, to the address set forth in Section 3 of this Agreement or to such other address as the Company may designate by notice to the Holders.

15. Supplements and Amendments.

The Company and the Underwriter may from time to time supplement or amend this Agreement without the approval of any Holders of Warrant Certificates and/or Warrant Securities in order to cure any ambiguity, to correct or supplement any provision contained herein which may be defective or inconsistent with any provisions herein, or to make any other provisions in regard to matters or questions arising hereunder which the Company and the Underwriter may deem necessary or desirable and which the Company and the Underwriter deem not to adversely affect the interests of the Holders of Warrant Certificates and/or Warrant Securities.

16. Successors.

All the covenants and provisions of this Agreement by or for the benefit of the Company and the Holders inure to the benefit of their respective successors and assigns hereunder.

17. Termination.

This Agreement shall terminate at the close of business on \_\_\_\_\_, 2008. Notwithstanding the foregoing, this Agreement will terminate on any earlier date when all Warrants have been exercised and all the Shares issuable upon exercise of the Warrants have been resold to the public; provided, however, that the provisions of Section 7 shall survive any termination pursuant to this Section 16 until the close of business on \_\_\_\_\_, 2011.

18. Governing Law.

This Agreement and each Warrant Certificate issued hereunder shall be deemed to be a contract made under the laws of the State of New York and for all purposes shall be construed in accordance with the laws of said State.

19. Benefits of This Agreement.

Nothing in this Agreement shall be construed to give to any person or corporation other than the Company and the Underwriter and any other registered holder or holders of the Warrant Certificates or Warrant Securities any legal or equitable right, remedy or claim under this Agreement; and this Agreement shall be for the sole and exclusive benefit of the Company and the Underwriter and any other holder or holders of the Warrant Certificates or Warrant Securities.

20. Counterparts.

This Agreement may be executed in any number of counterparts and each of such counterparts shall for all purposes be deemed to be an original, and such counterparts shall together constitute but one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed, as of the day and year first above written.

DELCATH SYSTEMS, INC.

By: \_\_\_\_\_  
Name: M.S. Koly  
Title: Chief Executive Officer

WHALE SECURITIES CO., L.P.

By: Whale Securities Corp.,  
General Partner

By: \_\_\_\_\_  
Name: William G. Walters  
Title: Chairman



EXHIBIT A

THE WARRANTS REPRESENTED BY THIS CERTIFICATE AND THE OTHER SECURITIES ISSUABLE UPON EXERCISE THEREOF HAVE NOT BEEN REGISTERED FOR PURPOSES OF PUBLIC DISTRIBUTION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), AND MAY NOT BE OFFERED OR SOLD EXCEPT (i) PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE ACT, (ii) TO THE EXTENT APPLICABLE, PURSUANT TO RULE 144 UNDER SUCH ACT (OR ANY SIMILAR RULE UNDER SUCH ACT RELATING TO THE DISPOSITION OF SECURITIES), OR (iii) UPON THE DELIVERY BY THE HOLDER TO THE COMPANY OF AN OPINION OF COUNSEL, REASONABLY SATISFACTORY TO COUNSEL FOR THE COMPANY, STATING THAT AN EXEMPTION FROM REGISTRATION UNDER SUCH ACT IS AVAILABLE.

THE TRANSFER OR EXCHANGE OF THE WARRANTS REPRESENTED BY THIS CERTIFICATE IS RESTRICTED IN ACCORDANCE WITH THE WARRANT AGREEMENT REFERRED TO HEREIN.

EXERCISABLE ON OR BEFORE  
5:00 P.M., NEW YORK TIME, \_\_\_\_\_, 2005

No. W- \_\_\_\_\_ Warrants

WARRANT CERTIFICATE

This Warrant Certificate certifies that \_\_\_\_\_ or registered assigns, is the registered holder of \_\_\_\_\_ (\_\_\_\_\_) Warrants to purchase, at any time from \_\_\_\_\_, 2000 until 5:00 P.M. New York City time on \_\_\_\_\_, 2005 ("Expiration Date"), up to \_\_\_\_\_ units ("Units"), each consisting of one fully-paid and non-assessable share of common stock, par value \$.01 per share (the "Common Stock"), of Delcath Systems, Inc., a Delaware corporation (the "Company"), and one Common Stock Purchase Warrant, each Common Stock Purchase Warrant entitling the holder thereof to purchase one share of Common Stock (collectively, the "Unit Warrants") at the initial exercise price, subject to adjustment in certain events (the "Exercise Price"), of \$6.60 per Unit upon surrender of this Warrant Certificate and payment of the Exercise Price at an office or agency of the Company, but subject to the conditions set forth herein and in the warrant agreement dated as of \_\_\_\_\_, 2000 between the Company and Whale Securities Co., L.P. (the "Warrant Agreement"). Payment of the Exercise Price may be made in cash, or by certified or official bank check in New York Clearing House funds payable to the order of the Company, or any combination thereof.

Each Unit Warrant issuable upon the exercise of a Warrant is initially exercisable from the Separation Date through \_\_\_\_\_, 2005, for one fully-paid and non-assessable share of Common Stock at an initial exercise price of \$10.50 per share. The Unit Warrants are issuable pursuant to the terms and provisions of a certain agreement dated as of \_\_\_\_\_, 2000

by and among the Company, the Underwriter and American Stock Transfer & Trust Company (the "Unit Warrant Agreement"). The Unit Warrant Agreement is hereby incorporated by reference in and made a part of this instrument and is hereby referred to (except as otherwise provided in the Warrant Agreement) for a description of the rights, limitations of rights, manner of exercise, anti-dilution provisions and other provisions with respect to the Unit Warrants.

No Warrant may be exercised after 5:00 P.M., New York City time, on the Expiration Date, at which time all Warrants evidenced hereby, unless exercised prior thereto, shall thereafter be void.

The Warrants evidenced by this Warrant Certificate are part of a duly authorized issue of Warrants issued pursuant to the Warrant Agreement, which Warrant Agreement is hereby incorporated by reference in and made a part of this instrument and is hereby referred to for a description of the rights, limitation of rights, obligations, duties and immunities thereunder of the Company and the holders (the words "holders" or "holder" meaning the registered holders or registered holder) of the Warrants.

The Warrant Agreement provides that upon the occurrence of certain events, the Exercise Price and the type and/or number of the Company's securities issuable thereupon may, subject to certain conditions, be adjusted. In such event, the Company will, at the request of the holder, issue a new Warrant Certificate evidencing the adjustment in the Exercise Price and the number and/or type of securities issuable upon the exercise of the Warrants; provided, however, that the failure of the Company to issue such new Warrant Certificates shall not in any way change, alter, or otherwise impair, the rights of the holder as set forth in the Warrant Agreement.

Upon due presentment for registration of transfer of this Warrant Certificate at an office or agency of the Company, a new Warrant Certificate or Warrant Certificates of like tenor and evidencing in the aggregate a like number of Warrants shall be issued to the transferee(s) in exchange for this Warrant Certificate, subject to the limitations provided herein and in the Warrant Agreement, without any charge except for any tax, or other governmental charge imposed in connection therewith.

Upon the exercise of less than all of the Warrants evidenced by this Certificate, the Company shall forthwith issue to the holder hereof a new Warrant Certificate representing such number of unexercised Warrants.

The Company may deem and treat the registered holder(s) hereof as the absolute owner(s) of this Warrant Certificate (notwithstanding any notation of ownership or other writing hereon made by anyone), for the purpose of any exercise hereof, and of any distribution to the holder(s) hereof, and for all other purposes, and the Company shall not be affected by any notice to the contrary.

All terms used in this Warrant Certificate which are defined in the Warrant Agreement shall have the meanings assigned to them in the Warrant Agreement.

IN WITNESS WHEREOF, the Company has caused this Warrant Certificate to be duly executed under its corporate seal.

Dated: \_\_\_\_\_, 2000

DELCATH SYSTEMS, INC.

By: \_\_\_\_\_  
Name: M.S. Koly  
Title: Chief Executive Officer

[FORM OF ELECTION TO PURCHASE]

The undersigned hereby irrevocably elects to exercise the right, represented by this Warrant Certificate, to purchase \_\_\_\_\_ Units and herewith tenders in payment for such securities cash or a certified or official bank check payable in New York Clearing House Funds to the order of Delcath Systems, Inc. in the amount of \$ \_\_\_\_\_, all in accordance with the terms hereof. The undersigned requests that a certificate for such securities be registered in the name of \_\_\_\_\_, whose address is \_\_\_\_\_, and that such Certificate be delivered to \_\_\_\_\_, whose address is \_\_\_\_\_.

Dated:

Signature: \_\_\_\_\_

(Signature must conform in all respects to name of holder as specified on the face of the Warrant Certificate.)

-----  
-----  
(Insert Social Security or Other  
Identifying Number of Holder)



DELCATH SYSTEMS, INC.

a Delaware corporation

and

American Stock Transfer & Trust Company  
Warrant Agent

and

Whale Securities Co., L.P.  
Underwriter

WARRANT AGREEMENT

Table of Contents

-----

Section -----	Page -----
1. Appointment of Warrant Agent.....	
2. Form of Warrant .....	
3. Countersignature and Registration.....	
4. Transfers and Exchanges .....	
5. Exercise of Warrants; Payment of Warrant Solicitation Fee.....	
6. Payment of Taxes .....	
7. Mutilated or Missing Warrants Warrants .....	
8. Reservation of Common Stock .....	
9. Warrant Price; Adjustments .....	
10. Fractional Interest .....	
11. Notices to Warrantholders .....	
12. Disposition of Proceeds on Exercise of Warrants.....	
13. Redemption of Warrants.....	
14. Merger or Consolidation or Change of Name of Warrant Agent.....	
15. Duties of Warrant Agent.....	
16. Change of Warrant Agent.....	
17. Identity of Transfer Agent .....	
18. Notices .....	
20. New York Contract .....	
21. Benefits of this Agreement .....	
22. Successors .....	
Exhibit A - Form of Warrant .....	

WARRANT AGENT AGREEMENT dated as of October , 2000, by and among Delcath Systems, Inc., a Delaware corporation (the "Company"), Whale Securities Co., L.P. (the "Underwriter") and American Stock Transfer & Trust Company, as warrant agent (hereinafter called the "Warrant Agent").

WHEREAS, the Company proposes to issue and sell to the public up to 1,380,000 units (the "Units") each Unit consisting of one share of the common stock of the Company, par value \$.01 per share (hereinafter, together with the stock of any other class to which such shares may hereafter have been changed, called "Common Stock"), and one Common Stock Purchase Warrant (the "Warrants");

WHEREAS, each Warrant will entitle the holder to purchase one share of Common Stock;

WHEREAS, the Company desires the Warrant Agent to act on behalf of the Company, and the Warrant Agent is willing to so act, in connection with the issuance, registration, transfer, exchange and exercise of the Warrants;

NOW, THEREFORE, in consideration of the premises and the mutual agreements herein set forth, the parties hereto agree as follows:

Section 1. Appointment of Warrant Agent. The Company hereby appoints the Warrant Agent to act as Warrant Agent for the Company in accordance with the instructions hereinafter set forth in this Agreement, and the Warrant Agent hereby accepts such appointment.



Section 2. Form of Warrant. The text of the Warrants and of the form of election to purchase Common Stock to be printed on the reverse thereof shall be substantially as set forth in Exhibit A attached hereto. Each Warrant shall entitle the registered holder thereof to purchase one share of Common Stock at a purchase price of Six Dollars Sixty Cents (\$6.60), at any time commencing on the Separation Date (as hereinafter defined) until 5:00 p.m. Eastern time, on October , 2005 (the "Warrant Exercise Period"). The securities comprising the Units will become detachable and separately transferable commencing October , 2005, or such earlier date as to which the Underwriter consents (the "Separation Date"). The warrant price and the number of shares of Common Stock issuable upon exercise of the Warrants are subject to adjustment upon the occurrence of certain events, all as hereinafter provided. The Warrants shall be executed on behalf of the Company by the manual or facsimile signature of the present or any future Chief Executive Officer, President or Vice President of the Company, attested to by the manual or facsimile signature of the present or any future Secretary or Assistant Secretary of the Company.

Warrants shall be dated as of the issuance by the Warrant Agent either upon initial issuance or upon transfer or exchange.

In the event the aforesaid expiration dates of the Warrants fall on a Saturday or Sunday, or on a legal holiday on which the New York Stock Exchange is closed, then the Warrants shall expire at 5:00 p.m. Eastern time on the next succeeding business day.

Section 3. Countersignature and Registration. The Warrant Agent shall maintain books for the transfer and registration of the Warrants. Upon the initial issuance of the Warrants, the Warrant Agent shall issue and register the Warrants in the names of the respective holders thereof. The Warrants shall be countersigned manually or by facsimile by the Warrant Agent (or

by any successor to the Warrant Agent then acting as warrant agent under this Agreement) and shall not be valid for any purpose unless so countersigned. Warrants may, however, be so countersigned by the Warrant Agent (or by its successor as Warrant Agent) and be delivered by the Warrant Agent, notwithstanding that the persons whose manual or facsimile signatures appear thereon as proper officers of the Company shall have ceased to be such officers at the time of such countersignature or delivery.

Section 4. Transfers and Exchanges. The Warrant Agent shall transfer, from time to time, any outstanding Warrants upon the books to be maintained by the Warrant Agent for that purpose, upon surrender thereof for transfer properly endorsed or accompanied by appropriate instructions for transfer. Upon any such transfer, a new Warrant shall be issued to the transferee and the surrendered Warrant shall be cancelled by the Warrant Agent. Warrants so cancelled shall be delivered by the Warrant Agent to the Company from time to time upon request. Warrants may be exchanged at the option of the holder thereof, when surrendered at the office of the Warrant Agent, for another Warrant, or other Warrants of different denominations of like tenor and representing in the aggregate the right to purchase a like number of shares of Common Stock.

Section 5. Exercise of Warrants; Payment of Warrant Solicitation Fee.

(a) Subject to the provisions of this Agreement, each registered holder of Warrants shall have the right, which may be exercised commencing at the opening of business on the first day of the Warrant Exercise Period, to purchase from the Company (and the Company shall issue and sell to such registered holder of Warrants) the number of fully paid and non-assessable shares of Common Stock specified in such Warrants upon surrender of such Warrants to the Company at the office of the Warrant Agent, with the form of election to purchase on the reverse

thereof duly filled in and signed, and upon payment to the Company of the warrant price, determined in accordance with the provisions of Sections 9 and 10 of this Agreement, for the number of shares of Common Stock in respect of which such Warrants are then exercised. Payment of such warrant price shall be made in cash or by certified check or bank draft to the order of the Company. Subject to Section 6, upon such surrender of Warrants and payment of the warrant price, the Company shall issue and cause to be delivered with all reasonable dispatch to or upon the written order of the registered holder of such Warrants and in such name or names as such registered holder may designate, a certificate or certificates for the number of full shares of Common Stock so purchased upon the exercise of such Warrants. Such certificate or certificates shall be deemed to have been issued, and any person so designated to be named therein shall be deemed to have become a holder of record of such shares of Common Stock, as of the date of the surrender of such Warrants and payment of the warrant price as aforesaid. The rights of purchase represented by the Warrants shall be exercisable, at the election of the registered holders thereof, either as an entirety or from time to time for a portion of the shares specified therein and, in the event that any Warrant is exercised in respect of less than all of the shares of Common Stock specified therein at any time prior to the date of expiration of the Warrants, a new Warrant or Warrants will be issued to the registered holder for the remaining number of shares of Common Stock specified in the Warrant so surrendered, and the Warrant Agent is hereby irrevocably authorized to countersign and to deliver the required new Warrants pursuant to the provisions of this Section and of Section 3 of this Agreement and the Company, whenever requested by the Warrant Agent, will supply the Warrant Agent with Warrants duly executed on behalf of the Company for such purpose. Anything in the foregoing to the contrary notwithstanding, no Warrant will be exercisable unless at the time of exercise the Company has

filed with the Securities and Exchange Commission a registration statement under the Securities Act of 1933, as amended (the "Act"), covering the shares of Common Stock issuable upon exercise of such Warrant and such shares have been so registered or qualified or deemed to be exempt under the securities laws of the state of residence of the holder of such Warrant. The Company shall use its best efforts to have all shares so registered or qualified on or before the date on which the Warrants become exercisable.

(b) If at the time of exercise of any Warrant after October , 2001 [one year after the Effective Date] (i) the market price of the Company's Common Stock is equal to or greater than the then purchase price of the Warrant, (ii) the exercise of the Warrant is solicited by the Underwriter at such time while the Underwriter is a member of the National Association of Securities Dealers, Inc. ("NASD"), (iii) the Warrant is not held in a discretionary account, (iv) disclosure of the compensation arrangement is made in documents provided to the holders of the Warrants; and (v) the solicitation of the exercise of the Warrant is not in violation of Regulation M (as such regulation or any successor regulation or rule may be in effect as of such time of exercise) promulgated under the Securities Exchange Act of 1934, then the Underwriter shall be entitled to receive from the Company upon exercise of each of the Warrant(s) so exercised a fee of five percent (5%) of the aggregate price of the Warrants so exercised (the "Exercise Fee"). The procedures for payment of the warrant solicitation fee are set forth in Section 5(c) below.

(c) (1) Within five (5) days of the last day of each month commencing with October , 2001, the Warrant Agent will notify the Underwriter of each Warrant Certificate which has been properly completed for exercise by holders of Warrants during the last month. The Company and Warrant Agent shall determine, in their sole and absolute discretion, whether a Warrant Certificate has been properly completed. The Warrant Agent will provide the

Underwriter with such information, in connection with the exercise of each Warrant, as the Underwriter shall reasonably request.

(2) The Company hereby authorizes and instructs the Warrant Agent to deliver to the Underwriter the Exercise Fee promptly after receipt by the Warrant Agent from the Company of a check payable to the order of the Underwriter in the amount of the Exercise Fee. In the event that an Exercise Fee is paid to the Underwriter with respect to a Warrant which the Company or the Warrant Agent determines is not properly completed for exercise or in respect of which the Underwriter is not entitled to an Exercise Fee, the Underwriter will promptly return such Exercise Fee to the Warrant Agent which shall forthwith return such fee to the Company.

The Underwriter and the Company may at any time, after October , 2001, and during business hours, examine the records of the Warrant Agent, including its ledger of original Warrant certificates returned to the Warrant Agent upon exercise of Warrants. Notwithstanding any provision to the contrary, the provisions of paragraphs 5(b) and 5(c) may not be modified, amended or deleted without the prior written consent of the Underwriter.

Section 6. Payment of Taxes. The Company will pay any documentary stamp taxes attributable to the initial issuance of Common Stock issuable upon the exercise of Warrants; provided, however, that the Company shall not be required to pay any tax which may be payable in respect of any transfer involved in the issue or delivery of any certificates of shares of Common Stock in a name other than that of the registered holder of Warrants in respect of which such shares are issued, and in such case neither the Company nor the Warrant Agent shall be required to issue or deliver any certificate for shares of Common Stock or any Warrant until the person requesting the same has paid to the Company the amount of such tax or has established to the Company's satisfaction that such tax has been paid.

Section 7. Mutilated or Missing Warrants. In case any of the Warrants shall be mutilated, lost, stolen or destroyed, the Company may, in its discretion, issue and the Warrant Agent shall countersign and deliver in exchange and substitution for and upon cancellation of the mutilated Warrant, or in lieu of and in substitution for the Warrant lost, stolen or destroyed, a new Warrant of like tenor and representing an equivalent right or interest, but only upon receipt of evidence satisfactory to the Company and the Warrant Agent of such loss, theft or destruction and, in case of a lost, stolen or destroyed Warrant, indemnity, if requested, also satisfactory to them. Applicants for such substitute Warrants shall also comply with such other reasonable regulations and pay such reasonable charges as the Company or the Warrant Agent may prescribe.

Section 8. Reservation of Common Stock. There have been reserved, and the Company shall at all times keep reserved, out of the authorized and unissued shares of Common Stock, a number of shares of Common Stock sufficient to provide for the exercise of the rights of purchase represented by the Warrants, and the transfer agent for the shares of Common Stock and every subsequent transfer agent for any shares of the Company's Common Stock issuable upon the exercise of any of the rights of purchase aforesaid are irrevocably authorized and directed at all times to reserve such number of authorized and unissued shares of Common Stock as shall be required for such purpose. The Company agrees that all shares of Common Stock issued upon exercise of the Warrants shall be, at the time of delivery of the certificates of such shares, validly issued and outstanding, fully paid and nonassessable and listed on any national securities exchange upon which the other shares of Common Stock are then listed. So long as any unexpired Warrants remain outstanding, the Company will file such post-effective amendments to the registration statement (Form SB-2, Registration No. 333-39470) (the "Registration

Statement") filed pursuant to the Act with respect to the Warrants (or other appropriate registration statements or post-effective amendment or supplements) as may be necessary to permit it to deliver to each person exercising a Warrant, a prospectus meeting the requirements of Section 10(a)(3) of the Act and otherwise complying therewith, and will deliver such a prospectus to each such person. To the extent that during any period it is not reasonably likely that the Warrants will be exercised, due to market price or otherwise, the Company need not file such a post-effective amendment during such period. The Company will keep a copy of this Agreement on file with the transfer agent for the shares of Common Stock and with every subsequent transfer agent for any shares of the Company's Common Stock issuable upon the exercise of the rights of purchase represented by the Warrants. The Warrant Agent is irrevocably authorized to requisition from time to time from such transfer agent stock certificates required to honor outstanding Warrants. The Company will supply such transfer agent with duly executed stock certificates for that purpose. All Warrants surrendered in the exercise of the rights thereby evidenced shall be cancelled by the Warrant Agent and shall thereafter be delivered to the Company, and such cancelled Warrants shall constitute sufficient evidence of the number of shares of Common Stock which have been issued upon the exercise of such Warrants. Promptly after the date of expiration of the Warrants, the Warrant Agent shall certify to the Company the total aggregate amount of Warrants then outstanding, and thereafter no shares of Common Stock shall be subject to reservation in respect of such Warrants which shall have expired.

#### Section 9. Warrant Price; Adjustments.

(a) The warrant price at which Common Stock shall be purchasable upon the exercise of the Warrants shall be \$6.60 per share or after adjustment, as provided in this Section, shall be such price as so adjusted (the "Warrant Price").

(b) The Warrant Price shall be subject to adjustment from time to time as follows:

(i) In case the Company shall at any time after the date hereof pay a dividend in shares of Common Stock or make a distribution in shares of Common Stock, then upon such dividend or distribution the Warrant Price in effect immediately prior to such dividend or distribution shall forthwith be reduced to a price determined by dividing:

(A) an amount equal to the total number of shares of Common Stock outstanding immediately prior to such dividend or distribution multiplied by the Warrant Price in effect immediately prior to such dividend or distribution, by

(B) the total number of shares of Common Stock outstanding immediately after such issuance or sale.

For the purposes of any computation to be made in accordance with the provisions of this Section 9(b)(i), the following provisions shall be applicable: Common Stock issuable by way of dividend or other distribution on any stock of the Company shall be deemed to have been issued immediately after the opening of business on the date following the date fixed for the determination of stockholders entitled to receive such dividend or other distribution.

(ii) In case the Company shall at any time subdivide or combine the outstanding Common Stock, the Warrant Price shall forthwith be proportionately decreased in the case of subdivision or increased in the case of combination to the nearest one cent. Any such adjustment shall become effective at the time such subdivision or combination shall become effective.



(iii) Within a reasonable time after the close of each quarterly fiscal period of the Company during which the Warrant Price has been adjusted as herein provided, the Company shall:

(A) file with the Warrant Agent a certificate signed by the Chief Executive Officer, President or Vice President of the Company and by the Treasurer or Assistant Treasurer or the Secretary or an Assistant Secretary of the Company, showing in detail the facts requiring all such adjustments occurring during such period and the Warrant Price after each such adjustment; and

(B) the Warrant Agent shall have no duty with respect to any such certificate filed with it except to keep the same on file and available for inspection by holders of Warrants during reasonable business hours, and the Warrant Agent may conclusively rely upon the latest certificate furnished to it hereunder. The Warrant Agent shall not at any time be under any duty or responsibility to any holder of a Warrant to determine whether any facts exist which may require any adjustment of the Warrant Price, or with respect to the nature or extent of any adjustment of the Warrant Price when made, or with respect to the method employed in making any such adjustment, or with respect to the nature or extent of the property or securities deliverable hereunder. In the absence of a certificate having been furnished, the Warrant Agent may conclusively rely upon the provisions of the Warrants with respect to the Common Stock deliverable upon the exercise of the Warrants and the applicable Warrant Price thereof.

(iv) Notwithstanding anything contained herein to the contrary, no adjustment of the Warrant Price shall be made if the amount of such adjustment shall be less than \$.05, but in such case any adjustment that would otherwise be required then to be made shall be carried forward and shall be made at the time and together with the next subsequent adjustment which, together with any adjustment so carried forward, shall amount to not less than \$.02.

(v) In the event that the number of outstanding shares of Common Stock is increased by a stock dividend payable in Common Stock or by a subdivision of the outstanding Common Stock, then, from and after the time at which the adjusted Warrant Price becomes effective pursuant to Subsection (b) of this Section by reason of such dividend or subdivision, the number of shares of Common Stock issuable upon the exercise of each Warrant shall be increased in proportion to such increase in outstanding shares. In the event that the number of shares of Common Stock outstanding is decreased by a combination of the outstanding Common Stock, then, from and after the time at which the adjusted Warrant Price becomes effective pursuant to this Section 9(b) by reason of such combination, the number of shares of Common Stock issuable upon the exercise of each Warrant shall be decreased in proportion to such decrease in the outstanding shares of Common Stock.

(vi) In case of any reorganization or reclassification of the outstanding Common Stock (other than a change in par value, or from par value to no par value, or as a result of a subdivision or combination), or in case of any consolidation of the Company with, or merger of the Company into, another corporation (other than a consolidation or merger in which the Company is the continuing corporation and which does not result in any reclassification of the outstanding Common Stock), or in case of any sale or conveyance to another corporation of the property of the Company as an entirety or substantially as an entirety, the holder of each Warrant then outstanding shall thereafter have the right to purchase the kind and amount of shares of Common Stock and other securities and property receivable upon such reorganization, reclassification, consolidation, merger, sale or conveyance by a holder of the number of shares of Common Stock which the holder of such Warrant shall then be entitled to purchase; such adjustments shall apply with respect to all such changes occurring between the date of this Warrant Agreement and the date of exercise of such Warrant.

(vii) Subject to the provisions of this Section 9, in case the Company shall, at any time prior to the exercise of the Warrants, make any distribution of its assets to holders of its Common Stock as a liquidating or a partial liquidating dividend, then the holder of Warrants who exercises its Warrants after the record date for the determination of those holders of Common Stock entitled to such distribution of assets as a liquidating or partial liquidating dividend shall be entitled to receive for the Warrant Price per Warrant, in addition to each share of Common Stock, the amount of such distribution (or, at the option of the Company, a sum equal to the value of any such assets at the time of such distribution as determined by the Board of Directors of the Company in good faith), which would have been payable to such holder had he been the holder of record of the Common Stock receivable upon exercise of its Warrant on the record date for the determination of those entitled to such distribution.

(viii) In case of the dissolution, liquidation or winding up of the Company, all rights under the Warrants shall terminate on a date fixed by the Company, such date to be no earlier than ten (10) days prior to the effectiveness of such dissolution, liquidation or winding up and not later than five (5) days prior to such effectiveness. Notice of such termination of purchase rights shall be given to the last registered holder of the Warrants, as the same shall appear on the books of the Company maintained by the Warrant Agent, by registered mail at least thirty (30) days prior to such termination date.

(ix) In case the Company shall, at any time prior to the expiration of the Warrants and prior to the exercise thereof, offer to the holders of its Common Stock any rights to subscribe for additional shares of any class of the Company, then the Company shall

give written notice thereof to the last registered holder thereof not less than thirty (30) days prior to the date on which the books of the Company are closed or a record date is fixed for the determination of the stockholders entitled to such subscription rights. Such notice shall specify the date as to which the books shall be closed or record date fixed with respect to such offer of subscription and the right of the holder thereof to participate in such offer of subscription shall terminate if the Warrant shall not be exercised on or before the date of such closing of the books or such record date.

(x) Any adjustment pursuant to the aforesaid provisions of this Section 9 shall be made on the basis of the number of shares of Common Stock which the holder thereof would have been entitled to acquire by the exercise of the Warrant immediately prior to the event giving rise to such adjustment.

(xi) Irrespective of any adjustments in the Warrant Price or the number or kind of shares purchasable upon exercise of the Warrants, Warrants previously or thereafter issued may continue to express the same price and number and kind of shares as are stated in the similar Warrants initially issuable pursuant to this Warrant Agreement.

(xii) The Company may retain a firm of independent public accountants (who may be any such firm regularly employed by the Company) to make any computation required under this Section 9, and any certificate setting forth such computation signed by such firm shall be conclusive evidence of the correctness of any computation made under this Section 9.

(xiii) If at any time, as a result of an adjustment made pursuant to Section 9(b)(vi) above, the holders of a Warrant or Warrants shall become entitled to purchase any securities other than shares of Common Stock, thereafter the number of such securities so

purchasable upon exercise of each Warrant and the Warrant Price for such shares shall be subject to adjustment from time to time in a manner and on terms as nearly equivalent as practicable to the provisions with respect to the Common Stock contained in Sections 9(b)(ii) through (v).

Section 10. Fractional Interest. The Warrants may only be exercised to purchase full shares of Common Stock and the Company shall not be required to issue fractions of shares of Common Stock on the exercise of Warrants. However, if a Warrant holder exercises all Warrants then owned of record by it and such exercise would result in the issuance of a fractional share, the Company will pay to such Warrant holder, in lieu of the issuance of any fractional share otherwise issuable, an amount of cash based on the market value of the Common Stock of the Company on the last trading day prior to the exercise date.

Section 11. Notices to Warrantholders.

(a) Upon any adjustment of the Warrant Price and the number of shares of Common Stock issuable upon exercise of a Warrant, then and in each such case the Company shall give written notice thereof to the Warrant Agent, which notice shall state the Warrant Price resulting from such adjustment and the increase or decrease, if any, in the number of shares purchasable at such price upon the exercise of a Warrant, setting forth in reasonable detail the method of calculation and the facts upon which such calculation is based. The Company shall also mail such notice to the holders of the Warrants at their addresses appearing in the Warrant register. Failure to give or mail such notice, or any defect therein, shall not affect the validity of the adjustments.

(b) In case at any time:

(i) the Company shall pay dividends payable in stock upon its Common Stock or make any distribution (other than regular cash dividends) to the holders of its Common Stock; or

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

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

(iv) there shall be a voluntary or involuntary dissolution, liquidation or winding up of the Company; then in any one or more of such cases, the Company shall give written notice in the manner set forth in Section 11(a) of the date on which (A) a record shall be taken for such dividend, distribution or subscription rights, or (B) such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding up shall take place, as the case may be. Such notice shall also specify the date as of which the holders of Common Stock of record shall participate in such dividend, distribution or subscription rights, or shall be entitled to exchange their Common Stock for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding up as the case may be. Such notice shall be given at least thirty (30) days prior to the action in question and not less than thirty (30) days prior to the record date in respect thereof. Failure to give such notice, or any defect therein, shall not affect the legality or validity of any of the matters set forth in this Section 11(b).

(c) The Company shall cause copies of all financial statements and reports, proxy statements and other documents that are sent to its stockholders to be sent by first-class mail, postage prepaid, on the date of mailing to such stockholders, to each registered holder of Warrants at his address appearing in the warrant register as of the record date for the determination of the stockholders entitled to such documents.

Section 12. Disposition of Proceeds on Exercise of Warrants.

(i) The Warrant Agent shall promptly forward to the Company all monies received by the Warrant Agent for the purchase of shares of Common Stock through the exercise of such Warrants; provided, however, that the Warrant Agent may retain an amount equal to the Exercise Fee, if any, until the Company has satisfied its obligations under Section 5(c)(2).

(ii) The Warrant Agent shall keep copies of this Agreement available for inspection by holders of Warrants during normal business hours.

Section 13. Redemption of Warrants. The Warrants are redeemable by the Company, in whole or in part, on not less than thirty (30) days' prior written notice at a redemption price of \$.10 per Warrant at any time commencing on the Separation Date; provided that (i) the closing bid quotation of the Common Stock on all twenty (20) trading days ending on the third trading day prior to the day on which the Company gives notice (the "Call Date") of redemption has been at least 150% of the then effective exercise price of the Warrants (the "Target Redemption Price") and the Company obtains the written consent of the Underwriter with respect to such redemption prior to the Call Date and (ii) the Warrants are currently exercisable. The redemption notice shall be mailed to the holders of the Warrants at their addresses appearing in the Warrant register. Holders of the Warrants will have exercise rights until the close of business on the date fixed for redemption.

Section 14. Merger or Consolidation or Change of Name of Warrant Agent. Any corporation or company which may succeed to the corporate trust business of the Warrant Agent by any merger or consolidation or otherwise shall be the successor to the Warrant Agent

hereunder without the execution or filing of any paper or any further act on the part of any of the parties hereto, provided that such corporation would be eligible to serve as a successor Warrant Agent under the provisions of Section 16 of this Agreement. In case at the time such successor to the Warrant Agent shall succeed to the agency created by this Agreement, any of the Warrants shall have been countersigned but not delivered, any such successor to the Warrant Agent may adopt the countersignature of the original Warrant Agent and deliver such Warrants so countersigned.

In case at any time the name of the Warrant Agent shall be changed and at such time any of the Warrants shall have been countersigned but not delivered, the Warrant Agent may adopt the countersignature under its prior name and deliver Warrants so countersigned. In all such cases such Warrants shall have the full force provided in the Warrants and in the Agreement.

Section 15. Duties of Warrant Agent. The Warrant Agent undertakes the duties and obligations imposed by this Agreement upon the following terms and conditions, by all of which the Company and the holders of Warrants, by their acceptance thereof, shall be bound:

(a) The statements of fact and recitals contained herein and in the Warrants shall be taken as statements of the Company, and the Warrant Agent assumes no responsibility for the correctness of any of the same except such as describe the Warrant Agent or action taken or to be taken by it. The Warrant Agent assumes no responsibility with respect to the distribution of the Warrants except as herein expressly provided.

(b) The Warrant Agent shall not be responsible for any failure of the Company to comply with any of the covenants in this Agreement or in the Warrants to be complied with by the Company.



(c) The Warrant Agent may consult at any time with counsel satisfactory to it (who may be counsel for the Company) and the Warrant Agent shall incur no liability or responsibility to the Company or to any holder of any Warrant in respect of any action taken, suffered or omitted by it hereunder in good faith and in accordance with the opinion or the advice of such counsel.

(d) The Warrant Agent shall incur no liability or responsibility to the Company or to any holder of any Warrant for any action taken in reliance on any notice, resolution, waiver, consent, order, certificate or other instrument believed by it to be genuine and to have been signed, sent or presented by the proper party or parties.

(e) The Company agrees to pay to the Warrant Agent reasonable compensation for all services rendered by the Warrant Agent in the execution of this Agreement, to reimburse the Warrant Agent for all expenses, taxes and governmental charges and other charges incurred by the Warrant Agent in the execution of this Agreement and to indemnify the Warrant Agent and save it harmless against any and all liabilities, including judgments, costs and reasonable counsel fees, for anything done or omitted by the Warrant Agent in the execution of this Agreement except as a result of the Warrant Agent's negligence, willful misconduct or bad faith.

(f) The Warrant Agent shall be under no obligation to institute any action, suit or legal proceeding or to take any other action likely to involve expenses unless the Company or one or more registered holders of Warrants shall furnish the Warrant Agent with reasonable security and indemnity for any costs and expenses which may be incurred, but this provision shall not affect the power of the Warrant Agent to take such action as the Warrant Agent may consider proper, whether with or without any such security or indemnity. All rights

of action under this Agreement or under any of the Warrants may be enforced by the Warrant Agent without the possession of any of the Warrants or the production thereof at any trial or other proceeding, and any such action, suit or proceeding instituted by the Warrant Agent shall be brought in its name as Warrant Agent, and any recovery of judgment shall be for the ratable benefit of the registered holders of the Warrants, as their respective rights and interests may appear.

(g) The Warrant Agent and any stockholder, director, officer, partner or employee of the Warrant Agent may buy, sell or deal in any of the Warrants or other securities of the Company or become pecuniarily interested in any transaction in which the Company may be interested, or contract with or lend money to or otherwise act as fully and freely as though it were not the Warrant Agent under this Agreement. Nothing herein shall preclude the Warrant Agent from acting in any other capacity for the Company or for any other legal entity.

(h) The Warrant Agent shall act hereunder solely as agent and its duties shall be determined solely by the provisions hereof.

(i) The Warrant Agent may execute and exercise any of the rights or powers hereby vested in it or perform any duty hereunder either itself or by or through its attorneys, agents or employees, and the Warrant Agent shall not be answerable or accountable for any such attorneys, agents or employees or for any loss to the Company resulting from such neglect or misconduct, provided reasonable care had been exercised in the selection and continued employment thereof.

(j) Any request, direction, election, order or demand of the Company shall be sufficiently evidenced by an instrument signed in the name of the Company by its Chief Executive Officer, President or a Vice President or its Secretary or an Assistant

Secretary or its Treasurer or an Assistant Treasurer (unless other evidence in respect thereof be herein specifically prescribed); and any resolution of the Board of Directors may be evidenced to the Warrant Agent by a copy thereof certified by the Secretary or an Assistant Secretary of the Company.

Section 16. Change of Warrant Agent. The Warrant Agent may resign and be discharged from its duties under this Agreement by giving to the Company notice in writing, and to the holders of the Warrants notice by mailing such notice to the holders at their addresses appearing on the Warrant register, of such resignation, specifying a date when such resignation shall take effect. The Warrant Agent may be removed by like notice to the Warrant Agent from the Company and the like mailing of notice to the holders of the Warrants. If the Warrant Agent shall resign or be removed or shall otherwise become incapable of acting, the Company shall appoint a successor to the Warrant Agent. If the Company shall fail to make such appointment within a period of thirty (30) days after such removal or after it has been notified in writing of such resignation or incapacity by the resigning or incapacitated Warrant Agent or after the Company has received such notice from a registered holder of a Warrant (who shall, with such notice, submit his Warrant for inspection by the Company), then the registered holder of any Warrant may apply to any court of competent jurisdiction for the appointment of a successor to the Warrant Agent. Any successor Warrant Agent, whether appointed by the Company or by such a court, shall be a bank or trust company, in good standing, incorporated under New York or federal law. After appointment, the successor Warrant Agent shall be vested with the same powers, rights, duties and responsibilities as if it had been originally named as Warrant Agent without further act or deed and the former Warrant Agent shall deliver and transfer to the successor Warrant Agent all cancelled Warrants, records and property at the time held by it

hereunder, and execute and deliver any further assurance or conveyance necessary for the purpose. Failure to file or mail any notice provided for in this Section, however, or any defect therein, shall not affect the validity of the resignation or removal of the Warrant Agent or the appointment of the successor Warrant Agent, as the case may be.

Section 17. Identity of Transfer Agent. Forthwith upon the appointment of any transfer agent for the shares of Common Stock or of any subsequent transfer agent for the shares of Common Stock or other shares of the Company's Common Stock issuable upon the exercise of the rights of purchase represented by the Warrants, the Company will file with the Warrant Agent a statement setting forth the name and address of such transfer agent.

Section 18. Notices. Any notice pursuant to this Agreement to be given by the Warrant Agent, by the Underwriter or by the registered holder of any Warrant to the Company, shall be sufficiently given if sent by first-class mail, postage prepaid, addressed (until another is filed in writing by the Company with the Warrant Agent) as follows:

Delcath Systems, Inc.  
51100 Summer Street  
Stamford, Connecticut 06905

Attention: M.S. Koly  
Chief Executive Officer

and a copy thereof to:

Morse, Zelnick, Rose & Lander LLP  
450 Park Avenue  
New York, New York 10022

Attention: Stephen A. Zelnick, Esq.

Any notice pursuant to this Agreement to be given by the Company, by the Underwriter or by the registered holder of any Warrant to the Warrant Agent shall be sufficiently

given if sent by first-class mail, postage prepaid, addressed (until another address is filed in writing by the Warrant Agent with the Company) as follows:

American Stock Transfer & Trust Company  
40 Wall Street  
New York, New York 10005

Attention: Michael Karfunkel

Any notice pursuant to this Agreement to be given by the Warrant Agent or by the Company to the Underwriter shall be sufficiently given if sent by first-class mail, postage prepaid, addressed (until another address is filed in writing with the Warrant agent) as follows:

Whale Securities Co., L.P.  
650 Fifth Avenue  
New York, New York 10019  
Attention: William G. Walters

and a copy thereof to:

Blank Rome Tenzer Greenblatt LLP  
405 Lexington Avenue  
New York, New York 10174  
Attention: Robert J. Mittman, Esq.

Section 19. Supplements and Amendments. The Company and the Warrant Agent may from time to time supplement or amend this Agreement in order to cure any ambiguity or to correct or supplement any provision contained herein which may be defective or inconsistent with any other provision herein, or to make any other provisions in regard to matters or questions arising hereunder which the Company and the Warrant Agent may deem necessary or desirable and which shall not be inconsistent with the provisions of the Warrants and which shall not adversely affect the interest of the holders of Warrants.

Section 20. New York Contract. This Agreement and each Warrant issued hereunder shall be deemed to be a contract made under the laws of the State of New York and

shall be construed in accordance with the laws of New York applicable to agreements to be performed wholly within New York.

Section 21. Benefits of this Agreement. Nothing in this Agreement shall be construed to give to any person or corporation other than the Company, the Warrant Agent and the registered holders of the Warrants any legal or equitable right, remedy or claim under this Agreement; but this Agreement shall be for the sole and exclusive benefit of the Company, the Warrant Agent and the registered holders of the Warrants.

Section 22. Successors. All the covenants and provisions of this Agreement by or for the benefit of the Company, the Warrant Agent or the Underwriter shall bind and inure to the benefit of their respective successors and assigns hereunder.

IN WITNESS WHEREOF, the parties have entered into this Agreement on the date first above written.

DELCATH SYSTEMS, INC.

By:

-----  
Name:  
Title:

AMERICAN STOCK TRANSFER & TRUST COMPANY

By:

-----  
Name:  
Title:

WHALE SECURITIES CO., L.P.

By: Whale Securities Corp.,  
General Partner

By:

-----  
Name:  
Title:

Morse, Zelnick, Rose & Lander, LLP  
450 Park Avenue - Room 902  
New York, NY 10022  
Tel: (212) 838-1177  
Fax: (212) 838-9190

(212) 838-1177

October 12, 2000

Delcath Systems, Inc.  
1100 Summer Street  
Stamford, CT 06905

Dear Sirs:

We have acted as counsel to Delcath Systems, Inc., a Delaware corporation (the "Company") in connection with the preparation of a registration statement on Form SB-2, (the "Registration Statement") filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Act"), to register the offering by (a) the Company of (i) 1,200,000 Units, each Unit consisting of one share of Common Stock and one Warrant to purchase a share of Common Stock (the "Warrants") (and the offering of an additional 180,000 Units if the over-allotment option is exercised); (ii) 1,200,000 shares of Common Stock included in the Units (and an additional 180,000 shares if the over-allotment Option is exercised), (iii) 1,200,000 Warrants included in the Units (and an additional 180,000 Warrants if the over-allotment option is exercised), (iv) 1,800,000 shares of Common Stock issuable upon exercise of the Warrants included in the Units (and an additional 180,000 shares if the over-allotment option is exercised), (v) an option (the "Underwriter's Option) to purchase 180,000 Units, (vi) 120,000 Units issuable on exercise of the Underwriter's Option, (vii) 120,000 shares of Common Stock included in the Units underlying the Underwriter's Option, (viii) 120,000 warrants included in Units underlying Underwriter's Option, (ix) 120,000 shares of Common Stock issuable upon exercise of the Warrants included in the Units underlying the Underwriter's Option, and any and all amendments to the Registration Statement, and any Registration Statements for any additional Units, shares of Common Stock, Warrants, Common Stock underlying the Units, Warrants underlying the Units, Common Stock underlying the Warrants, Underwriter's Option, Units underlying the Underwriter's Option, Common Stock underlying such Units, Warrants underlying such Units and Common Stock underlying such Warrants, pursuant to Rule 462(b) of the Act.

In this regard, we have reviewed the Certificate of Incorporation of the Company, as amended, resolutions adopted by the Company's Board of Directors, the Registration Statement, the proposed form of the Warrants and the Underwriter's Option, the other exhibits to the Registration Statement and such other records, documents, statutes and decisions as we have deemed relevant in rendering this opinion. Based upon the foregoing, we are of the opinion that:

Each Unit, each share of Common Stock included in the Units being offered, each Warrant included in the Units being offered, each share of Common Stock underlying such Warrants, (and as for any over-allotment option each Unit issued upon the exercise of such option, share of Common Stock included in such Units, each Warrant included in the Units being offered, and each share of Common Stock underlying such Warrants) the Underwriter's Option, the Units issuable upon exercise of the Underwriter's option, the Common Stock underlying those Units, the Warrants underlying those Units, and the Common Stock underlying those Warrants being offered pursuant to the Registration Statement and all amendments thereto and any Registration Statements pursuant to Rule 462(b) of the Act for additional Units, shares of Common Stock underlying such Units, Warrants underlying such Units, shares of Common Stock underlying such Warrants, the Underwriter's Option, the Units issuable upon the exercise of such option, the Common Stock underlying those Units, the Warrants underlying those Units, and the Common Stock underlying those Warrants have been duly and validly authorized for issuance and when issued as contemplated by the Registration Statement or upon exercise of the Warrants or the Underwriter's Option, will be legally issued, fully paid and non-assessable.

We hereby consent to the use of this opinion as Exhibit 5.1 to the Registration Statement and any and all amendments thereto, and any Registration Statements pursuant to Rule 462(b) of the Act for any additional Units, shares of Common Stock, Warrants, shares of Common Stock underlying the Warrants and Underwriter's Option (including the Units issuable upon the exercise of the Underwriter's Option, the Common Stock underlying these Units, the Warrants underlying these Units and the shares of Common Stock underlying these Warrants. In giving such opinion, we do not thereby admit that we are acting within the category of persons whose consent is required under Section 7 of the Act or the rules or regulations of the Securities and Exchange Commission thereunder. Members of this firm or their affiliates own an aggregate of 85,060 shares of Common Stock of the Company.

Very truly yours,

MORSE, ZELNICK, ROSE & LANDER, LLP



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  
October 12, 2000