

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

DELCATH SYSTEMS INC  
Form SB-2/A  
May 02, 2003

As filed with the Securities and Exchange Commission on May 2, 2003.

Registration No. 333-101661

-----  
UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
-----

Amendment No. 3  
to

Form SB-2  
Registration Statement  
under  
the Securities Act of 1933

DELCATH SYSTEMS, INC.  
-----

(Exact name of Registrant as specified in its charter)

Delaware

3841

06-1245881  
-----

(State or Other Jurisdiction  
of Incorporation or  
Organization)

(Primary Standard Industrial  
Classification Code Number)

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

1100 Summer Street  
Stamford, Connecticut 06905  
(203) 323-8668

(Address, including zip code, and telephone number, including area code,  
of registrant's executive offices)  
-----

M. S. KOLY  
President and 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 of all communications, including communications sent to the agent for  
service of process, should be sent to:

Paul G. Hughes, Esq.  
Cummings & Lockwood LLC  
Four Stamford Plaza  
107 Elm Street  
Stamford, CT 06902

Brian C. Daughney, Esq.  
Goldstein & DiGioia, LLP  
45 Broadway, 11th Floor  
New York, NY 10006  
212-599-3322

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

203-351-4207

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, 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 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. / /

Title of each class of securities to be registered	Proposed maximum aggregate offering price (1)	Am registered
Units, consisting of 5 shares of common stock, par value \$0.01 per share, and 5 warrants each to purchase 1 share of common stock (2) Common Stock, \$0.01 par value (3) Warrants to purchase shares of common stock (4) Shares of common stock underlying the warrants included in the units (5) (6) Underwriters warrants to purchase units (7) Units, consisting of 5 shares of common stock and 5 warrants each to purchase 1 share of common stock (5) Common stock, \$0.01 par value (3) Warrants to purchase shares of common stock (4) Units issuable upon exercise of the underwriters warrants (7) Shares of common stock underlying the warrants issuable upon exercise of the warrants underlying the underwriters warrants (5)	\$2,415,000	\$3

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

- 
- (1) Estimated solely for purposes of determining the registration fee pursuant to Rule 457 under the Securities Act. (2) Includes units issuable upon exercise of underwriters' over-allotment option. (3) Consists of shares of common stock included in the units registered hereby.
  - (4) Consists of warrants included in the units registered hereby. The warrants are offered as a component of the units for no additional consideration.
  - (5) Pursuant to Rule 416 under the Securities Act, this Registration Statement also registers (i) any additional shares of common stock that become issuable upon exercise of the warrants and (ii) any additional units that become issuable upon the exercise of the underwriters warrants to purchase units, in each by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without receipt of consideration which results in an increase in the number of the outstanding shares of common stock.
  - (6) Includes shares issuable pursuant to the exercise of the underwriters overallotment option. (7) No registration fee required pursuant to Rule 457(g) under the Securities Act. (8) The registration fee was previously paid when the Registration Statement was originally filed.

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 OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

CROSS REFERENCE SHEET

Showing Location in Prospectus of Information Required by Items of Form SB-2

REGISTRATION STATEMENT ITEM NUMBER AND HEADING	LOCATION IN PROS
1. Forepart of Registration Statement and Outside Front Cover Page of Prospectus	Outside Front Cover Page
2. Inside Front and Outside Back Cover Pages of Prospectus	Inside Front and Outside Prospectus
3. Summary Information and Risk Factors	Prospectus Summary; Risk
4. Use of Proceeds	Use of Proceeds
5. Determination of Offering Price	Underwriting
6. Dilution	Not Applicable
7. Selling Security Holders	Not Applicable
8. Plan of Distribution	Outside Front Cover Page Underwriting
9. Legal Proceedings	Business
10. Directors, Executive Officers, Promoters and Control Persons	Management
11. Security Ownership of Certain Beneficial Owners and Management	Principal Stockholders

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

12. Description of Securities	Description of Our Capital Securities
13. Interests of Named Experts and Counsel	Validity of Common Stock
14. Disclosure of Commission Position of Indemnification for Securities Act Liabilities	Not Applicable
15. Organization Within Last Five Years	Not Applicable
16. Description of Business	Business
17. Management's Discussion and Analysis or Plan of Operation	Plan of Operation
18. Description of Property	Business
19. Certain Relationships and Related Transactions	Related Party Transactions
20. Market for Common Equity and Related Stockholder Matters	Market for Common Equity Stockholder Matters
21. Executive Compensation	Management
22. Financial Statements	Index to Consolidated Financial Statement Schedule
23. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure	Changes In and Disagreements with Accountants on Accounting and Financial Disclosure

SUBJECT TO COMPLETION, DATED MAY 2, 2003.

[LOGO - DELCATH SYSTEMS, INC.]

\_\_\_\_\_ Units

This is a public offering of \$2.1 million of our securities. Our securities are being offered in units, with each unit consisting of (i) five shares of our common stock and (ii) five 2003 Warrants each to purchase one share of our common stock. The common stock and 2003 Warrants will trade separately immediately following the sale of the units.

Each 2003 Warrant entitles the holder to purchase one share of our common stock at a price of 25% of the unit offering price. The exercise price of our 2003 Redeemable Common Stock Purchase Warrants is subject to adjustment, including anti-dilution provisions for corporate events, such as stock splits. Under certain circumstances, we have the right to redeem the 2003 Warrants.

There is presently no public market for the 2003 Warrants. Our common stock is currently traded on the Nasdaq Small Cap Market under the symbol "DCTH" and on the Boston Stock Exchange under the symbol "DCT." At May 1, 2003, our common stock had a closing price of \$1.05 per share and our 2000 Warrants had a closing price of \$0.30 per Warrant on the Nasdaq Small Cap Market. The actual initial public offering price of the units will be based upon the market price of our common stock and by negotiations between Roan/Meyers Associates, L.P., as the representative of the underwriters, and us.

We have applied for listing of our 2003 Warrants on the Nasdaq Small Cap Market and the Boston Stock Exchange under the symbols "DCTHZ" and "DCT&W," respectively, and the listing of the additional shares of our common stock contained in the units. If our application for listing is not approved by the Nasdaq Small Cap Market or the Boston Stock Exchange, the underwriters may not proceed with the offering. We were notified by Nasdaq that, based on our stockholders' equity at September 30, 2002, we no longer meet one criterion for continued listing on the Nasdaq Small Cap Market. Based on the estimated net proceeds of the offering, we expect to meet this criterion immediately following

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

this offering. However, if we do not raise additional capital, we will likely fall below the minimum stockholder equity requirement during 2003.

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 4 for factors you should consider before investing in our securities.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

	Per Unit	Total
	-----	-----
Public offering price		
Underwriting discount		
Proceeds, before expenses		

We estimate the expenses of this offering will be approximately \$619,500, which will include a non-accountable expense allowance of 3% of the gross proceeds of this offering payable to the representative of the underwriters. We have granted the underwriters a 45-day option to acquire up to an additional 15% of the units to cover over-allotments.

The underwriters expect to deliver the securities to purchasers on or about May \_\_, 2003.

ROAN/MEYERS ASSOCIATES, L.P.

VIEWTRADE SECURITIES, INC.

The date of this prospectus is May \_\_, 2003

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

FOR CALIFORNIA INVESTORS

This offering was approved in California on the basis of a limited offering qualification. Investors who are residents of California must meet a "super suitability" standard of not less than \$250,000 liquid net worth (exclusive of home, home furnishings and automobiles), plus \$65,000 gross annual income or \$500,000 liquid net worth or \$1,000,000 net worth (inclusive of home, home furnishings and automobiles) or \$200,000 gross annual income. We did not have to demonstrate compliance with some or all of the merit regulations of the California Department of Corporations, as found in Title 10, California Code of Regulations, Rule 260.140 et seq.

Residents of the State of California will be unable to sell shares of

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

common stock and 2003 Warrants they purchase in this offering, and investors residing in all other states will be unable to sell shares of common stock and 2003 Warrants they purchase in this offering to California residents, pursuant to exemptions for secondary trading available under California Corporations Code Section 25104(h), as such exemptions have been withheld. However, secondary sales may be made to purchasers who meet the "super suitability" standards or there may be other exemptions to cover private sales by the bona fide owners of our securities for such owners' own account without advertising and without being effected by or through a broker dealer in a public offering.

### PROSPECTUS SUMMARY

The following is a summary that highlights information contained elsewhere in this prospectus. You should read the entire prospectus, including "Risk Factors" beginning on page 4 and our financial statements (including the notes) carefully before making an investment decision.

Except as otherwise noted, the information contained in this prospectus assumes that the underwriters' overallotment option is not exercised.

References in this prospectus to the "2003 Warrants" refer to the warrants included in the units offered hereby. References in this prospectus to the "2000 Warrants" refer to the warrants included in the units offered in our initial public offering.

### OUR BUSINESS

We have developed a drug-delivery system which is designed 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 filtering the blood before it is returned to the patient's circulatory system helps protect other parts of the body from the harmful side effects of chemotherapy agents while allowing higher dosages of chemotherapy agents to be administered to the diseased organ. While the current "gold standard" treatment option for liver tumors is surgery, many tumors are inoperable due to a combination of poor patient health and/or inability to remove the tumor because of its location. Even if a tumor is surgically removed, in the event of a recurrence, surgery typically cannot be repeated. We believe that the use of the Delcath system for delivering chemotherapy agents to the liver will allow treatment of tumors in patients with poor health and inoperable tumors and will permit multiple treatments in the event of a recurrence. We also 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 agents.

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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 premarket 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 malignant melanoma that spreads to the liver and to fund our Phase I clinical trials and commence Phase II clinical trials to demonstrate the safety and efficiency of using the Delcath system to deliver the chemotherapy agent melphalan to treat cancerous tumors in the liver.

### Corporate Information

Our executive offices are located at 1100 Summer Street, Stamford, Connecticut 06905. Our telephone number at this location is (203) 323-8668.

1

### THE OFFERING

Securities offered	units, each unit consist of five shares of common stock and five 2003 Warrants each to purchase one share of our common stock.
Common stock to be outstanding after this offering	shares.
Warrants and options to be outstanding after this offering	Warrants (including 2000 Warrants and the 2003 Warrants) options to purchase 1,145,684 shares of our common stock.
Term of the 2003 Warrants	Five years from the closing of this offering.
Exercise price of the 2003 Warrants	\$
Expiration date of the 2003 Warrants	, 2008.
Redemption	Commencing one year from the closing date of this offering, our 2003 Warrants may be redeemed at our option at a redemption price of \$0.01 per warrant provided (i) the average closing price of our common stock for the two trading days prior to the date of notice of redemption is at least \$ price and (ii) there is then an effective registration statement providing for issuance of the underlying shares of common stock.

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Nasdaq Small Cap Market symbols

"DCTH" for our common stock and "DCTH" for our 2003 Warrants.

Boston Stock Exchange symbols

"DCT" for our common stock and "DCT&W" for our 2003 Warrants.

2

### SUMMARY FINANCIAL DATA

The following summary financial data for the two years ended December 31, 2002 and cumulative from inception through December 31, 2002 are derived from our audited financial statements.

The data should be read in conjunction with the financial statements, related notes and other financial information, "Capitalization" and "Plan of Operation" appearing elsewhere in this prospectus.

	Years Ended December 31,		Cumulative from Inception (August 5, 1988) to December 31,
	2001	2002	2002
	----	----	----
	(in thousands)		
Statement of Operations Data:			
Total costs and expenses .....	\$ 2,069	\$ 1,897	\$16,714
Operating loss .....	(2,069)	(1,897)	(16,714)
Net loss attributable to common stockholders .....	(1,876)	(1,807)	
Net loss per share .....		(0.48)	(0.44)
Weighted average number of shares of common stock outstanding .....	3,904	4,085	

As of December 31, 2002

	Actual	As Adjusted(1)
	-----	-----
	(in thousands)	
Balance Sheet Data:		
Cash and cash equivalents .....	\$1,064	\$2,678
Certificate of deposit .....	370	370
Total assets .....	1,812	3,188
Total liabilities .....	175	85
Stockholders' equity .....	1,637	3,103

(1) The as adjusted amounts assume net proceeds of \$1,480,500 (excluding proceeds from any exercise of the overallotment option) from the sale of the



units offered hereby.

3

#### RISK FACTORS

You should consider carefully the following factors, as well as the other information set forth in this prospectus, prior to making an investment in the units. If any of the following risks and uncertainties actually occur, our business, financial condition or operating results may be materially and adversely affected. In this event, the trading price of our common stock or the 2003 Warrants, as applicable, may decline and you may lose part or all of your investment.

#### RISKS RELATED TO OUR BUSINESS AND FINANCIAL CONDITION

The following factors relate to risks that are material to our business and financial condition. If any of the possible events we describe below turns out to be the case, our business may be adversely affected and we may be forced to cease or curtail our operations which may result in the loss of your entire investment.

Our entire focus has been the development and commercialization of the Delcath system.

The Delcath system, an enabling technology for the isolation of various organs in the body to permit the delivery of otherwise unacceptably toxic doses of drugs, is our only product. If the Delcath system fails as a commercial product, we have no other products to sell.

Continuing losses may exhaust our capital resources. We have no revenue to date, substantial accumulated deficit, recurring operating losses and negative cash flow.

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 December 31, 2002, we have incurred cumulative losses of \$16 million which were principally incurred in connection with our product development efforts. For the years ended December 31, 2001 and December 31, 2002, we incurred net losses of \$1.9 million and \$1.8 million, respectively.

We have funded our operations through a combination of private placements of our securities and through the proceeds of our initial public offering which public offering was completed in October, 2000. The net proceeds of our initial public offering were approximately \$5.4 million. In our most recent placement, completed in April 2002, we received proceeds of approximately \$267,000 through the sale of 243,181 shares and warrants to purchase 20,265 shares. Please see a detailed discussion of our various sales of securities described in Note 2 to our financial statements.

If we continue to incur losses we may exhaust our capital resources, including those raised in this offering. As of December 31, 2002, we had cash and cash equivalents and short term investments of \$1.43 million.

The proceeds of this offering may not be sufficient to complete our planned clinical trials and our efforts to raise additional financing

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

may be unsuccessful.

The proceeds of this offering may not 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 use of doxorubicin with the Delcath system. Our ability to complete the Phase III clinical trials could be lessened to the extent we devote assets to clinical trials using melphalan with the Delcath system.

If we do not raise any additional capital required to commercialize the Delcath system, our potential to generate future revenues will be significantly limited even if we receive FDA pre-marketing approval.

The proceeds of this offering may not be sufficient to complete Phase III clinical trials using doxorubicin and will be insufficient to fund the costs of commercializing the Delcath system which will be significant. 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 commercially.

4

### RISKS RELATED TO FDA AND FOREIGN REGULATORY APPROVAL

The following factors relate to risks that are material to obtaining FDA and foreign regulatory approval. If any of the events we describe below turns out to be the case, our business may be adversely affected and we may be forced to cease or curtail our operations which may result in the loss of your entire investment.

If the FDA refuses to grant premarket approval or limits the circumstances under which the Delcath system may be used, our ability to market the Delcath system will be greatly reduced.

Premarket 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 before it will approve our application for premarket approval. Even if regulatory approval is granted, the approval may limit the uses for which the Delcath system may be marketed. If we fail to obtain FDA premarket approval, we will not be able to market the Delcath system. Additionally, if we obtain FDA premarket approval with substantial limitations on uses of the Delcath system, this would greatly reduce the market for the system.

If we do not obtain FDA premarket 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 application for premarket approval application for the Delcath system, we will not be able to export the Delcath system from the United States for marketing abroad unless approval has been

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

obtained from one of a number of developed nations. We have not begun to seek foreign regulatory approval and may not be able to obtain approval from one or more countries where we would like to sell the Delcath system. If we are unable to market the Delcath system internationally because we are not able to obtain required approvals, our international market opportunity will be materially limited.

Because of our limited experience, conduct of Phase III clinical trials and obtaining FDA premarket approval could be delayed.

We have experienced and may continue to experience delays in beginning, conducting and completing the trials, caused by many factors, including our lack of experience in arranging for clinical trials and in evaluating and submitting the data gathered from clinical trials, in designing trials to conform to the trial protocols authorized by the FDA, in complying with the requirements of institutional review boards at the sites where the trials will be conducted and in identifying clinical test sites and sponsoring physicians. Completion of our clinical trials will also depend on the ability of the clinical test sites to identify patients to enroll in the clinical 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. Any significant delay in completing clinical trials or in the FDA's responding to our submission or a requirement by the FDA for us to conduct additional trials would delay the commercialization of the Delcath system and our ability to generate revenues.

Third-party reimbursement may not be available to purchasers of the Delcath system or may be inadequate.

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, Medicare, Medicaid and private health insurance plans will not reimburse its use in the United States. We will not begin to seek to have third-party payors reimburse the cost of the Delcath system until after its use is approved by the FDA. Each third-party payor independently determines whether and to what extent it will reimburse for a medical procedure or product. Third-party payors in the United States or abroad may decide not to 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.

New products are under increased scrutiny as to whether or not they will be covered by the various healthcare plans and the level of reimbursement which will be applicable to respective covered products and procedures. A third-

party payor may deny reimbursement for the treatment and medical costs associated with the Delcath system, notwithstanding FDA or other regulatory approval, if that payor determines that the Delcath system is unnecessary, inappropriate, not cost effective, experimental or is used for a non-approved indication.

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

### RISKS RELATED TO MANUFACTURING, COMMERCIALIZATION AND MARKET ACCEPTANCE OF THE DELCATH SYSTEM

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

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 and with drug and device good manufacturing practice requirements. Many of the components of the Delcath system are manufactured by sole source suppliers. If any of our suppliers fails to meet our needs, or if we need to seek an alternate source of supply, we may be forced to suspend or terminate our clinical 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 could jeopardize our ability to supply the Delcath system to the market.

We do not have any contracts with suppliers for the manufacture of components for the Delcath system. If we are unable to obtain an adequate supply of the necessary components, we may not be able timely to complete our clinical trials.

We do not have any contracts with suppliers for the manufacture of components for the Delcath system. Certain components are available from only a limited number of sources. 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 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, commercialization of the Delcath system could be delayed.

Because of our limited experience in marketing products and our lack of adequate personnel to market and sell products, we may not be successful in marketing and selling the Delcath system even if we receive FDA premarket approval.

We have not previously sold, marketed or distributed any products and currently do not have the personnel, resources, experience or other capabilities to market the Delcath system adequately. 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 may not be successful in attracting or retaining such personnel. Our inability to attract and retain skilled sales and marketing personnel could adversely affect our business, financial condition and results of operations.

Market acceptance of the Delcath system will depend on substantial efforts and expenditures in an area with which we have limited experience.

Market acceptance of the Delcath system will depend upon a variety of factors including whether our clinical trials demonstrate a significant reduction in the mortality rate for the kinds of cancers treated on a cost-effective basis, our ability to educate physicians on the use of the Delcath system and our ability to convince healthcare payors that use of the

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Delcath system results in reduced treatment costs to patients. We only have limited experience in these areas and we may not 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, hospitals, patients and healthcare payors.

Rapid technological developments in treatment methods for liver cancer and competition with other forms of liver cancer treatments could result in a short product life cycle for the Delcath system.

Competition in the cancer treatment industry, particularly in the markets for systems and devices to improve the outcome of chemotherapy treatment, is intense. The Delcath system competes with all forms of liver cancer treatments that are alternatives to the "gold standard" treatment of surgical resection. Many of our competitors have substantially

6

greater resources, especially financial and technological. In addition, some of our competitors have considerable experience in conducting clinical trials and other regulatory procedures. These competitors are developing systems and devices to improve the outcome of chemotherapy treatment for liver cancer. If these competitors develop more effective or more affordable products or treatment methods, our profitability will be substantially reduced and the Delcath system could have a short product life cycle.

### RISKS RELATED TO 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 medical devices to the market, the healthcare industry has traditionally placed considerable emphasis on patent and trade secret protection for significant new technologies. 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 could be costly and could divert our attention from our business. If others file patent applications with respect to inventions for which we already have patents issued to us 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 could also be costly and could 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. Use of our limited funds to defend our intellectual property rights may also affect our financial condition adversely.

### RISKS RELATED TO PRODUCTS LIABILITY

We do not currently carry products liability insurance and we may not be able to acquire sufficient coverage in the future to cover large

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

claims.

Clinical trials, manufacturing 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 products 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 products liability insurance and we may not be able to acquire products liability insurance at sufficient coverage levels or at an acceptable cost. A successful products liability claim or recall would have a material adverse effect on our business, financial condition and results of operations.

### RISKS RELATED TO AN INVESTMENT IN OUR COMMON STOCK AND THIS OFFERING

The following factors relate to risks that are material to an investment in our common stock. Any of these factors could result in lowering the market value of our common stock and our 2003 Warrants.

There is a limited public float of our common stock and, at this time, no public market for our 2003 Warrants. Because of this, trades of relatively small amounts of our common stock can have a disproportionate effect on the market price for our common stock. The market price of our common stock may be volatile.

Of our outstanding common stock, approximately two-thirds can be considered to be in the public float. The term "public float" refers to shares freely and actively tradeable on the Nasdaq Small Cap Market and/or the Boston Stock Exchange and not owned by officers, directors or affiliates, as such term is defined under the Securities Act. Because of the relatively small public float and the limited trading volume of our common stock, purchases and sales of relatively small amounts of our common stock can have a disproportionate effect on the market price for our common stock. As a result, the market price of our common stock can be volatile.

The number of shares eligible for future sale may cause the market price of our common stock to be below the level it otherwise would.

The potential for sales of substantial amounts of our common stock, or "equity overhang," could adversely affect the market price of our common stock. Upon completion of this offering,                      shares of our common stock will be outstanding. Of these shares,                      shares sold in this offering or sold in our public offering in 2000 will be freely tradable without restriction or further registration under the Securities Act, except for shares held or purchased by

7

persons considered to be our "affiliates" or acting as "underwriters," as those terms are defined under the Securities Act. The remaining 1,597,521 shares of our common stock outstanding and held by existing stockholders will be considered "restricted securities" under the Securities Act and eligible for sale in compliance with Rule 144. Rule 144 provides volume and manner of sale restrictions and holding periods, which expire after the holder of our common stock ceases to meet the definitions of affiliate or underwriter.

In addition, we may issue substantial amounts of common stock upon

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

exercise of the 2000 Warrants, the 2003 Warrants or options outstanding under our stock option plans.

Sales of substantial amounts of common stock following this offering, or the perception that such sales could occur, could have an adverse effect on prevailing market prices for our common stock and the 2003 Warrants.

Anti-takeover provisions in our certificate of incorporation and by-laws and under Delaware law and our stockholders rights agreement may reduce the likelihood of a potential change of control.

Provisions of our certificate of incorporation, by-laws and Delaware law may have the effect of discouraging, delaying or preventing a change in control of us or unsolicited acquisition proposals that a stockholder might consider favorable. These include provisions:

- o providing for a classified board and permitting the removal of a director only for cause;
- o authorizing the board of directors to fill vacant directorships or increase the size of our board of directors; and
- o subjecting us to the provisions of Section 203 of the Delaware General Corporate Law, which provides that a Delaware corporation may not engage in any of a broad range of business combinations with a person or entity who owns 15% or more of the outstanding voting stock of a company for a period of three years from the date the person or entity became an interested stockholder unless (a) prior to such time our board of directors approved either the business combination or the transaction which resulted in the stockholder's becoming an interested stockholder or (b) upon consummation of the transaction which resulted in the stockholder's becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced or (c) at or subsequent to such time the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders by the affirmative vote of at least 66 2/3% of the outstanding voting stock not owned by the interested stockholder.

Furthermore, our board of directors has the authority to issue shares of preferred stock in one or more series and to fix the rights and preferences of the shares of any such series without stockholder approval. Any series of preferred stock is likely to be senior to the common stock with respect to dividends, liquidation rights and, possibly, voting rights. Our board's ability to issue preferred stock may have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock and the 2003 Warrants.

We also have a stockholders rights agreement which could have the effect of substantially increasing the cost of acquiring us unless our board of directors supports the transaction even if the holders of a majority of our common stock are in favor of the transaction.

Roan/Meyers Associates, L.P. has limited public offering experience which could affect the price of our common stock after this offering.

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

We have been advised by Roan/Meyers Associates, L.P., the representative of the underwriters, that it has not acted as lead underwriter in any firm commitment public offering in the last three years. This limited public offering experience could affect the subsequent development of a trading market of our common stock and the 2003 Warrants. You should consider this lack of public offering experience in deciding whether to buy our securities in this offering. To obtain detailed information regarding Roan/Meyers Associates, L.P. (or any underwriter), you should contact your state regulator or visit the website of the National Association of Securities Dealers, Inc. at "www.nasdr.com."

8

Our stockholders' equity is less than the amount prescribed for continued listing on the Nasdaq Small Cap Market. If we do not regain compliance with the continued listing standards, our stock may be delisted and we may not receive listing approval for the 2003 Warrants.

As of December 31, 2002, we no longer meet the minimum stockholders' equity requirement prescribed for continued listing on the Nasdaq Small Cap Market. In order to regain compliance, our stockholders' equity must be at least \$2.5 million. By letter, Nasdaq agreed to continue listing our common stock until March 28, 2003 notwithstanding that our stockholders' equity is below the minimum required. We have received no further formal extension.

In order to receive approval to list the 2003 Warrants on the Nasdaq Small Cap Market, we are required to be in compliance with the continued listing standards for the Nasdaq Small Cap Market with respect to our common stock. We are also required to maintain: (i) a minimum bid price of \$1.00 per share, (ii) a certain public float, (iii) a certain number of round lot shareholders and (iv) one of the following: a net income from continuing operations (in latest fiscal year or two of the three last fiscal years) of at least \$500,000, a market value of listed securities of at least \$35 million or a stockholders' equity of at least \$2.5 million. We currently are in compliance with the minimum bid price, public float and number of round lot holders requirements. Because we are a development stage company, we do not meet the net income requirement. We also do not meet the market value of listed securities requirement. In the event we are unable to obtain approval for listing on the Nasdaq Small Cap Market, we will likely have to apply for listing on the Nasdaq Over the Counter Bulletin Board or the Nasdaq Bulletin Board Exchange in order to maintain a public market for the trading of our common stock and the 2003 Warrants. In the event that the Nasdaq Small Cap Market does not allow the listing of the 2003 Warrants or determines to delist our common stock, the underwriters may not proceed with the offering.

Our exercise of our right to redeem the 2003 Warrants will prevent the holders from realizing any additional benefit from any increase in the price of our common stock.

Commencing one year from the closing date of this offering, we may redeem the 2003 Warrants at a redemption price of \$0.01 per warrant provided (i) the average closing price of our common stock for the twenty trading days prior to the date of notice of redemption is at least \$ \_\_\_\_\_ and (ii) there is an effective registration statement providing for the issuance of the underlying shares of common stock. Notice of our election to redeem the 2003 Warrants would force holders, in order to avoid accepting the redemption price of \$0.01 per warrant, either to exercise the warrants by paying the exercise price or sell



## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

the warrants in the market. A holder of the 2003 Warrants would be forced to choose between these two actions at a time when they might otherwise wish to continue to hold the 2003 Warrants.

A current prospectus and state blue sky registration may be required to exercise the 2003 Warrants.

A holder of the 2003 Warrants will be able to exercise the warrants only if the shares of our common stock issuable upon the exercise of the 2003 Warrants are registered for sale under the Securities Act of 1933 and a current prospectus is available for delivery. In addition, the shares of common stock issuable upon the exercise of the 2003 Warrants must, if required, be registered or otherwise qualified for sale under the securities laws of the state in which the holder of the 2003 Warrants resides.

The Nasdaq Small Cap Market may delist our securities.

Upon closing of this offering, we expect to meet the minimum stockholders' equity requirement to maintain listing on the Nasdaq Small Cap Market. However, it is likely that as of June 30, 2003, we may no longer meet the minimum stockholders' equity requirement. In that event and absent additional financing, we would expect that our common stock would likely be delisted from the Nasdaq Small Cap Market. As a result of such delisting, an investor could find it more difficult to dispose of, or to obtain accurate quotations as to the market value of, our securities.

If our common stock is delisted from the Nasdaq Small Cap Market, we may be subject to the risks relating to penny stocks.

If our common stock were to be delisted from trading on the Nasdaq Small Cap Market and the trading price of the common stock remains below \$5.00 per share on the date the common stock was delisted, trading in such securities would also be subject to the requirements of certain rules promulgated under the Exchange Act. These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a penny stock and

9

impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. The additional burdens imposed upon broker-dealers by such requirements may discourage broker-dealers from effecting transactions in our securities, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell our securities in the secondary market. A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than \$5.00 per share, subject to certain exceptions.

California investors may not be able to resell the securities.

This offering was approved in California on the basis of a limited offering qualification. Investors who are residents of California must meet a "super suitability" standard of not less than \$250,000 liquid net worth (exclusive of home, home furnishings and automobiles), plus \$65,000 gross annual income or \$500,000 liquid net worth or \$1,000,000 net worth (inclusive of home, home furnishings and automobiles) or \$200,000 gross annual income. We did not have to demonstrate compliance with some or all of the merit regulations of the

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

California Department of Corporations, as found in Title 10, California Code of Regulations, Rule 260.140 et seq.

Residents of the State of California will be unable to sell shares of common stock and 2003 Warrants they purchase in this offering, and investors residing in all other states will be unable to sell shares of common stock and 2003 Warrants they purchase in this offering to California residents, pursuant to exemptions for secondary trading available under California Corporations Code Section 25104(h), as such exemptions have been withheld. However, secondary sales may be made to purchasers who meet the "super suitability" standards or there may be other exemptions to cover private sales by the bona fide owners of our securities for such owners' own account without advertising and without being effected by or through a broker dealer in a public offering.

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this prospectus, including statements of our expectations, intentions, plans, objectives and beliefs, including those contained in or implied by our "Plan of Operation," are "forward-looking statements," within the meaning of Section 21E of the Securities Exchange Act of 1934, that are subject to certain events, risks and uncertainties that may be outside our control. These forward-looking statements may be identified by the use of words such as "expects," "anticipates," "intends," "plans" and similar expressions. They include statements of our future plans and objectives for our future operations and statements of future economic performance, information regarding our expected growth, our capital budget and future capital requirements, the availability of funds and our ability to meet future capital needs, the realization of our deferred tax assets and the assumptions described in this prospectus underlying such forward-looking statements. Actual results and developments could differ materially from those expressed in or implied by such statements due to a number of factors, including those described in the context of such forward-looking statements, our ability to achieve operating efficiencies, industry pricing and technology trends, evolving industry standards, domestic and international regulatory matters, general economic and business conditions, the strength and financial resources of our competitors, our ability to find and retain skilled personnel, the political and economic climate in which we conduct operations, the risks discussed in "Risk Factors" and other risk factors described from time to time in our other documents and reports filed with the Securities and Exchange Commission. We do not assume any responsibility to update any of our forward-looking statements regardless of whether factors change as a result of new information, future events or for any other reason.

### USE OF PROCEEDS

Our net proceeds from the sale of units being offered by this prospectus, after deducting the underwriting discount and estimated expenses of this offering, are estimated to be \$1,480,500.

We expect to use these net proceeds approximately as follows:

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Application of Net Proceeds -----	Approximate Dollar Amount -----	Approximate Percentage Net Proceeds -----
Research and development:		
Phase III clinical trials using the Delcath .... system with doxorubicin	\$ 964,000	65.1%
Phase I and Phase II clinical trials using the.. Delcath system with melphalan	189,000	12.8%

Application of Net Proceeds -----	Approximate Dollar Amount -----	Approximate Percentage Net Proceeds -----
Development of alternative filter for the Delcath.. system	119,000	8.0%
Working capital and general corporate purposes ....	208,500	14.1%
	-----	----
Total .....	\$1,480,500	100%
	=====	====

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;
- o fees and expenses of the clinical research organization and the statistical evaluation organization which we anticipate hiring to conduct the trials, collect and process the data and prepare and file a premarket approval application; and
- o the compensation and benefits of Delcath employees responsible for overseeing the completion of the clinical trials and filing a premarket approval application.

Phase I and Phase II clinical trials using the Delcath system with melphalan. These costs represent:

- o fees payable to the National Cancer Institute for the costs of treating patients, including the costs of the Delcath system;
- o fees and expenses of the clinical research organization and the statistical evaluation organization we anticipate hiring

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

to monitor the trials, collect and process the data and prepare and file the required FDA reports in order to receive approval to proceed with the next phase of the clinical trials; and

- o the compensation and benefits of Delcath employees responsible for overseeing the completion of each phase of the clinical trials and filing the required FDA report in order to receive approval to proceed with the next phase of the trials.

Development of alternative filter for use in the Delcath system. These costs represent:

- o the fees and expenses of a consultant to identify sources capable of supplying an activated carbon blood filter, including the design and production of a prototype filter; and
- o the fees of consultants to test the capability of the filter to cleanse the blood supply of most of the infused chemotherapy agent and to prepare reports of results to be submitted to the FDA to obtain approval to use the new filter with the Delcath system.

Working capital and general corporate purposes. These costs include general and administrative costs, including the salaries of our executive officers.

If the underwriters exercise the over-allotment option in full, we will realize additional net proceeds of \$274,050, which we expect we will use for working capital purposes.

11

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. If any of these factors change, we may find it necessary to reallocate a portion of the proceeds from one category to another 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 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 working capital requirements for at least eighteen to twenty-four 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. The proceeds of this offering may not be sufficient to fund our clinical trials with respect to the use of the Delcath system with doxorubicin to treat liver cancer. If we need additional financing, it may not be available or may be available only on terms that are not favorable to us.

We will invest proceeds not immediately required for the purposes

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

described above principally in United States government securities, short-term certificates of deposit, money market funds or other short-term interest-bearing investments.

### USE OF PROCEEDS OF INITIAL PUBLIC OFFERING

As noted above, the effective date of our registration statement relating to our initial public offering of our common stock was October 19, 2000. A total of 1,200,000 units were sold for \$6.00 per unit consisting of one share of common stock and one redeemable warrant to purchase one share of common stock for \$6.60 per share until October 18, 2005. The initial public offering resulted in gross proceeds of \$7.2 million, \$720,000 of which was paid as the underwriting discount. Cash expenses relating to the offering, including non-accountable expense reimbursement to the underwriters, totaled approximately \$1.45 million. Our net proceeds were approximately \$5.4 million. From the time of receipt through December 31, 2002, the net proceeds were applied toward:

Application of Net Proceeds	Approximate
	(in thousand)
Research and development:	
Phase III clinical trials using the Delcath system with doxorubicin .....	\$2,009
Phase I clinical trials using the Delcath system with melphalan .....	901
Research and development stage clinical trials for other chemotherapy agents	87
Repayment of indebtedness .....	270
Working capital and general corporate purposes .....	671
	-----
Total .....	\$3,938
	=====

### MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Units consisting of our common stock and our 2000 Warrants traded on the Nasdaq Small Cap Market under the symbol "DCTHU" from October 9, 2000, the effective date of the registration statement under the Securities Act relating to our initial public offering of our common stock, until October 19, 2001. In accordance with the terms of our initial public offering, effective October 22, 2001, our common stock and our 2000 Warrants were decoupled from the units issued October 19, 2000 and commenced separate trading. The shares of common stock currently trade under the symbol "DCTH" and the 2000 Warrants currently trade under the symbol "DCTHW." We do not currently meet the minimum stockholders' equity requirement for continued listing on the Nasdaq Small Cap Market and, as of the date hereof, our common stock could be delisted. The following table sets forth the per share range of high and low sales prices of the units and the common stock for the periods indicated as reported on the Nasdaq Small Cap Market:

#### Unit Price Range

-----

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

	2001 ----	
	High ----	Low ---
Quarter ended March 31, 2001	\$5.69	\$2.19
Quarter ended June 30, 2001	3.20	1.25

12

	High ----	Low ---
Quarter ended September 30, 2001	2.92	1.26
October 1, 2001 - October 19, 2001	1.35	1.00

Common Stock Price Range  
-----

	2001 ----	
	High ----	Low ---
Quarter ended December 31, 2001 (since October 19 only)	\$1.795	\$0.56

	2002 ----	
	High ----	Low ---
Quarter ended March 31, 2002	\$2.90	\$0.94
Quarter ended June 30, 2002	1.90	0.68
Quarter ended September 30, 2002	1.11	0.63
Quarter ended December 31, 2002	2.66	0.31

	2003 ----	
	High ----	Low ---
Quarter ended March 31, 2003	\$1.79	\$0.94
Quarter ending June 30, 2003 (through April 30, 2003)	\$1.29	\$0.95

Our common stock and our 2000 Warrants are also listed on the Boston Stock Exchange under the symbols "DCT" and "DCT/U," respectively.

As of April 14, 2003, there were approximately 82 stockholders of record of our common stock and approximately 696 additional beneficial owners of

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

our common stock.

### DIVIDEND POLICY

We have never paid cash dividends on our common stock and anticipate that we will continue to retain our earnings, if any, to finance the growth of our business. Our board of directors has the sole discretion in determining whether to declare and pay dividends in the future. Whether we pay cash dividends on our common stock 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 December 31, 2002 and as adjusted for the effect of this offering including the application of the net proceeds.

	December 31, 2002	
	Actual	As Adjusted
	(in thousands)	
Common Stock .....	\$ 41	\$ 62
Additional paid-in capital .....	19,049	20,495

13

	December 31, 2002	
	Actual	As Adjusted
	(in thousands)	
Accumulated deficit .....	(17,453)	(17,453)
Total stockholders' equity ....	1,637	3,103
Total capitalization .....	\$ 1,637	\$ 3,103

### SELECTED FINANCIAL DATA

The following selected financial data for the two years ended December 31, 2002 and cumulative from inception through December 31, 2002 are derived from our audited financial statements.

The data should be read in conjunction with the consolidated financial statements, related notes and other financial information, "Capitalization" and "Plan of Operation" appearing elsewhere in this prospectus.

Cumulative from

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Years Ended		Inception (August 5,
December 31,		1988)
2001	2002	to December 31,
----	----	2002
----	----	----

(in thousands)

Statement of Operations Data:

Total costs and expenses .....	\$ 2,069	\$ 1,897	\$ 16,714
Operating loss .....	(2,069)	(1,897)	(16,714)
Net loss attributable to common stockholders .....	(1,876)	(1,807)	
Net loss per share .....	(0.48)	(0.44)	
Weighted average number of shares of common stock outstanding.....	3,904	4,085	

As of December 31, 2002

Actual	As Adjusted <sup>1</sup>
-----	-----

(in thousands)

Balance Sheet Data:

Cash and cash equivalents	\$1,064	\$2,678
Certificate of deposit	370	370
Total assets	1,812	3,188
Total liabilities	175	85
Stockholders' equity	1,637	3,103

(1) The as adjusted amounts assume net proceeds of \$1,480,500 (excluding proceeds for any exercise of the overallotment option) from the sale of the units offered hereby.

The above tables do not reflect (i) up to \_\_\_\_\_ units issuable in connection with the underwriters' overallotment option, (ii) up to 1,145,684 shares of common stock reserved for issuance upon exercise of stock options issued pursuant to our stock option plans and (iii) up to \_\_\_\_\_ shares of common stock issuable upon exercise of warrants (including the 2003 Warrants we plan to issue in connection with this offering).

PLAN OF OPERATION

Since our founding in 1988, 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 for the development of our medical device, the clinical trials of our product and the pursuit of patents worldwide, which now total nine. We expect to continue to



## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

incur significant losses from costs for product development, clinical studies, securing patents, regulatory activities, manufacturing and establishing a sales and marketing organization without any significant revenues. A detailed description of the cash used to fund historical operations is in the financial statements and the notes thereto. Without an FDA-approved product and commercial sales, we will continue to be dependent upon existing cash and the sale of equity or debt to fund future activities. While 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.

During 2001, we initiated the clinical trial of the system for isolated liver perfusion using the chemotherapy agent, melphalan. The Phase I clinical trial at the National Cancer Institute marks an expansion in the potential labeled usage for the Delcath system beyond doxorubicin, the chemotherapy agent used in our initial clinical trials. Enrollment of new patients in the Phase I trial continued throughout 2002.

NCI is currently preparing a clinical trial protocol for a Phase II trial of melphalan, based on the data collected in the Phase I study. Enrollment in this Phase II study is expected to begin during 2003. The Principal Investigator at the NCI has informed us that he plans to publish and/or present his findings in appropriate medical forums once treatment within Phase I of the trial is completed.

The following tables describe the dates each phase of our clinical trials began, the currently estimated cost to complete each phase of the clinical trial and the amount spent as of March 31, 2003 for our trials with each of doxorubicin and melphalan.

### Doxorubicin

Phase	Date Commenced	Estimated Additional Cost to Complete	Amount Spent
-----	-----	-----	-----
Phase I	1990	0	(2)
Phase II	1990	0	(2)
Phase III	(1)	\$4,600,000 (3)	\$2,109,000
-----			

(1) We expect the Phase III clinical trials with doxorubicin to commence in 2003.

(2) The Phase I and II trials were conducted as a combined trial. All costs with respect to these two trials were incurred before October 2000, the date of our initial public offering. Prior to the initial public offering, we did not account for our research and development expenses by project. From inception through December 31, 1999, the period in which the Phase I and Phase II clinical trials were conducted, approximately 73% of our expenses were attributable to research and development. We estimate that of this amount, \$7.6 million was spent on the combined Phase I and Phase II trial.

(3) The cost to complete will be significantly affected by the time period over which the trials are conducted. In turn, the time period will be significantly affected by the number of sites that agree to conduct the trials and the time it takes to enroll the required number of patients in the treated group and the control group. The FDA may also instruct us to increase the number

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

of patients in our trial. Therefore, the estimate is subject to change over time.

Melphalan

Phase -----	Date Commenced -----	Estimated Additional Cost to Complete -----	Amount Spent -----
Phase I	2001	\$150,000 (1)	\$1,080,000
Phase II	(2)	\$740,000 (3)	0
Phase III	(4)	(4)	(4)

15

-----  
 (1) Phase I of the clinical trial will continue until the Principal Investigator determines that he has reached the maximum tolerated dose level of melphalan for treated patients. We currently estimate that treatments will continue through June 30, 2003. However, this estimate is subject to change.

(2) Commencement date is pending completion of the Phase I clinical trial and obtaining FDA approval to commence Phase II.

(3) We expect that the Phase II clinical trials will be conducted at the National Cancer Institute. The cost to complete will be significantly affected by the time period over which the trials are conducted. The FDA may also instruct us to increase the number of patients in our trial. Therefore, the estimate is subject to change over time.

(4) We cannot estimate the date of commencement or the cost to complete Phase III of the melphalan clinical trial because we have not yet obtained approval of our study protocol from the FDA.

We also announced that the Sydney Melanoma Unit of the University of Sydney Sydney Cancer Centre plans to proceed with a Phase III study of our drug delivery system for inoperable cancer in the liver, pending approval of the hospital's Institutional Ethics Committee. Other potential sites are not as far along as Sydney in their preparations to participate in this clinical trial.

Our management continues to speak to potential investors and investment analysts at a series of meetings in several major U. S. cities and in Europe. On April 3, 2002 we raised \$267,500 upon completion of a private placement of 243,181 shares of common stock with an investment group.

Over the next twelve months, we expect to incur substantial expenses related to the research and development of our technology, including Phase III clinical trials using doxorubicin with the Delcath system and Phase I and Phase II clinical trials using melphalan with the Delcath system. Additional funds, when available, will be committed to pre-clinical and clinical trials for the use of other chemotherapy agents with the Delcath system for the treatment of liver cancer and the development of additional products and components. We will also continue efforts to qualify additional sources of the key components of our device, in an effort to further reduce manufacturing costs and minimize dependency on a single source of supply.

### LIQUIDITY AND CAPITAL RESOURCES

Without raising additional funds, we currently anticipate that our available funds will be sufficient to meet our anticipated needs for working

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

capital and capital expenditures through at least the next twelve months. We are not projecting any capital expenditures that will significantly affect our liquidity during the next twelve months. Upon the closing of this offering, we anticipate hiring an additional employee to serve as Director of Research and Development. Our cash and cash equivalents and short term investments at December 31, 2002 totaled \$1.43 million.

Our future liquidity and capital requirements will depend on numerous factors, including the progress of our research and product development programs, the success or failure of our clinical studies, the timing and costs of making various United States and foreign regulatory filings, obtaining approvals and complying with regulations, the timing and effectiveness of product commercialization activities, including marketing arrangements overseas, the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights and the effect of competing technological and market developments.

Our future results are subject to substantial risks and uncertainties. We expect to require additional working capital in the future and such working capital may not be available on acceptable terms, if at all.

### FUTURE CAPITAL NEEDS, ADDITIONAL FUTURE FUNDING

Our future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history and we may never achieve consistent profitability. We had working capital at December 31, 2002 of \$1.4 million. We expect to require additional working capital in the future, and such working capital may not be available on acceptable terms, if at all. In addition, we may need additional capital in the future to fully implement our strategy as set forth herein.

16

### APPLICATION OF CRITICAL ACCOUNTING POLICIES

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. Certain accounting policies have a significant impact on amounts reported in the financial statements. A summary of those significant accounting policies can be found in Note 1 to our financial statements included herein. We have not adopted any significant new accounting policies during the year ended December 31, 2002, but have reclassified our Statements of Operations to reflect cost and expense accounts on a functional basis for 2002 and prior.

### BUSINESS

#### General

We were incorporated under Delaware law in 1988. We are a development stage company, and we have developed the Delcath system to isolate the liver from the general circulatory system and to administer chemotherapy

and other therapeutic agents directly to the liver. Since our inception, we have raised approximately \$14 million in funds (net of fundraising expenses), and we have invested approximately \$11 million of those funds in research and development costs associated with development and testing of the Delcath system.

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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 premarket approval. We plan to conduct Phase III clinical trials designed to secure premarket approval in the United States and possibly in foreign markets for use of the Delcath system with a particular chemotherapy agent, doxorubicin, currently used to treat malignant melanoma that has spread to the liver. We also plan to continue our clinical trial for the use of the Delcath system with another chemotherapy agent, melphalan, which is also currently used to treat malignant melanoma that has spread to the liver. Additionally, we plan to continue pre-clinical and clinical trials on the use of the Delcath system with other chemotherapy agents used to treat liver cancer.

### STRATEGY

Our objectives are 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 Completing clinical trials to obtain FDA premarket 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 premarket approval of commercial sale of the Delcath system in the United States for use in administering doxorubicin in the treatment of melanoma that has spread to the liver.
- o Obtaining 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 August 2001, we commenced a Phase I clinical trial at the National Cancer Institute using melphalan, a chemotherapy agent. In addition to researching the use of other chemotherapy 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 and to raise additional funds for these purposes. Additional FDA premarket 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 a 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

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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. Additionally, Australia has been cited as having the highest incidence of skin cancer in the world. Given that our current Phase III clinical trials are with a chemotherapy agent that is used to treat malignant melanoma that has spread to the liver, upon obtaining FDA premarket approval, we intend to target the Australian market. We also 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 1,334,100 Americans will be diagnosed with cancer in 2003. According to the American Cancer Society's "Cancer Facts and Figures 2003," 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 Institutes of Health, in the American Cancer Society's "Cancer Facts & Figures 2003," estimates the overall costs of cancer in the year 2002 to be \$171.7 billion, including \$61 billion in direct medical costs, \$15.5 billion for indirect morbidity costs attributable to lost productivity due to illness and \$95.2 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. Metastatic, or secondary, 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. According to the American Cancer Society's "Cancer Facts & Figures 2003," the five-year survival rate for liver cancer patients, both primary and secondary, is approximately 7%, compared to the 62% for all other forms of cancer combined. In the liver, tumors can be surgically removed only when they are located in one of the liver's two lobes. However, since symptoms of liver cancer often do not appear until the disease has advanced, more than 70% 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 also 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 the 2002 World Health Report, liver cancer is the third most common form of cancer worldwide, accounting for 616,000 deaths. The American Cancer Society in its "Cancer Facts & Figures 2003" has projected that in the United States there will be approximately 17,300 new cases of primary melanoma and 54,200 new cases of metastatic melanoma.

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.

#### CURRENT LIVER CANCER TREATMENTS

The prognosis for primary and secondary liver cancer patients is poor. Although limited treatment options are currently available for liver cancer, they are typically ineffective, are generally associated with significant side-effects

18

and can even cause death. Traditional treatment options, discussed in more detail below, 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 tumors 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 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 removal 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 micro metastases in the liver

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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 1980's, 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 very high 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.

19

### 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 ice ball. 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:

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

- 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 track 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 treatments for liver cancer .

### 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, removal of tumors 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.

### TREATMENT WITH 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 agents 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 the protection from the side-effects of chemotherapy to other parts of the body that is provided by the



## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Delcath system allows for higher chemotherapy doses 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.

20

The Delcath system kit includes the following disposable components that we purchase from third-party suppliers:

- 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 system 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, a major vessel of the heart. 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 leaves 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, another major vessel of the heart, thus restoring the cleansed blood to normal circulation. Infusion is

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

administered over a period of thirty minutes. Filtration occurs during infusion and for thirty minutes afterward. The catheters are removed and manual pressure is maintained on the catheter puncture sites for approximately fifteen minutes. The entire procedure takes approximately two to three hours to administer.

During Phase I and Phase 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 that is being conducted presently at The National Cancer Institute and was previously conducted at Yale University, M.D. Anderson Cancer Center and Wright Patterson Air Force Base.

### OUR PHASE III CLINICAL TRIALS

Phase III clinical trials are a prerequisite for FDA approval of Delcath's premarket approval 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.

21

We have conducted Phase I and II 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 twenty-three 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. We believe that this supports our hypothesis that the Delcath system permits the delivery of higher dosages of chemotherapy agents to the cancer site while at the same time minimizing damage to healthy tissue.

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

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

- o the safety of the system at higher dosage levels of chemotherapy than those used in conventional intravenous chemotherapy delivery.

Though not demonstrated in a statistically significant manner because of the limited number of patients tested, 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 premarket 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 which requires us to obtain approval of new labeling for the drug being used in the clinical trials. The application to change the labeling must be filed by a drug manufacturer holding an existing new drug application or an abbreviated new drug application. We have reached a preliminary oral understanding with a drug manufacturer holding an existing license for doxorubicin to submit an application to the FDA supporting the new labeling based on data from the Phase III clinical trial. The premarket approval application must demonstrate the clinical utility of a particular drug when administered through the Delcath system. To do so, we must demonstrate, in a statistically significant manner, that administering doxorubicin with the Delcath system results in survival times of patients that are longer than those obtained from administering doxorubicin intravenously.

With a substantial portion of the proceeds that we receive from this offering, we intend to conduct Phase III 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 our protocols for conducting the Phase III clinical trials.

We expect the Phase III clinical trials to be conducted at several medical centers such as the NCI and the Sydney Cancer Centre and to involve a minimum of 122 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 the other half, the control group, will be treated with either of two specified chemotherapy agents delivered intravenously. Trials will commence upon approval of a budget by the respective institutions. Once a budget is approved, the trials will commence at that institution. We expect that trials will begin in 2003. However, our timetable is subject to uncertainty and we cannot assure you that we can meet our planned schedule. We do not know whether 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 organization ("CRO") to conduct these trials. The CRO represents the clinical trial sponsor. They ensure that the principal investigator follows the established protocol and collects the clinical data. We have not begun negotiations with a CRO and we cannot assure you that we will be able to engage a CRO on

acceptable terms and conditions in a timely manner or at all. The CRO and principal investigators 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 our 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 of the CRO to perform as expected or required, including failure of the principal investigators 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 premarket approval. We believe that we will acquire sufficient data to seek FDA premarket approval of the Delcath system within twelve to eighteen months of the last patient enrolled but it may take substantially longer.

We do not know how long the FDA may take to evaluate our submission, and they may require that additional trials be conducted or may not grant approval.

The FDA premarket approval we are currently seeking is limited to administration of doxorubicin with the Delcath system to treat patients suffering from metastatic melanoma which has spread to the liver. If we are granted this approval, we plan to seek additional FDA premarket 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, as

well as supplemental new drug application approval for each drug used with the Delcath system. 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 premarket 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.

#### OUR CLINICAL TRIAL AND AGREEMENT WITH THE NATIONAL CANCER INSTITUTE

In June 2001, the Company announced that The National Institutes of Health/The National Cancer Institute approved a clinical study protocol for administering escalating doses of another chemotherapy agent, melphalan, through the Delcath system to patients with unresectable cancer of the liver.

The Phase I clinical trial conducted at The National Cancer Institute ("NCI") began in September 2001 and involved a total of 24 patients, all experiencing metastatic liver cancer. The goal of a Phase I clinical trial is to determine the maximum tolerated dose of melphalan that can be administered before it becomes toxic to the patient's system.

This clinical trial, which will also include a Phase II study, is subject to the terms and conditions of the Cooperative Research and Development Agreement (the "CRADA") between us and NCI. We obtained FDA approval to conduct the Phase I clinical trial; however, further FDA approval is necessary to conduct Phase II studies. The goal of a Phase II clinical trial is to determine various factors such as the appropriate dosage, the timing of each dose and the

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

efficacy of the proposed dose. We cannot estimate how long it will be until we receive FDA approval to commence the Phase II study. The scope of the study is:

- o To develop a Delcath system-based Phase I treatment protocol for the regional therapy of organs using escalating doses of melphalan delivered through the utilization of the Delcath system; and
- o To develop Delcath system-based Phase II treatment protocols as a follow-up to Phase I studies. The Phase II study will involve patients with specific histologies (diseases) who have unresectable cancers confined to the liver using the maximum tolerated dose of melphalan administered using the Delcath system.

The patients will be treated with up to four series of infusions based upon toxicity and response to treatment. The Phase II study is expected to begin shortly after completion of the Phase I study and to take twelve to eighteen months.

The CRADA commits NCI to perform the research necessary under the Phase I and Phase II protocols approved by the FDA with Delcath acting as the sponsor and NCI providing the principal investigator. Delcath will provide funding to NCI in the amount of \$918,750 payable in quarterly installments over the five-year term of the agreement unless the CRADA is terminated early. The CRADA can be terminated at any time by either party. In the event of an early termination, we would be responsible for unfunded costs incurred prior to the termination date and all reasonable termination costs. The term of the agreement is intended to allow for what the parties expect to be the potential

23

maximum amount of time necessary to complete and evaluate Phase I and Phase II trials. An amendment to the CRADA would be necessary if the parties decide to initiate additional clinical trials using other chemotherapy agents. We are using money raised in our initial public offering and will use a portion of the net proceeds this offering to fund this project. If the results of the Phase I and Phase II trials are successful, we will probably need additional capital to pay for the expenses associated with a Phase III clinical trial.

### RESEARCH FOR HEPATITIS TREATMENT

Another disease that 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 sixty-one NCI designated Cancer Centers in the United States recognized by NCI, beginning with the hospitals participating in the Phase III clinical trials, as well as key foreign institutions including the Sydney Melanoma Unit of the University of

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Sydney Sydney Cancer Centre. 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 (non-curative) 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. This is done either by an interventional radiologist or a surgeon.

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 four sales representatives to market the system in the United States.

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.

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 against the control group a statistically measurable increase in life expectancy 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.

### 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, at that time, invested \$1,000,000 in Delcath.

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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 that 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

Because the Delcath system is characterized by the FDA as an experimental device, its use is not now 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 cost of the Delcath system until after its use is approved by the FDA.

We believe that the Delcath system will provide significant cost savings in that it should reduce treatment and hospitalization costs associated with the side-effects of chemotherapy. Our planned wholesale price to the hospitals for the Delcath system kit is approximately \$4,000. A patient normally undergoes four treatments with the Delcath system, each requiring a new system kit. Each treatment with the Delcath system, including the cost of the treatment kit, has an estimated cost of approximately \$12,000, resulting in a total estimated treatment cost of approximately \$48,000. This compares to a total estimated 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 manufacture 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 ("GMP") and quality system requirements ("QSR"). If we sell the Delcath system in some foreign markets, our facility will also need ISO 9000 approval from the European Union which is a required approval that European manufacturers must obtain from the International Organization for Standardization.

The double balloon catheter is being 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 must also meet FDA GMP and QSR requirements. 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 clinical trials or for commercial sale.

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

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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 must also meet the FDA GMP and QSR requirements. Medtronic's manufacturing facility is also ISO 9000 approved and, thus, the components it manufactures may be used in European markets.

Currently, we purchase the activated charcoal filters used in the Delcath system from Asahi Medical Products of Japan. Asahi has informed us that it will discontinue manufacturing these filters in the near future. We have ordered a final shipment of filters from Asahi which we expect will be sufficient to meet our needs for the next twelve months.

25

However, as part of our application process with the FDA, we obtained approval to utilize filters from any manufacturer that falls within certain performance parameters and meets the specifications on file with the FDA. Therefore, we are currently actively seeking an alternative filter manufacturer that is capable of providing us with the quality of filters that are required to meet the specifications on file with the FDA in the quantity that we will require to conduct future clinical trials and to market the Delcath system commercially. We have already identified one potential supplier in the United States. Any supplier must also meet the FDA GMP and QSR requirements.

### 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.

The Delcath system competes with all forms of liver cancer treatments that 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 Delcath's 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 reduced.

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,



## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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

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 premarket approval 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 that has an approved new drug application from the FDA. Melphalan, the drug that will be administered through the Delcath system in the NCI-sponsored study, is a chemotherapy agent that also has new drug application approval from the FDA. 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 a dose strength that differs from those currently approved, approval for revised labeling of doxorubicin and melphalan products permitting their use with the Delcath system must be obtained. The supplemental new drug application to change the labeling must be filed by a drug manufacturer holding an existing approved new drug application or an abbreviated approved new drug application. We are currently in discussions with a drug manufacturer who holds an existing approved new drug application for doxorubicin for the manufacturer to submit a supplemental new drug application supporting the new labeling, assuming data from the Phase III clinical trial is favorable. We are also currently in discussions with the drug manufacturers that hold an approved new drug application or an approved abbreviated new drug application and plan actively to solicit one of them to file an application for new labeling with the FDA for melphalan.

26

Under the Federal Food, Drug, and Cosmetic Act, the FDA regulates the preclinical and clinical testing, design, manufacture, labeling, distribution, sales, marketing, postmarket 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 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

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

- o criminal prosecution of a company and its officers and employees.

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

Medical Devices. The Delcath system is a Class III medical device. Class III medical devices are those which are subject to the most stringent regulatory controls because insufficient information exists to assure safety and efficacy solely through general or special controls such as labeling requirements, mandatory performance standards and post-market surveillance. FDA premarket approval is required for Class III medical devices. It is subject to the most stringent controls applied by the FDA to assure reasonable safety and effectiveness. An application for premarket approval must be supported by data concerning the device and its components, including the manufacturing and labeling of the device and the results of animal and laboratory testing and human clinical trials. The conduct of clinical trials is subject to FDA regulations and to continuing oversight by institutional review boards at hospitals and research centers where the trials are conducted and by 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 sign 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 thirty 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 premarket approval application expeditiously. 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 is likely to refer this matter to an advisory committee of experts to obtain views about the Delcath system. This process is referred to as a "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.

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 is not favorable, the FDA will deny approval of the application or issue a "not approvable letter." The FDA may also determine that additional preclinical 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 a supplement to a premarket approval application for changes to a device if they affect the safety and effectiveness of the device, including new indications for use; labeling changes; changes in the manufacture of the device; 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 thirty days after the FDA is provided with notice of these changes unless the FDA advises the premarket approval application holder within thirty days of receipt of the notice that the notice is inadequate or that premarket approval 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 promoting of devices for indications or uses that have not been approved by the FDA. Further, the Federal Food, Drug, and Cosmetic Act authorizes the FDA to impose postmarket 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 hospital or ambulatory treatment center.

The Federal 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 design controls, covering initial design and design changes be in place;
- 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

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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 premarket approval application.

Investigational devices that require FDA premarket 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 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. A manufacturer of a chemotherapy agent must obtain FDA approval of a supplemental 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 both doxorubicin and melphalan does not provide for its delivery with the Delcath system. We must partner with the holders of an approved new drug application for doxorubicin and melphalan to make this change to the labeling of both agents. We are seeking to partner with drug companies for this purpose, but we have no assurance that we will find partners or that

28

the FDA will approve the application. If this approval is obtained, it would not have a negative effect on the manufacturers of either doxorubicin or melphalan. Rather, the drug manufacturer would have the opportunity to expand the use of the drugs as a result of changing their label to include the Delcath labeling.

Phase III clinical trial protocols using doxorubicin have been approved by the FDA under our 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 where the trials will be conducted. We are seeking the approval of institutional review boards at several medical centers by assembling and providing them with information with respect to the trials.

The FDA requires that, in order to obtain FDA 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 FDA approval of both a supplemental new drug application for revised labeling for the drugs and a premarket approval application providing for the use of doxorubicin with the Delcath system. The trial protocols were approved by both the FDA division that reviews 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. The foregoing facts will also apply if our clinical trial using melphalan is successful in Phases I, II and III.

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

If we successfully complete the clinical trials with both agents, we believe the manufacturers of doxorubicin and melphalan will submit to the FDA a supplemental new drug application to deliver the agent to the liver through the Delcath system. Under the Federal Food, Drug, and Cosmetic Act, the Delcath system cannot be marketed until the supplemental new drug application and the premarket approval application are approved, and then only in conformity with any 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 premarket approval or clearance.

In April 1996, legislation was enacted that permits a medical device which requires FDA premarket 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.

In order for us to market and sell the Delcath system in the European Community, we must obtain a CE mark, which is the official marking required by the European Community for all electric and electronic equipment that will be sold anywhere 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 emphasis 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:

29

Summary Description of Patents

-----  
Isolated perfusion method for cancer treatment

Patent No.

-----  
U.S. #5,069,662

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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
Catheter with slideable balloon to adjust isolated segment	U.S. #5,919,163
Isolated perfusion method for kidney cancer	U.S. #6,186,146

The Company has filed a patent application covering technology to treat glandular cancer and other diseases within glands. This patent reflects modifications to the design and use of the Delcath system.

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

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.

### EMPLOYEES

As of April 14, 2003, we had 5 full-time employees. Upon completion of this offering, we intend to recruit additional personnel. None of our employees is represented by a union and we believe relationships with our employees are good.

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

### FACILITIES

We currently occupy approximately 3,600 square feet of office space at 1100 Summer Street, Stamford, Connecticut, pursuant to a lease which will expire in 2003. We have occupied these facilities since 1992 and the space is adequate for our current needs. If we require additional space in the future, we believe that satisfactory space will be available at commercially reasonable rates in or near our current facility.

The Company believes that its facilities and equipment are in good condition and are suitable for its operations as presently conducted and for its foreseeable future operations.

### MANAGEMENT

#### EXECUTIVE OFFICERS AND DIRECTORS

Our executive officers and directors are as follows:

Name	Age	Position
----	---	-----
M. S. Koly	62	President, Chief Executive Officer, Treasurer and Director

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Samuel Herschkowitz, M.D.	53	Chairman, Chief Technical Officer and Director
Thomas S. Grogan	51	Chief Financial Officer
Mark A. Corigliano	39	Director
Daniel Isdaner	38	Director
Victor Nevins	81	Director

M. S. Koly has been our President, Chief Executive Officer and Treasurer since 1999. In 1988, Mr. Koly was elected to our board of directors. 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

30

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.

Samuel Herschkowitz, M.D., has been our Chief Technical Officer since 1999. In 1988, Dr. Herschkowitz was elected the Chairman of our board of directors. 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.

Thomas S. Grogan was appointed the Company's Chief Financial Officer in September 2001. Prior to joining Delcath, Mr. Grogan was Vice President of Business Development for The Jockey Club from 2000-2001. In 1999, he was the Chief Financial Officer for U.S. Homecare Corporation, a publicly traded provider of home healthcare services. From 1998-1999, he was the Chief Financial Officer of the healthcare division of Fairchild Properties, a privately held owner and operator of skilled nursing facilities. From 1993-1998, he was the Chief Financial Officer of NHS National Health Services, Inc., a privately held provider of medical services to corporations, industrial sites and corrections institutions. He is a CPA, and holds a B.A. degree from Fordham University and an M.B.A. degree from Cornell University.

Mark A. Corigliano was elected to our board of directors in 2001. Since 1991, Mr. Corigliano has been Managing Director of Coast Cypress Associates, a company that designs and implements microcomputer systems. His specialty is the design and installation of accounting systems. Since 1993, he has also served in a senior financial capacity as Controller and Manager of Special Projects for DC Associates, a restaurant management organization located in New York City. Mr. Corigliano also serves as Treasurer of Rolls Royce Owners' Club, a non-profit organization with 8,500 members worldwide. He holds a B.S. degree in accounting from Seton Hall University.

Daniel Isdaner was elected to our board of directors in 2001. Since 1994, Mr. Isdaner has been the owner and director of Camp Mataponi, Inc., a children's' summer camp located in Naples, Maine. He also serves on the board of directors of the American Camping Association-New England Division and the Jewish Community Center of Southern New Jersey. Mr. Isdaner holds a B.S.B.A. degree

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

from the Boston University School of Management.

Victor Nevins was elected to our board of directors in 2001. Since 1957, Mr. Nevins has been Chief Executive Officer of Max Abramson Enterprises, a medium-sized privately held conglomerate headquartered in Flushing, New York. He also is a licensed real estate broker and, in 1962, he founded Victor Nevins Realty. From 1968-1997, he served on the board of directors of Flushing Hospital and Medical Center as Vice President of the Board, member of the Finance Committee, Chairman of both the House and Grounds and Human Resources Committees and liaison to the Medical Board. He currently is a Director and past President of the Flushing Chamber of Commerce, a Director of the Flushing Merchants Association, and a Director of the American Red Cross, North Shore Chapter.

### 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 provisions 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.

Each of our directors has been elected to serve until his successor has been elected and duly qualified. The directorship terms of Mr. Nevins and Mr. Corigliano will expire at the annual meeting of stockholders in 2003, the directorship term of Mr. Isdaner will expire at the annual meeting of stockholders in 2004 and the directorship terms of Dr. Herschkowitz and Mr. Koly will expire at the annual meeting of stockholders in 2005.

### COMMITTEES OF THE BOARD OF DIRECTORS

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

31

The audit committee approves the selection of our independent accountants and meets and interacts with the independent accountants to discuss questions in regard to 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 and quarterly 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. The audit committee also reviews the fees to be paid to and the performance of our independent accountants. Currently, the members of the audit committee are of Messrs. Corigliano and Isdaner. Messrs. Corigliano and Isdaner satisfy the requirements for independent directors contained in the rules governing companies listed on the Nasdaq Stock Market.

The compensation and stock option committee reviews the salaries and benefits of all officers and stock option grants to all employees, consultants, directors and other individuals compensated by us. The compensation and stock option committee is empowered by the board of directors to act independently. The compensation and stock option committee also administers our stock option and other employee benefits plans. Currently, the members of the compensation and stock option committee are Messrs. Nevins and Corigliano.



## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

### DIRECTOR COMPENSATION

Our current policy regarding compensation of directors provides that directors may be paid a fixed sum for their attendance at each meeting of the board of directors or a stated salary as a director, and each may be reimbursed for his or her expenses. Currently, directors who are also employees do not receive any compensation for serving on the board of directors. Non-employee directors 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 other compensation. In addition, each non-employee director that served on our board of directors in 1999 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, and 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, all of which are vested. In December 2001, each non-employee director received an option to purchase 30,000 shares of common stock at a purchase price of \$0.85 per share that vest as to 50% of the shares covered on the first and second anniversaries of the date of grant.

On September 17, 2002, our compensation and stock option committee granted stock options to Mr. Koly and Dr. Herschkowitz, at an exercise price equal to \$0.71 per share, the fair market value at the close of trading on that date as reported by The Wall Street Journal. On September 17, 2002, our compensation and stock option committee granted stock options to directors other than Mr. Koly and Dr. Herschkowitz, at an exercise price of \$0.71 per share, the fair market value at the close of trading on that date as reported by The Wall Street Journal. The stock options granted to the directors during 2002 are indicated below:

Name ----	Incentive Stock Options -----	Non-Qualified Stock Options -----
M. S. Koly	100,000	0
Samuel Herschkowitz, M.D.	30,000	0
Mark Corigliano	0	30,000
Daniel Isdaner	0	30,000
Victor Nevins	0	30,000

### 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

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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 -----
Morton G. Glickman, M.D.	Professor Emeritus of Diagnostic Radiology, Yale University School of Medicine	Cardiovascular and Interventional Radiology	Founder and St
William N. Hait, M.D., Ph.D.	Director, The Cancer Institute of New Jersey	Medical Consultant and Scientific Advisor	Founder and St
T.S. Ravikumar, M.D.	Chairman, Department of Surgery, Montefiore Medical Center	Surgical Oncology	Former Princip Investigator o 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 is currently the Chairman of the Department of Surgery at Montefiore Medical Center. 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:

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Name -----	Title -----	Specialty -----
Harvey J. Ellis, C.C.P.	Chief of Cardiac Perfusion, Bridgeport Hospital	Perfusion Consultant
Seymour H. Fein, M.D.	President, Fein & Associates	Regulatory and Medical Oncology
Durmus Koch	President, Bipore, Inc.	Manufacturing
James H. Muchmore, M.D.	Associate Professor of Surgery, Tulane University School of Medicine	Oncology and Perfusion Consultant
John Quiring, Ph.D.	Principal, QST Consulting	Biostatistician

33

OTHER KEY CONSULTANTS

Jonathan A. Foltz, CFA, 40, consults with us on identifying alternative product sources and potential partnering opportunities. He was our Director of Operations from 1992 until August 2001. 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.

EXECUTIVE COMPENSATION

The following table sets forth, for the fiscal years ended December 31, 2002, 2001 and 2000, certain compensation paid by us, including salary, bonuses and certain other compensation, to our Chief Executive Officer and all other executive officers whose annual compensation for the year ended December 31, 2002, exceeded \$100,000.

SUMMARY COMPENSATION TABLE

Name and Principal Position -----	Year ----	Salary ----- (\$) ---	Bonus (\$) -----	Securities Underlying Options (\$) -----
M.S. Koly President, Chief Executive Officer and Treasurer	2002	187,500	0	100,000
	2001	164,750	17,500 (1)	100,000
	2000	98,200	0	102,000
Samuel Herschkowitz Chairman of the Board and Chief Technical Officer	2002	136,667	0	30,000

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

	2001	120,000	10,000 (1)	30,000
	2000	20,000	0	0
Thomas S. Grogan				
Chief Financial Officer	2002	122,500	0	30,000
	2001	35,500	0	30,000

-----

(1) Bonuses were declared in 2001, payable in January 2002.

Equity Compensation Plan Information

	(a)	(b)	
	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	N re futur ref
	-----	-----	-----
Equity compensation plans approved by security holders	885,684	\$2.94	
Equity compensation plans not approved by security holders	0	0	

34

OPTION GRANTS IN LAST FISCAL YEAR

The following table sets forth information concerning stock options which were granted during 2002 to the executive officers named in the Summary Compensation Table.

Name	Number of Shares of Common Stock Underlying Option (1)	Percent of Total Options Granted to Employees in 2002	Exercise Price (\$)
----	-----	-----	-----
M. S. Koly	100,000	58.8%	0.71
S. Herschkowitz	30,000	17.6%	0.71
T. Grogan	30,000	17.6%	0.71

(1) Options vest equally over two years on anniversary dates.

AGGREGATE OPTION EXERCISES IN LAST FISCAL YEAR AND FISCAL YEAR-END OPTION VALUES

The following table sets forth information with respect to the

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

executive officers named in the Summary Compensation Table concerning the exercise of options during the year ended December 31, 2002 and unexercised options held as of the end of fiscal 2002.

Name	Year	Shares Received on Exercise	Value Realized	Number of Securities Underlying Unexercised Options at FY- End Exercisable/ Unexercisable	Value of Unexercised In-the-Money Options at FY-End (\$) (1) Exercisable/ Unexercisable
----	----	-----	-----	-----	-----
M. S. Koly	2002	0	0	291,746/150,000	52,500/146,500
S. Herschkowitz	2002	0	0	159,836/45,000	12,000/40,200
T. Grogan	2002	0	0	6,000/54,000	4,800/47,400

(1) Calculated based on the fair market value of \$1.65 per share at the close of trading on December 31, 2002 as reported by The Wall Street Journal, minus the exercise price of the option.

### EMPLOYMENT AGREEMENTS

On October 30, 2001 we amended the employee agreements dated April 30, 1996, with M. S. Koly and Samuel Herschkowitz, M.D. The agreements provide for a lump-sum severance payment of one year's base salary upon notice of termination at any time without cause. In the event of termination without cause due to a change in control (as defined in the employment agreement), Mr. Koly is entitled to a lump sum severance payment equal to the greater of two years' base salary or the base salary due for the remaining term of the agreement. Mr. Koly's amended employment agreement provides for a base salary of \$225,000 per annum and extends the term of the agreement until December 1, 2004. The amendment also provides that in the event we close on a private placement or public offering with gross proceeds of at least \$5,000,000, a new three-year term of employment shall commence upon the closing.

The initial term of Dr. Herschowitz's employment agreement was three years with automatic successive one year renewal periods thereafter. In addition to the termination provisions set forth in the employment agreement, either party may terminate the employment agreement by providing a minimum of three months' prior written notice. The agreement provides for a lump-sum severance payment of one year's base salary upon notice of termination at any time without cause. In the event of termination without cause due to a change in control (as defined in the employment agreement), Dr. Herschowitz is entitled to a lump sum severance payment equal to the greater of one year's base salary or the base salary due for the remaining term of the agreement. Dr. Herschowitz's amendment provides for a base salary of \$140,000 per annum.

### STOCK OPTION PLANS

On October 15, 1992, our board of directors and stockholders adopted

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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 (the "2000 Plan"). On May 8, 2001, the board of directors adopted the 2001 Stock Option Plan (the "2001 Plan"). The 2000 Plan and the 2001 Plan were each approved by the shareholders at the Annual Meeting of Shareholders held on June 12, 2001. On November 13, 2001, our board of directors authorized the amendment of the 2001 Plan to give the compensation and stock option committee discretion to issue stock options with net issuance provisions. 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, 207,030 shares of common stock for issuance upon exercise of options granted from time to time under the 1992 Non-Incentive Stock Option Plan; 300,000 shares of common stock for issuance from time to time under the 2000 Plan and 750,000 shares of common stock for issuance from time to time under the 2001 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 employees. 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 Plan and the 2001 Plan, we may grant incentive options to employees, and non-qualified options to employees and non-employees including directors, consultants, agents and independent contractors. The stock option plans are administered by the compensation and stock option committee, appointed by our board of directors.

Subject to the provisions of each of the stock option plans, the compensation and stock option committee will determine who will 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.

As of December 31, 2002, 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 were granted to employees and directors and terminate on the fifth anniversary of their grant date. We will not grant any additional options under these plans. As of December 31, 2002, we have granted incentive stock options to purchase 150,600 shares of common stock under our 2000 Plan at a weighted average price of \$2.96 and non-qualified stock options to purchase 133,420 shares, net of 84,000 expired options, of common stock under our 2000 Plan at a weighted average price of \$1.65. As of December 31, 2002, we have granted incentive stock options to purchase 330,000 shares of common stock under our 2001 Plan at a weighted average price of \$0.70 and we have granted non-qualified stock options to purchase 90,000 shares of common stock under our 2001 Plan at a price of \$0.71.

PRINCIPAL STOCKHOLDERS

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

The following table sets forth certain information known by us regarding the beneficial ownership of our common stock as of April 14, 2003, for (i) each stockholder known by us to own beneficially 5% or more of the outstanding shares of our common stock, (ii) each executive officer and director and (iii) all directors and executive officers as a group.

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

36

Directors, Executive Officers and 5% Stockholders: (1) -----	Shares Beneficially Owned (2) -----	Percentage of Common Shares Outstanding (3) -----
M. S. Koly (4)	1,627,848	36.9%
Venkol Trust (5)	1,245,864	30.2%
Samuel Herschkowitz, M.D. (6)	178,074	4.2%
Yenom X Partners (7)	263,446	6.4%
Mark A. Corigliano (8)	28,000	*
Daniel Isdaner (9)	30,500	*
Victor Nevins (10)	37,100	*
Thomas S. Grogan (11)	6,000	*
All directors and executive officers as a group (6 persons) (12)	1,907,522	41.2%

-----  
\* Less than 1% of total voting securities

(1) Except as otherwise noted in the footnotes to this table, each person or entity named in the table has sole voting and investment power with respect to all shares owned, based on the information provided to us by the persons or entities named in the table.

(2) Shares of common stock subject to options or warrants exercisable within 60 days of April 14, 2003 are deemed outstanding for computing the percentage of the person or entity holding such options or warrants.

(3) Percentage of beneficial ownership is calculated on the basis of the amount of outstanding securities (common stock) at April 14, 2003 (4,118,897 common shares) plus, for each person or entity, any securities that the person or entity has the right to acquire within 60 days pursuant to stock options or other rights.

(4) Mr. Koly is a director of Delcath. Includes 78,507 shares held by Mr. Koly, 11,731 shares held by M. Ted Koly, Mr. Koly's son as to which Mr. Koly disclaims beneficial ownership and approximately 181,000 shares held by the Venkol Trust in which Mr. Koly has a pecuniary interest. The figure above also includes the vested portion (291,746 shares) of stock options to purchase shares of common stock.

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

(5) Mr. Koly is the trustee of Venkol Trust and is deemed the beneficial owner of its shares because of his voting power. Mr. Koly has a pecuniary interest in approximately 181,000 of such shares.

(6) Dr. Herschkowitz is the Chairman of the board of directors of Delcath. The figure above includes 18,238 shares held by Dr. Herschkowitz. The figure excludes approximately 181,000 shares held by Venkol Trust in which Dr. Herschkowitz has a pecuniary interest. The figure also includes the vested portion (159,836 shares) of stock options to purchase shares of common stock.

(7) The figure above represents 243,181 shares owned directly by Yenom X Partners and 20,265 shares which could be acquired within 60 days upon exercise of warrants.

(8) Mr. Corigliano is a director of Delcath. The figure above represents 11,500 shares owned directly by him and 1,500 shares issuable upon exercise of warrants. The figure above also includes the vested portion (15,000 shares) of stock options to purchase shares of common stock.

(9) Mr. Isdamer is a director of Delcath. The figure above represents 8,000 shares directly owned by him or jointly with his wife and 7,500 shares issuable upon exercise of warrants. The figure above also includes the vested portion (15,000 shares) of stock options to purchase shares of common stock.

(10) Mr. Nevins is a director of Delcath. The figure above represents 16,100 shares owned directly by him and 4,000 shares issuable upon exercise of warrants owned by her. The above figure also represents 1,000 shares owned directly by his wife and 1,000 shares issuable upon the exercise of warrants. The figure above also includes the vested portion (15,000 shares) of stock options to purchase shares of common stock.

37

(11) Mr. Grogan is the Chief Financial Officer of Delcath. The figure above represents the vested portion of stock options to purchase shares of common stock.

(12) The number of shares beneficially owned by all directors and executive officers as a group includes 502,582 shares of common stock issuable within 60 days of April 14, 2003 upon exercise of stock options granted to directors and executive officers pursuant to our various stock option plans and 14,000 shares of common stock issuable upon exercise of warrants.

### RELATED PARTY TRANSACTIONS

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 bore 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, respectively. Each of the promissory notes was timely re-paid.

We believe that each of the transactions with our officers, directors



## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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 that may legally be made 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 that may legally be made 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 OUR CAPITAL STOCK AND OTHER SECURITIES

Our authorized capital stock consists of 35,000,000 shares of common stock, \$0.01 par value per share and 10,000,000 shares of preferred stock, \$0.01 par value per share, whose rights and designation have not yet been established. The description in the sections below of our certificate of incorporation and by-laws refers to our Amended and Restated Certificate of Incorporation and Amended and Restated By-Laws, respectively. As April 14, 2003, we had 4,118,897 shares of common stock issued and outstanding and no shares of preferred stock outstanding.

### UNITS

Each unit offered consists of five shares of common stock and five 2003 Warrants each to purchase one share of common stock. The common stock and the 2003 Warrants will trade separately immediately following the sale of the units. Immediately prior to the closing of this offering, there will be 4,118,897 shares of common stock outstanding. After giving effect to the issuance of the shares of common stock included in the units

offered by this prospectus, assuming the underwriters do not exercise their over-allotment option, there will be shares of common stock outstanding upon the closing of this offering.

Holder 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.

Holder 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

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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.

### WARRANTS

#### 2003 Warrants

General. Each 2003 Warrant will entitle the holder of the 2003 Warrant to purchase one share of common stock at a price of per share (25% of the unit offering price), subject to adjustment, at any time up to five years from the date of closing of this offering.

The 2003 Warrants will be issued in registered form under a warrant agreement by and between Delcath and American Stock Transfer & Trust Company, as warrant agent. 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 thereof.

Redemption. We may redeem some or all of the 2003 Warrants at a price of \$0.01 per warrant, upon thirty days' notice, at any time commencing one year from the closing date of this offering provided that the average closing bid quotation of our common stock on all twenty trading days ending on the day on which we give notice has been at least \$ price and there is then an effective registration statement providing for the issuance of the underlying shares of common stock. The warrant holders shall have the right to exercise their 2003 Warrants until the close of business on the date fixed for redemption. Redemption of the 2003 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 2003 Warrants included in the units offered hereby 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 2003 Warrants will be exercisable unless, at the time of exercise, Delcath has an effective registration statement under the Securities Act covering the shares of common stock issuable upon exercise of the 2003 Warrants 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. We will use our 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 2003 Warrants. However, if a warrant holder exercises all 2003 Warrants then owned of record by him or her, we will pay to the warrant holder, in lieu of the issuance of any

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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 2003 Warrants included in the units offered hereby are subject to adjustment in specified circumstances, including in the event of a stock dividend, recapitalization, reorganization, merger or consolidation of Delcath. However, the 2003 Warrants are not subject to adjustment for issuances of common stock at prices below the exercise price of the 2003 Warrants.

### 2000 Warrants

In accordance with the terms of our initial public offering, effective October 22, 2001, our common stock and 2000 Warrants that constituted the units we sold in 2000 commenced separate trading. A description of the material terms of the 2000 Warrants is set forth below.

General. Each 2000 Warrant entitles the holder of the warrant to purchase one share of common stock at a price of \$6.60, subject to adjustment, until October 2005.

39

The 2000 Warrants were issued in registered form under a warrant agreement by and among Delcath, American Stock Transfer & Trust Company, as warrant agent, and Whale Securities Co., L.P., the underwriter.

Redemption. We may redeem some or all of the 2000 Warrants at a price of \$0.10 per warrant, upon thirty days' notice, at any time, provided that the closing bid quotation of our common stock on all twenty 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 2000 Warrants and we have received the written consent of the underwriter for the redemption. The warrant holders shall have the right to exercise their 2000 Warrants until the close of business on the date fixed for redemption. Redemption of the 2000 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 2000 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 2000 Warrant will be exercisable unless, at the time of exercise, we have an effective registration statement under the Securities Act 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. We will use our best efforts to have all the shares so registered or qualified on or before the exercise date and to maintain a current

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

prospectus relating thereto until the expiration of the 2000 Warrants, subject to the terms of the warrant agreement.

No fractional shares will be issued upon exercise of the 2000 Warrants. However, if a warrant holder exercises all 2000 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 closing price or last reported sale price 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 2000 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 2000 Warrants are not subject to adjustment for issuances of common stock at prices below the exercise price of the 2000 Warrants.

### PREFERRED STOCK

Under our certificate of incorporation, our 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 our board of directors without approval from the stockholders. These rights, designations and preferences may include:

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

If our board of directors decides to issue any preferred stock, that issuance could have the effect of delaying or preventing a third-party from taking control of us. 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 our shares. 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 shares of preferred stock.

ANTI-TAKEOVER EFFECTS OF DELAWARE LAW AND OUR AMENDED AND RESTATED CERTIFICATE OF INCORPORATION AND BY-LAWS

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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 that person's affiliate or associate who is an owner of 15% or more of our outstanding voting stock for a period of three years from the date that this person became an interested stockholder unless (a) prior to such time our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder or (b) upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced or (c) at or subsequent to such time the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders by the affirmative vote of at least 66 2/3% of the outstanding voting stock not owned by the 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.

### LIMITATION ON LIABILITY AND INDEMNIFICATION MATTERS

As authorized by the Delaware General Corporation Law, our certificate of incorporation provides that none of our directors will 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 derives 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 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 permit further limits on 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 do 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 a 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

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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, such indemnification is against public policy as expressed in the Securities Act and is unenforceable.

41

### RIGHTS AGREEMENT

On October 30, 2001, we entered into a Rights Agreement with American Stock Transfer & Trust Company (the "Rights Agreement"). The purposes of the Rights Agreement are to deter and protect our shareholders from certain coercive and otherwise unfair takeover tactics and to enable the board of directors to represent effectively the interests of stockholders in the event of a takeover attempt. The Rights Agreement does not deter negotiated mergers or business combinations that the board of directors determines to be in the best interests of us and our stockholders.

To implement the Rights Agreement the board of directors declared a dividend of one common stock purchase right (a "Right") for each share of our common stock outstanding at the close of business on November 14, 2001 (the "Record Date") or issued by us on or after such date and prior to the earlier of the Distribution Date, the Redemption Date or the Final Expiration Date (as such terms are defined in the Rights Agreement). The dividend was issued on November 14, 2001 to stockholders of record on the Record Date. Each Right entitles the registered holder to purchase from us one share of common stock at a price of \$5.00 per share, subject to adjustment (the "Purchase Price").

#### Rights Attached to Common Stock Initially

Common stock certificates will evidence the Rights. A notation on the certificates will incorporate the Rights Agreement and advise the certificate holder of the existence of the Rights. Until triggered, the Rights are transferred only with the common stock. Common stock certificates issued after November 14, 2001 contain a legend referencing the existence of the Rights Agreement. The transfer of outstanding common stock prior to the occurrence of a Distribution Date will also constitute the transfer of the Rights associated with the common stock.

#### Distribution of Rights

The Rights will separate from the common stock on the Distribution Date. The Distribution Date will be the date the Rights separate from the common stock and will be the earlier to occur of the following two events:

- o the close of business on the first day of a public announcement that a person or group of affiliated or associated persons (an "Acquiring Person") has acquired beneficial ownership of 15% or more of the outstanding common stock; or
- o ten business days following the commencement of, or announcement of an intention to make, a tender or exchange offer the consummation of which would result in the

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

beneficial ownership by a person or group of 15% or more of such outstanding common stock.

As soon as practicable following the Distribution Date, separate certificates evidencing the Rights ("Right Certificates") will be mailed to holders of record of the common stock as of the close of business on the Distribution Date and such separate Right Certificates alone will evidence the Rights. The Rights are not exercisable until the Distribution Date. The Rights will expire on October 30, 2011, unless earlier redeemed or extended by the board of directors.

### Right to Purchase Company Stock

In the event a person becomes the owner of 15% or more of the outstanding shares of common stock and thus becomes an Acquiring Person (a "Flip-In Event"), the Rights not held by the Acquiring Person "flip-in" and, instead of continuing as rights to buy one share of common stock, become rights to buy from us shares of common stock having a value equal to two times the Purchase Price under the Right. In other words, a Rights holder (other than the Acquiring Person) may purchase common stock at a 50% discount.

In the event there is insufficient common stock to permit exercise in full of the Rights, we must issue cash, property or other securities of the Company with an aggregate value equal to twice the Purchase Price.

Upon the occurrence of any Flip-In Event, any Rights owned by an Acquiring Person, its affiliates and associates and certain transferees thereof shall become null and void.

42

### Right to Purchase Acquiring Person Stock

In the event that a person becomes an Acquiring Person and the Company is then merged with the common stock being exchanged or converted in the merger, then each Right (other than those formerly held by the Acquiring Person, which became void) would "flip-over" and be exercisable for a number of shares of common stock of the acquiring company having a market value of two times the Purchase Price under the Right. In other words, a Rights holder may purchase the acquiring company's common stock at a 50% discount.

### Exchange of Rights for Common Stock

After a Flip-In Event occurs but before a "flip-over" event (as described above) occurs and before an Acquiring Person becomes the owner of 50% or more of our common stock, the board of directors may cause the Rights (either in whole or in part) to be exchanged for shares of common stock (or equivalent securities of equal value) at a one-to-one exchange ratio or pursuant to an equivalent cashless exercise method. Rights held by the Acquiring Person, however, which became void upon the Flip-In Event would not be entitled to participate in such exchange.

### Redemption

The Rights may be redeemed by the board of directors at a redemption price of \$0.01 per Right at any time prior to the earlier of:

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

- o the time that a person or a group becomes an Acquiring Person, or
- o October 30, 2011, the expiration date of the Rights Agreement.

Immediately upon redemption and without further action and without any notice, the right to exercise the Rights will terminate and the only right of the holders will be to receive the redemption price.

### Expiration of Rights

The Rights will expire on October 30, 2011, unless the expiration date is extended by amendment or unless the Rights are earlier redeemed or exchanged by us as described above.

### Amendments or Supplements

For so long as the Rights are redeemable, the terms of the Rights may be amended or supplemented by the board of directors at any time and from time to time without the consent of the holders of the Rights. At any time when the Rights are not redeemable, the board of directors may amend or supplement the terms of the Rights, provided that such amendment does not adversely affect the interests of the holders of the Rights.

### No Rights as Stockholders

Until a Right is exercised, the holder thereof will have no rights as a stockholder of the Company, including, without limitation, the right to vote or to receive dividends.

### Miscellaneous

In order to prevent dilution, the Purchase Price, the number of shares of common stock or other securities or property purchasable upon exercise of each Right and the number of Rights outstanding are subject to adjustment from time to time as provided in the Rights Agreement.

We are not required to issue fractions of Rights or to distribute Right Certificates which evidence fractional Rights (except as may be provided for in the Rights Agreement). In lieu of such fractional Rights, we will pay to the registered holders of the Right Certificates with respect to which such fractional Rights would otherwise be issuable, an amount of cash equal to the same fraction of the current market value of a whole Right.

### Transfer Agent and Warrant Agent

The transfer agent for our common stock, the 2000 Warrants and the 2003 Warrants is American Stock Transfer & Trust Company.

### SHARES ELIGIBLE FOR FUTURE SALE

After the closing of this offering, we will have \_\_\_\_\_ shares of common stock issued and outstanding of which the \_\_\_\_\_ 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



Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/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.

Of the approximately remaining \_\_\_\_\_ shares of common stock that will be outstanding, 1,597,521 are restricted securities as that term is defined under Rule 144.

Except for 243,181 shares, all of the restricted shares are eligible for resale under Rule 144; provided, that shares held by affiliates are subject to limits on volume of sales during any three-month period.

In general, under Rule 144, as currently in effect, a person or group of persons whose shares are aggregated, who has beneficially owned restricted shares for at least one year 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 our affiliates.

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 restricted shares under Rule 144 without regard to any of the limitations described above.

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

We and the underwriters for this offering have entered into an underwriting agreement with respect to the units being offered. Subject to certain conditions, each underwriter has severally agreed to purchase, and we have agreed to sell to them, severally, the respective number of units set forth opposite their names at the public offering price less the underwriting discounts and commission set forth on the cover page of this prospectus below. Roan/Meyers Associates L.P. is the representative of the underwriters.

Underwriters -----	Number of Units -----
Roan/Meyers Associates, L.P. ....	_____
ViewTrade Securities, Inc.....	_____
 Sterling Financial Investment Group, Inc.....	 _____
Advanced Equities, Inc.....	_____

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Total.....

=====

The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the units offered hereby are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the units offered by this prospectus if any

44

units are taken except for those covered by the overallotment option. These conditions include requirements that no stop order be in effect and that no proceedings for such purpose be instituted or threatened by the Securities and Exchange Commission.

The representative has informed us that the underwriters propose to offer the units directly to the public at the public offering price set forth on the cover page hereof and part to certain dealers at a price that represents a concession not in excess of \$ per unit 10% below the public offering price. Any underwriter may allow, and such dealers may re-allow, a concession not in excess of \$ per unit to other dealers including the underwriters. The representative may re-allocate a portion of its concession or non-accountable expense allowance in its discretion among other members of the underwriting syndicate or selling group.

We have granted to the underwriters an option, exercisable for 45 days from the date of this prospectus, to purchase up to an aggregate of an additional 15% of the total units sold at the public offering price set forth on the cover page hereof, less underwriting discounts and commissions. The underwriters may exercise such option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the units offered hereby. To the extent such option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase approximately the same percentage of such additional units as the number set forth next to such underwriter's name in the preceding table bears to the total number of units set forth next to the names of all underwriters in that table.

We have also agreed to issue to the representative a unit option agreement granting the representative the right to purchase up to 10% of the units sold (not including the possible exercise of the overallotment option) at an exercise price equal to 165% of the initial offering price of the units. The exercise price and the number of underlying securities in the warrants contained in the representative's units are subject to adjustment upon the same terms as contained the 2003 Warrants being sold in the units. The sale price of the unit option is \$0.001 multiplied by the number of units covered by the option. The securities to be delivered upon exercise of the representative's warrants are the same as the units being sold to the public in this offering; provided, however, the exercise price of the representative's warrant received upon exercise of its unit option agreement is equal to 165% of the exercise price of the 2003 Warrants. These warrants are exercisable during the four-year period beginning one year from the date of effectiveness of the registration statement of which this prospectus forms a part. The representative's Unit Purchase Option will be restricted from sale, transfer, assignment or hypothecation for a period of one year from the effective date of the offering except to officers or

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

partners (not directors) of the underwriter and members of the selling group and/or their officers or partners in compliance with NASD Rule 2710(c) (7) (A).

The representative's unit purchase option is not redeemable by us. In addition, we have agreed to certain "demand and piggyback" registration rights for the securities underlying the representative's unit purchase option. The holder of the representative's unit purchase option can demand, on one occasion, at anytime until five years from the effective date of the registration statement, that we register the shares and warrants for resale under the Securities Act. The "piggyback" registration provisions provide that we will include the underlying shares and 2003 Warrants in any registration statement filed by us during the five-year period commencing after the effective date with certain exceptions.

The holder of the representative's unit purchase option will have, in that capacity, no voting, dividend or other stockholder rights. Any profit realized by the representative on the sale of the securities issuable upon exercise of the representative's unit purchase option may be deemed to be additional underwriting compensation. The securities underlying the representative's unit purchase option are being registered in the registration statement of which this prospectus forms a part. During the term of the representative's unit purchase option, the holders thereof are given the opportunity to profit from a rise in the market price of our common stock. We may find it more difficult to raise additional equity capital while the representative's unit purchase options are outstanding.

The 2003 Warrants are subject to redemption provided: (i) at least one year has passed since the closing date of the offering; (ii) we provide investors with at least 30 days' notice of redemption; (iii) the average closing bid quotation of our common stock for the 20-day period prior to the date of notice of redemption is at least \$ \_\_\_\_\_ and (iv) there is an effective registration statement providing for the issuance of the underlying shares of common stock. We have agreed, in connection with the exercise of the 2003 Warrants pursuant to solicitation following a notice of redemption from the Company, to pay to Roan/Meyers a fee of 5% of the exercise price for each 2003 Warrant exercised; provided, however, that Roan/Meyers will not be entitled to receive such compensation in connection with warrant exercise transactions in which (i) the market price of our common stock at the time of exercise is lower than the exercise price of the 2003 Warrants; (ii) the 2003 Warrants are held in any discretionary account; (iii) disclosure of compensation arrangements is not made, in addition to the disclosure provided in this prospectus, in documents provided

45

to holders of the 2003 Warrants at the time of exercise; (iv) at the time of exercise, the holder of the 2003 Warrant that is electing to exercise has not confirmed in writing that Roan/Meyers solicited such exercise; or (v) the solicitation or

exercise of the 2003 Warrants was in violation of Regulation M under the Securities and Exchange Act of 1934. In addition, unless granted an exemption by the Securities and Exchange Commission from Regulation M, Roan/Meyers will be prohibited from engaging in any market making activities or solicited brokerage activities until the later termination of such solicitation activity or the termination by waiver or otherwise of any right Roan/Meyers may have to receive a fee for the exercise of the 2003 Warrants following such solicitation. Such a

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

prohibition, while in effect, could impair the liquidity and market price of the securities offered pursuant to this offering.

We have also previously paid to Roan/Meyers \$45,000 on account of the underwriters expenses in connection with this offering to be applied to the non-accountable expense allowance equal to 3% of the gross proceeds of the offering (including proceeds from the sale, if any, of the over-allotment option securities).

### REGULATION M

In order to facilitate the offering of the units, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the units. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of units available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing units in the open market. In determining the source of units to close out a covered short sale, the underwriters will consider, among other things, the open market price of the units compared to the price available under the over-allotment option. The underwriters may also sell units in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing units in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the unit in the open market after pricing that could adversely affect investors who purchase in the offering. As an additional means of facilitating the offering, the underwriters may bid for, and purchase, units in the open market to stabilize the price of the units. The underwriting syndicate may also reclaim selling concessions allowed to an underwriter or a dealer for distributing the units in the offering, if the syndicate repurchases previously distributed units to cover syndicate short positions or to stabilize the price of the unit (commonly referred to as the imposition of "penalty bids"). These activities may raise or maintain the market price of the units offered hereby above independent market levels or prevent or retard a decline in the market price of the units offered hereby. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

### DETERMINATION OF OFFERING PRICE

The initial public offering price of the units offered by this prospectus and the exercise price of the 2003 Warrants were determined by negotiation between us and the representative. Among the factors considered in determining the initial public offering price of the units and the exercise price of the warrants were:

- o our history and our prospects;
- o the trading price of our common stock prior to the date of this prospectus;
- o the industry in which we operate;
- o the status and development prospects for our proposed products;

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

- o our past and present operating results;
- o the previous experience of our executive officers; and
- o the general condition of the securities markets at the time of this offering.

46

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the units. The price of our common stock and the 2003 Warrants is subject to change as a result of market conditions and other factors.

### CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS AND FINANCIAL DISCLOSURE

On April 12, 2002, KPMG LLP resigned as our independent auditors. The report of KPMG on our balance sheet as of December 31, 2001 and the related statements of operations, stockholders' equity and cash flows for each of the years in the two-year period ended December 31, 2001 and for the period from August 5, 1988 (inception) to December 31, 2001 did not contain any adverse opinion or disclaimer of opinion, nor were they modified as to uncertainty, audit scope or accounting principles.

In connection with the audits of the periods described above, and the subsequent interim period through April 12, 2002, there were no disagreements between us and KPMG on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to KPMG's satisfaction, would have caused KPMG to make reference to the subject matter of the disagreement(s) in connection with its reports.

On April 25, 2002, we engaged Eisner LLP, formerly Richard A. Eisner & Company, LLP, New York, New York, as our independent auditors.

### LEGAL MATTERS

The validity of the common stock and the 2003 Warrants offered hereby will be passed upon for Delcath by Cummings & Lockwood LLC, Stamford, Connecticut, counsel for Delcath. Goldstein & DiGioia LLP, New York, New York, has served as counsel for the underwriters.

### EXPERTS

Our financial statements as of December 31, 2002 and for each of the two years then ended and cumulative from inception (August 5, 1988) to December 31, 2002 have been included in this prospectus in reliance upon the report of Eisner LLP, independent auditors, appearing elsewhere herein, based upon their authority as experts in accounting and auditing.

### WHERE YOU CAN FIND MORE INFORMATION

We file periodic reports under the Securities Exchange Act of 1934, as amended, that include information about us. We have also filed with the SEC in Washington, D.C., a registration statement under the Securities Act with the respect to the units offered by this prospectus. This prospectus does not contain all the information set forth in the registration statement and the

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

exhibits and schedules thereto. For further information with respect to us and the units, we refer you to the registration statement and the exhibits and schedules filed therewith. The registration statement and the exhibits and schedules forming a part thereof may be inspected without charge at the public reference facilities maintained by the SEC at 450 Fifth Street, N.W., Washington, D.C. 20549 and copies of such materials can be obtained from the Public Reference Section of the SEC at 450 Fifth Street, N.W., Washington, D.C. 20549, at prescribed rates. Please call the SEC at 1-800-SEC-0330 for further information regarding the public reference facilities. In addition, the SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC at [http:// www.sec.gov](http://www.sec.gov).

Statements made in this prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete. With respect to each such contract, agreement or other document filed as an exhibit to the registration statement, we refer you to the exhibit to the registration statement referencing the item for a more complete description of the matter involved, and each such statement is qualified in its entirety by reference thereto.

DELCATH SYSTEMS, INC.  
INDEX TO FINANCIAL STATEMENTS

Audited Financial Statements as of December 31, 2002 and for each of the two years in the period ended December 31, 2002, and cumulative from inception (August 5, 1988) to December 31, 2002:

	Page
	----
Independent Auditors' Report.....	F-2
Balance Sheet as of December 31, 2002.....	F-3
Statements of Operations for the years ended December 31, 2001 and 2002 and cumulative from inception (August 5, 1988) to December 31, 2002.....	F-4
Statements of Stockholders' Equity for the years ended December 31, 2001 and 2002 and cumulative from inception (August 5, 1988) to December 31, 2002.....	F-5
Statements of Cash Flows for the years ended December 31, 2001 and 2002 and cumulative from inception (August 5, 1988) to December 31, 2002.....	F-6
Notes to Financial Statements.....	F-7

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

INDEPENDENT AUDITORS' REPORT

The Board of Directors  
Delcath Systems, Inc.:

We have audited the accompanying balance sheet of Delcath Systems, Inc. (a development stage company) as of December 31, 2002, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2002 and for the period from August 5, 1988 (inception) to December 31, 2002. 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 auditing standards generally accepted in the United States of America. 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 enumerated above present fairly, in all material respects, the financial position of Delcath Systems, Inc. (a development stage company) as of December 31, 2002, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2002 and for the period from August 5, 1988 (inception) to December 31, 2002, in conformity with accounting principles generally accepted in the United States of America.

/s/ Eisner LLP  
Eisner LLP  
New York, NY  
February 6, 2003

F-2

DELCATH SYSTEMS, INC.  
(A Development Stage Company)

Balance Sheet

December 31,  
2002  
-----

Assets

Current assets:

Cash and cash equivalents .....	\$ 1,063,650
Certificate of deposit .....	370,000
Interest receivable .....	5,406
Prepaid insurance .....	96,583

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Total current assets .....	1,535,639
Furniture and fixtures, net .....	13,750
Deferred costs in connection with a proposed financing transaction .....	238,571
Due from affiliate .....	24,000
	-----
Total assets .....	\$ 1,811,960
	=====
Liabilities and Stockholders' Equity	
Current liabilities:	
Accounts payable and accrued expenses .....	\$ 175,170
	-----
Total current liabilities .....	175,170
	-----
Stockholders' equity:	
Preferred stock, \$.01 par value; 10,000,000 shares authorized; no shares issued and outstanding .....	--
Common stock, \$.01 par value; 15,000,000 shares authorized; 4,146,997 shares issued and 4,118,897 outstanding .....	41,189
Additional paid-in capital .....	19,049,406
Deficit accumulated during development stage .....	(17,453,805)
	-----
Total stockholders' equity .....	1,636,790
	-----
Total liabilities and stockholders' equity .....	\$ 1,811,960
	=====

See accompanying notes to financial statements

F-3

DELCATH SYSTEMS, INC.  
(A Development Stage Company)  
Statements of Operations

	Year ended December 31,		Cu from (Augu Decem
	2001	2002	
	-----	-----	-----
Costs and expenses:			
General and administrative expenses .....	\$ 953,652	\$ 723,763	\$



Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Research and development costs .....	1,115,004	1,173,275	
	-----	-----	-----
Total costs and expenses .....	2,068,656	1,897,038	
	-----	-----	-----
Operating loss .....	(2,068,656)	(1,897,038)	
Other income (expense):			
Interest income .....	208,220	89,992	
Interest expense .....	(15,571)	--	
	-----	-----	-----
Net loss .....	\$ (1,876,007)	\$ (1,807,046)	\$
	=====	=====	=====
Common share data:			
Basic and diluted loss per share .....	\$ (0.48)	\$ (0.44)	
	=====	=====	-----
Weighted average number of basic and diluted common shares outstanding .....	3,903,816	4,085,049	
	=====	=====	-----

See accompanying notes to financial statements.

F-4

DELCATH SYSTEMS, INC.  
(A Development Stage Company)

Statements of Stockholders' Equity

Years ended December 31, 2002 and 2001 and  
cumulative from inception (August 5, 1988) to December 31, 2000

	Common stock \$.01 par value				No. sh
	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 8, 1990	--	--	(414,059)	(4,141)	
Sale of stock, October 2, 1990 .....	--	--	17,252	173	
Sale of stock, January 23, 1991 .....	--	--	46,522	465	

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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	--	--	
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	--	--	
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	--	--	
Sale of stock, April 14, 2000 .....	230,873	2,309	--	--	
Dividends paid on preferred stock ..	690,910	6,909	--	--	
Conversion of preferred stock .....	833,873	8,339	--	--	
Sale of stock, October 19, 2000 ....	1,200,000	12,000	--	--	1
Shares issued as compensation for stock sale .....	85,000	850	--	--	
Stock options issued as compensation .....	--	--	--	--	
Deficit accumulated from inception to December 31, 2000 .....	--	--	--	--	
	-----	-----	-----	-----	-----
Balance at December 31, 2000 .....	3,903,852	39,039	--	--	3
Sum of fractional common shares cancelled after year 2000 stock splits .....	(36)	(1)	--	--	
Stock warrants issued as compensation .....	--	--	--	--	
Net loss for year ended December 31, 2001 .....	--	--	--	--	
	-----	-----	-----	-----	-----
Balance at December 31, 2001 .....	3,903,816	39,038	--	--	3
Sale of stock on April 3, 2002 .....	243,181	2,432	--	--	
Repurchases of stock, November .....	--	--	(28,100)	(281)	
and December 2002					
Net loss for year ended .....	--	--	--	--	
December 31, 2002 .....	--	--	--	--	
	-----	-----	-----	-----	-----
Balance at December 31, 2002 .....	4,146,997	\$ 41,470	(28,100)	\$ (281)	4
	=====	=====	=====	=====	=====

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

	Class A preferred stock		Class B preferred stock		Addi pa cap
	\$.01 par value		\$.01 par value		
	No. of shares	Amount	No. of shares	Amount	
Shares issued in connection with the formation of the Company as of August 22, 1988 .....	--	\$ --	--	\$ --	\$
Sale of preferred stock, August 22, 1988 .....	2,000,000	20,000	--	--	4
Shares returned as of March 8, 1990 .....	--	--	--	--	
Sale of stock, October 2, 1990 .....	--	--	--	--	
Sale of stock, January 23, 1991 .....	--	--	416,675	4,167	1,4
Sale of stock, August 30, 1991 .....	--	--	--	--	
Sale of stock, December 31, 1992 .....	--	--	--	--	1,0
Sale of stock, July 15, 1994 .....	--	--	--	--	1,1
Sale of stock, December 19, 1996 .....	--	--	--	--	9
Shares issued in connection with conversion of short-term borrowings as of December 22, 1996 .....	--	--	--	--	1,7
Sale of stock, December 31, 1997 .....	--	--	--	--	7
Exercise of stock options .....	--	--	--	--	
Shares issued as compensation .....	--	--	--	--	
Amortization of compensatory stock options granted .....	--	--	--	--	2,4
Forfeiture of stock options .....	--	--	--	--	(2
Shares issued in connection with exercise of warrants .....	--	--	--	--	2
Sale of stock, January 16, 1998 .....	--	--	--	--	4
Sale of stock, September 24, 1998 .....	--	--	--	--	
Shares returned, April 17, 1998 .....	--	--	--	--	
Amortization of compensatory stock options granted .....	--	--	--	--	1,1
Forfeiture of stock options .....	--	--	--	--	(4
Exercise of stock options .....	--	--	--	--	
Sale of stock, June 30, 1999 .....	--	--	--	--	7
Amortization of compensatory stock options granted .....	--	--	--	--	
Forfeiture of stock options .....	--	--	--	--	(5
Shares issued in connection with exercise of warrants .....	--	--	--	--	
Sale of stock, April 14, 2000 .....	--	--	--	--	4
Dividends paid on preferred stock .....	--	--	--	--	9
Conversion of preferred stock .....	(2,000,000)	(20,000)	(416,675)	(4,167)	
Sale of stock, October 19, 2000 .....	--	--	--	--	5,3
Shares issued as compensation for stock sale .....	--	--	--	--	
Stock options issued as compensation .....	--	--	--	--	
Deficit accumulated from inception to December 31, 2000 .....	--	--	--	--	
Balance at December 31, 2000 .....	--	--	--	--	18,6

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Sum of fractional common shares cancelled after year 2000					
stock splits .....	--	--	--	--	
Stock warrants issued as compensation .....	--	--	--	--	1
Net loss for year ended December 31, 2001 .....	--	--	--	--	
	-----	-----	-----	-----	-----
Balance at December 31, 2001 .....	--	\$ --	--	\$ --	\$ 18,8
Sale of stock on April 3, 2002 .....	--	--	--	--	2
Repurchases of stock, November .....	--	--	--	--	(
and December 2002					
Net loss for year ended December 31, 2002 .....	--	--	--	--	
	-----	-----	-----	-----	-----
Balance at December 31, 2002 .....	--	\$ --	--	\$ --	\$ 19,0
	=====	=====	=====	=====	=====

F-5

DELCATH SYSTEMS, INC.  
(A Development Stage Company)  
Statements of Cash Flows

	Year ended December 31,	
	2001	2002
	-----	-----
Cash flows from operating activities:		
Net loss .....	\$ (1,876,007)	\$ (1,807,046)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense .....	--	--
Stock and warrant compensation expense issued for consulting services .....	198,000	--
Depreciation expense .....	5,014	6,410
Amortization of organization costs .....	--	--
Changes in assets and liabilities:		
(Increase) decrease in prepaid expenses .....	(501)	(26,916)
Decrease (increase) in interest receivable .....	(20,920)	47,882
Due from affiliate .....	--	--
(Decrease) increase in accounts payable and accrued expenses .....	(622,835)	(910)
	-----	-----
Net cash used in operating activities .....	(2,317,249)	(1,780,580)
	-----	-----

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Cash flows from investing activities:		
Purchase of furniture and fixtures .....	(13,260)	(6,664)
Purchase of short-term investments .....	(1,500,000)	(370,000)
Proceeds from maturities of short-term investments .....	--	1,500,000
Organization costs .....	--	--
	-----	-----
Net cash provided by (used in) investing activities .....	(1,513,260)	1,123,336
	-----	-----
Cash flows from financing activities:		
Deferred costs in connection with a proposed financing transaction .....	--	(238,571)
Net proceeds from sale of stock and exercise of stock options and warrants .....	--	267,500
Repurchases of outstanding common stock .....	--	(51,103)
Dividends paid .....	--	--
(Repayments of) proceeds from short-term borrowings .....	(230,000)	--
	-----	-----
Net cash (used in) provided by financing activities .....	(230,000)	(22,174)
	-----	-----
(Decrease) increase in cash and cash equivalents .....	(4,060,509)	(679,418)
Cash and cash equivalents at beginning of period .....	5,803,577	1,743,068
	-----	-----
Cash and cash equivalents at end of period .....	\$ 1,743,068	\$ 1,063,650
	=====	=====
Cash paid for interest .....	\$ 36,141	\$ --
	=====	=====
Supplemental non-cash activities:		
Conversion of debt to common stock .....	\$ --	\$ --
	=====	=====
Common stock issued for preferred stock dividends .	\$ --	\$ --
	=====	=====
Conversion of preferred stock to common stock .....	\$ --	\$ --
	=====	=====
Common stock issued as compensation for stock sale .....	\$ --	\$ --
	=====	=====

See accompanying notes to financial statements

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

DELCATH SYSTEMS, INC.  
Notes to Audited Financial Statements  
December 31, 2001 and 2002

### (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). The Company is seeking to complete clinical trials in order to obtain FDA pre-marketing approval for the use of its delivery system using doxorubicin and melphalan, chemotherapeutic agents, to treat malignant melanoma that has spread to the liver.

#### (b) Basis of Financial Statement Presentation

The accounting and financial reporting policies of the Company conform to accounting principles generally accepted in the United States of America. 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 on a straight line basis over the estimated useful lives of the assets of five years. Accumulated depreciation amounted to \$21,074 at December 31, 2002.

#### (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

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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

F-7

granted, prior to the Company's stock becoming publicly traded, 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. Such cost is then recognized over the period the recipient is required to perform services to earn such compensation. If a stock option does not become vested 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 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 (loss) and pro forma earnings (loss) per share disclosures for employee stock option grants 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.

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 No. 123, the Company's net loss and net loss per share for the years ended December 31, 2001 and 2002 would have been increased to the pro forma amounts indicated as follows:

	2001 ----	2002 ----
Net loss	\$ (1,876,007)	\$ (1,807,046)
Stock-based employee compensation expense included in net loss, net of related tax effects	0	0
Stock-based employee compensation determined under the fair value based method, net of related tax effects	(133,263)	(44,769)
	-----	-----
Pro forma net loss	\$ (2,009,270)	\$ (1,851,815)
	=====	=====

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Loss per share (basic and diluted):			
As reported	\$	(0.48)	\$ (0.44)
Pro forma		(0.51)	(0.45)

The per share weighted average fair value of stock options granted during 2001 and 2002 was \$.28 and \$.30, respectively, estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for the grants for 2001 and 2002, respectively: risk free interest rates of 2.84% and 3.6%-4.95% respectively, and volatility of 41% and 26.7% - 36.3%, respectively, while no dividend yield and expected lives of five years were assumed for both years.

(f) Loss Per Share

The Company follows the provisions of SFAS No. 128, "Earnings Per Share," which requires presentation of both basic and diluted earnings per share (EPS) on the face of the Statements of Operations. Basic EPS excludes dilution, and is computed using the weighted average number of common shares outstanding during the period. The diluted EPS calculation assumes all

F-8

dilutive stock options or contracts to issue Common Stock were exercised or converted into Common Stock at the beginning of the period.

For the years ended December 31, 2001 and 2002, the following potential common shares were excluded from the computation of diluted EPS because their effects would be antidilutive:

	2001	2002
	----	----
Shares issuable upon exercise of options	902,936	1,145,684
Shares issuable upon exercise of warrants	1,626,938	1,516,985
Common Stock purchase rights issuable only in the event that a non-affiliated person or group acquires 15% of the Company's then outstanding Common Stock	6,408,690	6,781,566
	-----	-----
Totals	8,938,564	9,444,235
	=====	=====

(g) Research and Development Costs



## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Research and development costs include the costs of materials, personnel, outside services and applicable indirect costs incurred in development of the Company's proprietary drug delivery system. All such costs are charged to expenses when incurred.

(h) Statements of Cash Flows

For purposes of the statements of cash flows, the Company considers highly liquid debt instruments with maturities of three months or less at date of acquisition to be cash equivalents. At December 31, 2002 cash equivalents excluded a certificate of deposit in the amount of \$370,000.

(i) Reclassifications

Reclassifications have been made to reflect cost and expense accounts on a functional basis for 2001 and prior, which is consistent with the Company's current presentation.

F-9

Operating costs and expenses were previously presented as follows:

	Year ended December 31, 2001	Cumulative from inception (August 5, 1988) to December 31, 2001
	-----	-----
Legal, consulting and accounting fees	\$ 1,034,025	\$ 6,025,255
Stock option compensation expense ...	--	2,520,170
Compensation and related expenses ...	557,087	3,304,703
Other operating expenses .....	477,544	2,967,024
	-----	-----
Total costs and expenses .....	\$ 2,068,656	\$14,817,152
	=====	=====

(j) Stock Splits

All share and per share amounts give retroactive effect to stock splits effected by the Company.

(2) Stockholders' Equity

(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 BGH - Delaware

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Common Shares. 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 Common Shares 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 by certain stockholders 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 Treasury Stock, \$.01 par value, for an aggregate amount of \$25,000.

F-10

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 \$2,000,000. Under the terms of the private placement, 46,522 shares of Common Treasury Stock 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 Shares purchased 117,650 of the Class B Preferred Shares sold in the private placement.

On August 30, 1991, the Company sold an additional 1,353 shares of Common Treasury Stock 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 our 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 Shares purchased 27,604 of the Common Treasury Shares sold.

Effective January 1, 1994, the Company issued 1,725 shares of Common Treasury Stock at \$1.45 per share for a total price of \$2,500 upon the exercise of stock options by an employee of the Company.

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

During the first quarter of 1994, the Company increased its authorized number of Common Shares 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 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 Shares purchased six (6) of the units sold. During August 1997, the holders of warrants exercised 8,916 warrants to purchase 8,916 Common Shares 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 Treasury Stock 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 in Japan, Korea, China, Taiwan, and Hong Kong through December 31, 2004. No value was attributed to the distribution rights. In addition, under certain conditions, 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

F-11

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 23,003 shares of Common Stock 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 Common Shares 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.

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

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 received \$775,000 and issued 53,483 shares of Common Stock. During January 1998, the Company received an additional \$500,000 and issued another 34,505 shares of Common Stock. In April 1998, under the terms of restricted stock sale 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 Common Shares at \$10.87 per share. These warrants expired unexercised in April 2001.

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

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 restricted 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 expired April 30, 2002), yielding proceeds to the Company of \$776,192.

In April 2000, the Company sold 230,873 Common Shares at \$2.17 per share to existing stockholders in a rights offering yielding proceeds to the Company of \$501,825.

The Company completed an initial public offering ("IPO") on October 19, 2000 of 1,200,000 units for \$6.00 per unit, each unit consisting of one share of Common Stock and one redeemable warrant to purchase one share of Common Stock at a price of \$6.60 until October 18, 2005. In connection with the initial public offering, the Company received \$7,200,000 before offering costs (\$5,371,468 after expenses). The Company also issued to the underwriters warrants to purchase 120,000 units for \$6.60 per unit, each unit consisting of one Common Share and one redeemable warrant to purchase one share of Common Stock at a price of \$10.50

F-12

until October 18, 2005. The Company also issued 85,000 shares of Common Stock valued at \$510,000 for legal services provided in connection with the offering.

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

Also, in connection with the initial public offering, the holders of the 2,000,000 outstanding shares of the Company's Class A Preferred Stock and the 416,675 outstanding shares of the Company's Class B Preferred Stock agreed to convert their shares into Common Stock prior to the closing of the offering. Upon the conversion of the Company's Class A Preferred Stock and the Company's Class B Preferred Stock into 833,873 shares of Common Stock, the holders of the Class A and Class B shares received an aggregate of \$499,535 in cash and 690,910 shares of Common Stock valued at \$990,070 in payment of declared dividends.

In December 2000, the Company issued 1,720 Common Stock options at an exercise price of \$3.31, fair valued at \$2.21 per option for a total of \$3,800, and 1,720 warrants to purchase Common Stock at an exercise price of \$6.00, fair valued at \$0 per warrant, as compensation for consulting services. Both the options and warrants expire December 1, 2005.

The Company issued the following Common Stock warrants in 2001 for consulting services:

(1) 150,000 fully vested warrants to purchase 150,000 units at \$7.00 per unit, through January 4, 2005, each unit consisting of one fully-paid and non-assessable share of Common Stock, and one Common Stock purchase warrant entitling the holder to purchase one share of Common Stock for \$6.60 per share. None of these warrants have been exercised as of December 31, 2002. Such warrants, valued at \$175,000, were recognized as an expense in the first quarter of 2001; and

(2) 150,000 warrants to purchase up to 150,000 shares of Common Stock, through April 30, 2005, for \$6.60 per share. 25,000 of such warrants vested in 2001 and the remaining 125,000 warrants would have vested by May 2002 if the share price of the Company's Common Stock exceeded certain share price levels above the IPO price by May 2002. As of May 2002, none of the thresholds had been met, and the 125,000 remaining warrants did not vest and were forfeited. None of the 25,000 vested warrants had been exercised as of December 31, 2002. The 25,000 vested, non-contingent warrants have been valued at \$23,000, and were recognized as an expense in the first quarter of 2001. The expenses, as noted in (1) and (2) above, recognized with these two warrant issues are non-cash expenses.

The values of the above warrants were \$1.17 per warrant for warrants described in (1) above, and \$ .90 per warrant for the 25,000 warrants that vested immediately described in (2) above, and were estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions, respectively: risk free interest rates of 4.95% and 5.9%, volatility of 26.7% and 22.9%, expected lives of four years and four and one half years, with no dividend yield for either issue.

In 2001, the Company cancelled a total of 36 shares of Common Stock which represented the total of fractional shares resulting from stock splits during September and October 2000 in connection with the Company's initial public offering.

On October 30, 2001, the Company entered into a Rights Agreement with American Stock Transfer & Trust Company (the "Rights Agreement") in connection with the implementation of the Company's

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

stockholder rights plan (the "Rights Plan"). The purposes of the Rights Plan are to deter, and protect the Company's shareholders from, certain coercive and otherwise unfair takeover tactics and to enable the Board of Directors to represent effectively the interests of shareholders in the event of a takeover attempt. The Rights Plan does not deter negotiated

F-13

mergers or business combinations that the Board of Directors determines to be in the best interests of the Company and its shareholders.

To implement the Rights Plan, the Board of Directors declared a dividend of one Common Stock purchase right (a "Right") for each share of Common Stock of the Company, par value \$0.01 per share (the "Common Stock") outstanding at the close of business on November 14, 2001 (the "Record Date") or issued by the Company on or after such date and prior to the earlier of the Distribution Date, the Redemption Date or the Final Expiration Date (as such terms are defined in the Rights Agreement). The rights expire October 30, 2011. Each Right entitles the registered holder to purchase from the Company one share of Common Stock, at a price of \$5.00 per share, subject to adjustment (the "Purchase Price"), in the event that a person, or group announces that it has acquired, or intends to acquire, 15% or more of the Company's outstanding Common Stock.

On April 3, 2002, the Company received \$267,500 by completing a private placement of 243,181 shares of its Common Stock and warrants to purchase up to 20,265 shares of Common Stock at an exercise price of \$1.32 per share that expire on April 3, 2005.

(b) Common Stock Repurchases

Pursuant to a stock repurchase plan approved in 2002 by the Company's Board of Directors, the Company repurchased 28,100 shares of Common Stock for \$51,103 during 2002. The Company has been authorized by the Board of Directors to purchase up to seven percent of its outstanding Common Stock.

(c) Stock Option Plans

The Company established an Incentive Stock Option Plan, a Non-Incentive Stock Option Plan, the 2000 Stock Option Plan and the 2001 Stock Option Plan (collectively, the "Plans") under which stock options may be granted. Additionally, the Company has entered into separate contracts apart from the Plans under which options to purchase Common Stock have been granted. A stock option grant 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 Compensation Committee of 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 Option Plans were approved and became effective on November 1, 1992. During 2000 and 2001, respectively, the 2000 and 2001 Stock Option Plans became

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

effective. Options granted under the Plans vest as determined by the Company and expire over varying terms, but not more than five years from the date of grant. Stock option activity for the period January 1, 2001 through December 31, 2002 is as follows:

F-14

	The Plans		Other Option Grants	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2000	689,684	\$ 3.82	17,252	\$ 2.90
Granted during 2001	280,000	.83	--	--
Expired during 2001	(84,000)	3.31	--	--
Outstanding at December 31, 2001	885,684	2.94	17,252	2.90
Granted during 2002	260,000	.71	--	--
Expired during 2002	--		(17,252)	2.90
Outstanding at December 31, 2002	1,145,684	\$ 2.43	--	\$ --

F-15

The following summarizes information about shares subject to option at December 31, 2002:

Options outstanding				Options
Number outstanding	Range of exercise prices	Weighted average exercise price	Weighted average remaining life in years	Number exercisable
100,000	\$ .60	\$ .60	3.92	50,000
260,000	.71	.71	4.25	

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

150,000	.85	.85	4.00	66,000
30,000	1.53	1.53	3.67	7,500
172,525	2.90	2.90	2.00	172,525
164,020	3.31	3.31	2.95	164,020
269,139	4.93	4.93	1.00	269,139
-----				-----
1,145,684	\$ .60 - \$4.93	\$2.43	2.88	729,184
=====	=====	=====	=====	=====

At December 31, 2001, options for 622,936 shares were exercisable at a weighted average exercise price of \$3.89 per share.

(3) Income Taxes

As of December 31, 2002, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$12,882,000 which may be available to offset future federal taxable income, if any, through 2022. The use of net operating loss carryforwards is subject to limitation in the event of a change in the Company's ownership, as defined by federal income tax regulations. The net operating loss carryforwards resulted in a deferred tax asset of approximately \$4,380,000 at December 31, 2002 (\$3,777,000 at December 31, 2001). Management does not expect the Company to be taxable in the near future and established a 100% valuation allowance against the deferred tax asset created by the net operating loss carryforwards at December 31, 2002 and 2001. The valuation allowance increased \$603,000 during the year ended December 31, 2002 and \$568,000 during the year ended December 31, 2001.

(4) Due From Affiliate

The Company sublet office space from a corporation controlled by an officer of the Company (the "affiliate"), whose lease with the landlord expired August 1997. Thereafter, the Company's occupancy of the premises continued pursuant to an informal arrangement, under which the Company remitted monthly rental payments directly to the landlord. Rent expense incurred pursuant to this arrangement amounted to \$87,376 for 2001. The informal arrangement was replaced as of January 1, 2002 with a lease agreement between the Company and the landlord (see Note 6). In connection with its occupancy, the Company paid the affiliate \$24,000 which the affiliate then paid to the landlord as a deposit on the lease.

(5) Deferred Costs in Connection with a Proposed Financing Transaction

On December 5, 2002, the Company filed with the Securities and Exchange Commission a registration statement for the issuance of units, each unit to consist of Common Shares and warrants to purchase Common Shares. The Company has incurred \$238,571 of costs associated

F-16

with the transaction. These costs will be netted against the proceeds from the stock offering and charged to additional paid-in capital, or charged to expense if the transaction is not consummated. As of December 31, 2002, \$21,705 of these costs were accrued.



## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

### (6) Rents

On April 1, 2002, the Company executed an Amendment of Lease (the "Amendment") directly with the landlord. The Amendment is effective January 1, 2002 and expires December 22, 2003, and can be renewed by the Company for an additional three years. Rent expense under this lease for the year ended December 31, 2002 was \$89,082. Future minimum rent under this lease is \$91,055 for the year ending December 31, 2003. (7) Subsequent Event

On January 31, 2003, the stockholders voted to approve an amendment to the Company's Certificate of Incorporation to increase the authorized number of shares of Common Stock, par value \$0.01 per share, from 15 million to 35 million.

F-17

[LOGO - DELCATH SYSTEMS INC.]

### TABLE OF CONTENTS

PROSPECTUS SUMMARY.....	1
THE OFFERING.....	2
SUMMARY FINANCIAL DATA.....	3
RISK FACTORS.....	4
SPECIAL NOTE REGARDING	
FORWARD-LOOKING	
STATEMENTS.....	10
USE OF PROCEEDS.....	10
MARKET FOR COMMON EQUITY	
AND RELATED STOCKHOLDER	
MATTERS.....	12
DIVIDEND POLICY.....	13
CAPITALIZATION.....	13
SELECTED FINANCIAL DATA.....	14
PLAN OF OPERATION.....	15
BUSINESS.....	17
MANAGEMENT.....	30
PRINCIPAL STOCKHOLDERS.....	36
RELATED PARTY	
TRANSACTIONS.....	38
DESCRIPTION OF OUR CAPITAL	
STOCK AND OTHER	
SECURITIES.....	38
SHARES ELIGIBLE FOR FUTURE	
SALE.....	44
UNDERWRITING.....	44
CHANGES IN AND DISAGREEMENTS	
WITH ACCOUNTANTS AND	
FINANCIAL DISCLOSURE.....	47

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

LEGAL MATTERS.....47  
 EXPERTS.....47  
 WHERE YOU CAN FIND MORE  
 INFORMATION.....47  
 INDEX TO FINANCIAL  
 STATEMENTS.....F-1

PART II

Item 25. Other Expenses of Issuance and Distribution

The following table sets forth the expenses (other than the underwriting discounts and commissions of 10% and the representative's non-accountable expense allowance of 3%) 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 .....	\$318
Filing Fee - National Association of Securities Dealers, Inc.....	845
Filing Fee - Boston Stock Exchange.....	12,500
Filing Fee - Nasdaq Small Cap Market.....	26,500
Fees and Expenses of Accountants .....	65,000
Fees and Expenses of Counsel .....	200,000
Printing and Engraving Expenses .....	20,500
Blue Sky Fees and Expenses .....	10,000
Transfer Agent Fees .....	5,000
Miscellaneous Expenses .....	6,337
	-----
Total:	\$346,500
	=====

ITEM 27. EXHIBITS

Exhibit No. -----	Description -----
1	Form of Underwriting Agreement. (incorporated by reference to Exhibit 1 to Amendment No. 1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-101661)).
3.1	Amended and Restated Certificate of Incorporation of Delcath Systems, Inc. (incorporated by reference to Exhibit 3.1 to Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2002 (File No. 001-16133)).
3.2	Amended and Restated By-Laws of Delcath Systems, Inc. (incorporated by reference to Exhibit 3.2 to Amendment No.

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

- 1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
- 4.1 Form of Underwriter's Unit Purchase Warrant Agreement (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-101661)).
- 4.2 Specimen 2003 Warrant (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-101661)).
- 4.2 Specimen 2003 Warrant.
- 4.3 Warrant Agreement, dated January 5, 2001, by and between Delcath Systems, Inc. and Euroland Marketing Solutions, Ltd. (incorporated by reference to Exhibit 4.5 to the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2000 (Commission File No. 001-16133)).
- 4.4 Warrant No. W-2 to purchase up to 150,000 units granted to Euroland Marketing Services, Ltd. (incorporated by reference to Exhibit 4.6 to the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2000 (Commission File No. 001-16133)).
- 4.5 Rights Agreement, dated October 30, 2001, by and between Delcath Systems, Inc. and American Stock Transfer & Trust Company, as Rights Agent (incorporated by reference to Exhibit 4.7 to Registrant's Form 8-A dated

II-1

Exhibit No. -----	Description -----
4.6	November 12, 2001 (Commission File No. 001-16133)). Form of Warrant Agreement by and between Delcath Systems, Inc. and Whale Securities Co., L.P. (incorporated by reference to Exhibit 4.2 to Amendment No. 5 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
4.7	Form of Warrant Agreement by and between American Stock Transfer & Trust Company, as warrant agent, Whale Securities Co., L.P. and Delcath Systems, Inc. (incorporated by reference to Exhibit 4.3 to Amendment No. 5 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
4.8	Form of Warrant Agent Agreement by and between Delcath Systems, Inc. and American Stock Transfer & Trust Company, as warrant agent with respect to the 2003 Warrants.
5	Opinion of Cummings & Lockwood LLC.
10.1	1992 Incentive Stock Option Plan (incorporated by reference to Exhibit 10.1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
10.2	1992 Non-Incentive Stock Option Plan (incorporated by reference to Exhibit 10.2 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
10.3	2000 Stock Option Plan (incorporated by reference to Exhibit 10.3 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

- 10.4 2001 Stock Option Plan (incorporated by reference to Exhibit 10.12 to Amendment No. 1 to Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2001 (Commission File No. 001-16133)).
- 10.5 Employment Agreement, dated April 30, 1996, between Delcath Systems, Inc. and M.S. Koly, as amended on April 30, 1999 (incorporated by reference to Exhibit 10.4 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
- 10.6 Employment Agreement, dated April 30, 1996, between Delcath Systems, Inc. and Samuel Herschkowitz, M.D., as amended on April 30, 2000 (incorporated by reference to Exhibit 10.4 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
- 10.7 Distributorship Agreement, dated as of December 27, 1996, by and between Delcath Systems, Inc. and Nissho Corporation (incorporated by reference to Exhibit 10.6 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
- 10.8 Consulting Services Agreement, between Delcath Systems, Inc. and Euroland Marketing Solutions, Ltd. (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2000 (Commission File No. 001-16133)).
- 10.9 Amendment to Key Employment Agreement, dated October 30, 2001, by and between Delcath Systems, Inc. and M. S. Koly (incorporated by reference to Exhibit 10.10 to Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2001 (Commission File No. 001-16133)).
- 10.10 Amendment to Key Employment Agreement, dated October 30, 2001, by and between Delcath Systems, Inc. and Samuel Herschkowitz (incorporated by reference to Exhibit 10.11 to Registrant's Quarterly Report on Form 10-Q for

II-2

Exhibit No. -----	Description -----
	the period ended September 30, 2001 (Commission File No. 001-16133)).
23.1	Consent of Eisner LLP.
23.2	Consent of Cummings & Lockwood LLC (to be contained in Exhibit 5 hereto).
24	Powers of Attorney (incorporated by reference to Exhibit 24 to the Registrant's Registration Statement on Form SB-2 (Registration No. 333-101661)).

II-3

SIGNATURES

Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

In accordance with the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements of filing on Form SB-2 and authorized this amendment to its registration statement to be signed on its behalf by the undersigned, in City of Stamford, State of Connecticut on May 2, 2003.

DELCATH SYSTEMS, INC.

By: /s/ M. S. Koly

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

Pursuant to the requirements of the Securities Act of 1933, this amendment to the registration statement has been signed below by the following persons in the capacities and on the date indicated.

Signature -----	Title -----	)
M.S.	KOLY Chief Executive Officer (Principal Executive Officer) and Director	)
THOMAS S. GROGAN	Chief Financial Officer (Principal Financial and Accounting Officer)	)
SAMUEL HERSCHOWITZ, M.D.	Chairman and Director	)
MARK A. CORIGLIANO	Director	)
DANIEL ISDANER	Director	)
VICTOR NEVINS	Director	)

) By /s/ M. S. Koly  
-----  
M. S. Koly  
Attorney-in-fact

) Date: May 2, 2003

EXHIBIT INDEX

Exhibit No. -----	Description -----
1	Form of Underwriting Agreement. (incorporated by reference to Exhibit 1 to Amendment No. 1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-101661)).
3.1	Amended and Restated Certificate of Incorporation of Delcath Systems, Inc. (incorporated by reference to Exhibit 3.1 to Registrant's Annual Report on Form 10-KSB for the

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

- 3.2 year ended December 31, 2002 (File No. 001-16133)).  
Amended and Restated By-Laws of Delcath Systems, Inc. (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
- 4.1 Form of Underwriter's Unit Warrant Agreement (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-101661)).
- 4.2 Specimen 2003 Warrant (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-101661)).
- 4.2 Specimen 2003 Warrant.
- 4.3 Warrant Agreement, dated January 5, 2001, by and between Delcath Systems, Inc. and Euroland Marketing Solutions, Ltd. (incorporated by reference to Exhibit 4.5 to the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2000 (Commission File No. 001-16133)).
- 4.4 Warrant No. W-2 to purchase up to 150,000 units granted to Euroland Marketing Services, Ltd. (incorporated by reference to Exhibit 4.6 to the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2000 (Commission File No. 001-16133)).
- 4.5 Rights Agreement, dated October 30, 2001, by and between Delcath Systems, Inc. and American Stock Transfer & Trust Company, as Rights Agent (incorporated by reference to Exhibit 4.7 to Registrant's Form 8-A dated November 12, 2001 (Commission File No. 001-16133)).
- 4.6 Form of Warrant Agreement by and between Delcath Systems, Inc. and Whale Securities Co., L.P. (incorporated by reference to Exhibit 4.2 to Amendment No. 5 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
- 4.7 Form of Warrant Agreement by and between American Stock Transfer & Trust Company, as warrant agent, Whale Securities Co., L.P. and Delcath Systems, Inc. (incorporated by reference to Exhibit 4.3 to Amendment No. 5 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
- 4.8 Form of Warrant Agent Agreement by and between Delcath Systems, Inc. and American Stock Transfer & Trust Company, as warrant agent with respect to the 2003 Warrants.
- 5 Opinion of Cummings & Lockwood LLC.
- 10.1 1992 Incentive Stock Option Plan (incorporated by reference to Exhibit 10.1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
- 10.2 1992 Non-Incentive Stock Option Plan (incorporated by reference to Exhibit 10.2 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).

Exhibit No.  
-----

Description  
-----

## Edgar Filing: DELCATH SYSTEMS INC - Form SB-2/A

- 333-39470)).
- 10.3 2000 Stock Option Plan (incorporated by reference to Exhibit 10.3 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
- 10.4 2001 Stock Option Plan (incorporated by reference to Exhibit 10.12 to Amendment No. 1 to Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2001 (Commission File No. 001-16133)).
- 10.5 Employment Agreement, dated April 30, 1996, between Delcath Systems, Inc. and M.S. Koly, as amended on April 30, 1999 (incorporated by reference to Exhibit 10.4 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
- 10.6 Employment Agreement, dated April 30, 1996, between Delcath Systems, Inc. and Samuel Herschkowitz, M.D., as amended on April 30, 2000 (incorporated by reference to Exhibit 10.4 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
- 10.7 Distributorship Agreement, dated as of December 27, 1996, by and between Delcath Systems, Inc. and Nissho Corporation (incorporated by reference to Exhibit 10.6 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
- 10.8 Consulting Services Agreement, between Delcath Systems, Inc. and Euroland Marketing Solutions, Ltd. (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2000 (Commission File No. 001-16133)).
- 10.9 Amendment to Key Employment Agreement, dated October 30, 2001, by and between Delcath Systems, Inc. and M. S. Koly (incorporated by reference to Exhibit 10.10 to Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2001 (Commission File No. 001-16133)).
- 10.10 Amendment to Key Employment Agreement, dated October 30, 2001, by and between Delcath Systems, Inc. and Samuel Herschkowitz (incorporated by reference to Exhibit 10.11 to Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2001 (Commission File No. 001-16133)).
- 23.1 Consent of Eisner LLP.
- 23.2 Consent of Cummings & Lockwood LLC (to be contained in Exhibit 5 hereto).
- 24 Powers of Attorney (incorporated by reference to Exhibit 24 to the Registrant's Registration Statement on Form SB-2 (Registration No. 333-101661)).