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DELCATH SYSTEMS INC
Form S-3
April 19, 2004

As filed with the Securities and Exchange Commission on April 19, 2004.

Registration No. 333-_____

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

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

DELCATH SYSTEMS, INC.
(Exact name of Issuer as specified in its charter)

1100 Summer Street
3rd Floor
Stamford, Connecticut 06905
(203) 323-8668
(Address, Including Zip Code, and Telephone Number, Including
Area Code of Registrant's Principal Executive Office)

M. S. Koly
President and Chief Executive Officer
Delcath Systems, Inc.
1100 Summer Street
3rd Floor
Stamford, Connecticut 06905
(203) 323-8668

Copies to:

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APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: As soon as practicable after this Registration Statement becomes effective.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. []

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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, other than securities offered only in connection with dividend or interest reinvestment plans, please check the following box. [X]

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

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier registration. If the delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. []

CALCULATION OF REGISTRATION FEE UNDER THE SECURITIES ACT OF 1933

| Title of each class of securities to be registered ----- | Number of shares to be registered ----- | Proposed maximum offering price per share (1) ----- | Proposed maximum aggregate offering price ----- | A reg |
|---|--|--|--|----------|
| Common Stock, par value \$0.01 per share, registered for resale by selling shareholders | 2,871,420 | \$2.74 (1) | \$7,867,691 | |
| Common Stock, par value \$0.01 per share, issuable upon exercise of warrants issued in 2000 | 1,200,000 | \$6.60 (2) | \$7,920,000 | |
| Common Stock, par value \$0.01 per share, issuable on exercise of warrants issued in 2003 | 1,898,070 | \$0.775 (3) | \$1,471,004 | |
| | | | ----- \$17,258,695 ===== | ===== |

(1) Estimated in accordance with Rule 457(c) under the Securities Act of 1933, as amended, solely for the purpose of calculating the registration fee. The price shown is the closing price of the Common Stock on April 14, 2004, as reported by the Nasdaq SmallCap Market.

(2) Estimated based on the exercise price of the warrants upon exercise of which such shares may be issued in accordance with Rule 457(g) under the Securities Act of 1933, as amended.

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 EFFECTIVVE IN ACCORDANCE WITH SECTION 8(a) OF

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

Subject to Completion. Dated April 19, 2004

DELCATH SYSTEMS, INC.

Up to 5,969,490 Shares of Common Stock

This prospectus relates to two offerings of our common stock.

The first offering is a primary offering by us of up to 3,098,070 shares that may be issued upon the exercise of warrants that we issued in 2000 and 2003 and that are currently publicly traded. We will receive the proceeds of any exercise of these warrants. If all of these warrants were to be issued, we would receive net proceeds of approximately \$[_____] (after our estimated expenses of these offerings of \$[_____]). Based on the recent prices of our common stock on the Nasdaq SmallCap Market in comparison to the exercise price of the 2003 Warrants, we expect that we will elect to redeem the 2003 Warrants as promptly as practicable. Based on those prices in comparison to the exercise price of our 2000 Warrants, we believe it is likely that few if any of the 2000 Warrants will be exercised.

The second offering is the resale of:

- o up to 1,879,636 shares that we issued in connection with the exercise of warrants we issued as part of a private placement in 2002 and in private placements in 2004 (including shares that we may issue upon exercise of the warrants we issued as part of the private placements in 2004); and
- o up to 991,784 shares that we might issue on the exercise of unit warrants to the underwriters of our public offerings and of warrants that we might issue upon exercise of warrants issued to the placement agents in our 2004 private placement.

If any of the shares described in the preceding paragraph are resold, we will not receive any of the proceeds which will go to the person who sells the shares.

The exercise prices of our 2004 Warrants, 2003 Warrants and 2000 Warrants are subject to adjustment, including anti-dilution provisions for corporate events, such as stock splits. It is possible that none of the 2004 Warrants, the 2003 Warrants or the 2000 Warrants will be exercised.

Our common stock is currently traded on the Nasdaq Small Cap Market and the Boston Stock Exchange under the symbols "DCTH" and "DCT," respectively. Our 2000 Warrants currently trade on the Nasdaq Small Cap Market under the symbol "DCTW." Our 2003 Warrants currently trade on the OTC Bulletin Board and the Boston Stock Exchange under the symbols "DCTHZ" and "DCT&W," respectively. On April __, 2004, our common stock had a closing price of \$ _____ per share, our 2003 Warrants had a closing price of \$0.__ per Warrant and our 2000 Warrants had a closing price of \$0.__ per Warrant.

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Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 1 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 passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2004.

THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. NEITHER WE NOR THE SELLING SHAREHOLDERS MAY SELL THESE SECURITIES UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IT IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

[INSERT BLUE SKY LEGENDS AS NECESSARY]

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No dealer, salesman or other person has been authorized to give any information or to make any representations other than those contained or incorporated in this prospectus. If given or made, such information or representations must not be relied upon as having been authorized by Delcath Systems, Inc., by the selling security holders or by any other person deemed to be an underwriter. Neither the delivery of this prospectus nor any sale made hereunder shall under any circumstances create an implication that the information contained herein is correct as of any time subsequent to the date hereof or that there has been no change in the affairs of Delcath Systems, Inc. since the date hereof. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy the common stock or the warrants covered by this prospectus by anyone in any jurisdiction in which such offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

In this prospectus, "Delcath," "we," "us" and "our" refer in each case to Delcath Systems, Inc.

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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 our securities. 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 securities, as applicable, may decline and you may lose part or all of your investment.

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, a substantial accumulated deficit, recurring operating losses and negative cash flow.

We expect to incur significant and increasing losses while generating

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minimal revenues over the next few years. From our inception on August 5, 1988 through December 31, 2003, we have incurred cumulative losses of \$18.2 million which were principally incurred in connection with our product development efforts. For the years ended December 31, 2002 and December 31, 2003, we incurred net losses of \$1.8 million and \$2.3 million, respectively.

We have funded our operations through a combination of private placements of our securities and through the proceeds of our public offerings in 2000 and 2003. Please see a detailed discussion of our various sales of securities described in Note 2 to our 2003 financial statements that are included in our Annual Report on Form 10-KSB for the year ended December 31, 2003. In addition, we received gross proceeds of approximately \$3.5 million from private placements we completed in 2004 and approximately \$[] million on exercise of warrants in 2004.

If we continue to incur losses we may exhaust our capital resources, including those raised in this offering. As of December 31, 2003, we had cash and cash equivalents and short term investments of \$2.3 million.

We will likely need additional funding to complete our planned clinical trials and our efforts to raise additional financing may be unsuccessful.

Our resources may not be sufficient to enable us to complete our Phase III clinical trials and obtain FDA premarket 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 that may be required to commercialize the Delcath system, our potential to generate future revenues will be significantly limited even if we receive FDA premarket approval.

Our current resources 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.

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.

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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 against a control group 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 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 conducting and completing the trials, caused by many factors, including our limited experience in arranging for clinical trials and in evaluating and submitting the data gathered from clinical trials, 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.

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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 system if they do not receive substantial reimbursement for the cost of the procedures using our products from third-party payors, including

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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.

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.

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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 Delcath system results in reduced treatment costs to patients. We have only 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 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

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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

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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 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. 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 Securities

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 warrants.

There is a limited public float of our common stock and of our 2000 Warrants 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] (including the shares that could be sold by the selling security holders named herein) 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 beneficially 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.

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As of April 15, 2004, [_____] shares of our common stock will be outstanding. Of these shares, [_____] (including the shares that could be sold by the selling security holders named herein) will be freely tradable without restriction or further registration under the Securities Act. The remaining [_____] 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 exercise of 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 our publicly-traded warrants.

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

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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

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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 warrants.

We also have a stockholder 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.

Our common stock is listed on the Nasdaq SmallCap Market. If we fail to meet the requirements of The Nasdaq Stock Market for continued listing, our common stock could be delisted.

Our common stock is currently listed on the Nasdaq SmallCap Market. To keep such listing, we are 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 the 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. At times, we have not met one or more of these criteria. If we do not meet all of the applicable criteria, our common stock could be delisted from the Nasdaq SmallCap Market.

If our common stock is delisted from the Nasdaq SmallCap 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 SmallCap Market and the trading price of the common stock remains below \$5.00 per share on the date the common stock were 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 impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally

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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.

Our public offering in 2003 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

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

Residents of the State of California may be unable to sell shares of common stock they purchase in this offering, and investors residing in all other states may be unable to sell shares of common stock 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 and in the documents incorporated herein by reference, including statements of our expectations, intentions, plans, objectives and beliefs, 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 and in the documents incorporated herein by reference 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. We advise you to review any additional disclosures we make in our Form 10-KSB, Form 10-QSB and Form 8-K reports filed with the SEC.

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OUR BUSINESS

General

Since our founding in 1988, we have been a development stage company engaged primarily in developing a drug-delivery system which is designed to isolate the liver from the general circulatory system and to administer

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chemotherapy and other therapeutic agents directly to the liver. 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.

A more complete description of our business is contained in our Annual Report on Form 10-KSB for the year ended December 31, 2003. See "Incorporation of Certain Documents by Reference."

Corporate Information

Our executive offices are located at 1100 Summer Street, Stamford, Connecticut 06905. Our telephone number at this location is (203) 323-8668. We maintain a corporate website located at <http://www.delcathsystems.com>. The contents of our website are not included as part of this prospectus.

THE OFFERING

- | | |
|--|--|
| Common stock offered by the Company | o 3,098,070 shares, consisting of: 1,898,070 shares issuable upon exercise of the currently outstanding 2003 Warrants; and 1,200,000 shares issuable upon exercise of the currently outstanding 2000 Warrants. |
| Common Stock offered by the Selling Shareholders | o 240,000 shares issuable upon exercise of the outstanding unit warrants held by Whale Securities Co., L.P., the managing underwriter of our initial public offering in 2000, or upon exercise of the 2000 Warrants that would be issued upon exercise of the unit warrants; o 20,265 shares issued upon exercise of warrants issued in connection with a private placement to an accredited investor in 2002; o 677,410 shares issuable upon exercise of the outstanding unit warrants held by Roan/Myers Associates, L.P., the managing underwriter of our 2003 public offering or its transferees, or upon exercise of the 2003 Warrants that would be issued upon exercise of the unit warrants; o 1,859,371 shares issued in connection with private placements in 2004 to accredited investors or issuable upon exercise of warrants issued to such investors; and o 74,374 shares issuable upon exercise of outstanding warrants issued to the placement agents in connection with the 2004 private |

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placements to accredited investors.

- Shares outstanding at April 15, 2004 o _____ shares
- Term of the 2000 Warrants o exercisable at any time until
October 18, 2005.

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- Term of the 2003 Warrants o exercisable at any time until May
20, 2008
- Redemption o Our 2000 Warrants may be redeemed
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 Whale
Securities Co., L.P., the lead
underwriter of our 2000 public
offering, for the redemption.
- o Commencing May 20, 2004, 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 20 trading days prior
to the date of notice of redemption
is at least \$1.24 and (ii) there is
then an effective registration
statement providing for the
issuance of the underlying shares
of common stock.
- o Commencing one year from the
effective date of the registration
statement of which this prospectus
is a part, our 2004 Warrants may
be redeemed at our option at a
redemption price of \$0.10 per
warrant provided (i) the average
per share market value of our
common stock for the 20 trading
days prior to the date of notice of
redemption is at least \$6.02, (ii)
a registration statement providing
for the issuance of the underlying
shares of common stock is effective
and has been effective for at least

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60 consecutive calendar days and (iii) trading in our common stock has not been suspended by the SEC or the Nasdaq SmallCap Market.

Trading symbols of our publicly traded securities

- o Our common stock is traded on the Nasdaq SmallCap Market under the symbol "DCTH".
- o Our 2000 Warrants are traded on the Nasdaq SmallCap Market under the symbol "DCTHW".
- o Our 2003 Warrants are traded on the OTC Bulletin Board and the Boston Stock Exchange under the symbols "DCTHZ" and "DCT&W," respectively.

Terms of our Common Stock

As of April 15, 2004, there were _____ shares of our common stock outstanding. Assuming all outstanding 2004 Warrants, 2003 Warrants (including the unit warrants issued to the underwriters) and 2000 Warrants (including the unit warrants issued to the underwriters) are exercised for the issuance of _____ shares of common stock, there would be _____ shares of common stock outstanding.

Holders of common stock are entitled to one vote for each share on all matters submitted to a stockholder vote. Holders of common stock do not have cumulative voting rights. Therefore, holders of a majority of the shares of common stock voting for the election of directors can elect all of the directors. Holders of common stock are entitled to share in all dividends that the board of directors, in its discretion, declares from legally available funds. In any liquidation, dissolution or winding up of Delcath, each

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outstanding share entitles its holder to participate pro rata in all assets that remain after payment of liabilities and after providing for each class of stock, if any, having preference over the common stock.

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

Terms of the 2004 Warrants

As of the date hereof, there were 446,256 outstanding 2004 Warrants (including those issued to the placement agents in connection with the private placements). Each 2004 Warrant entitles the holder thereof to purchase one share of common stock at a price of \$3.01 per share. The 2004 Warrants are redeemable

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as described above under "The Offering."

Terms of the 2003 Warrants

As of the date hereof, there were 1,898,070 outstanding 2003 Warrants. Each 2003 Warrant entitles the holder thereof to purchase one share of common stock at a price of \$0.775 per share, subject to adjustment, at any time up to May 20, 2008. Each unit warrant held by Roan/Myers Associates, L.P. or its transferees entitles the holder thereof to purchase five shares of our common stock and five 2003 Warrants for a purchase price of \$5.12. The 2003 Warrants issuable upon exercise of the unit warrant would have the same terms as the provisions of the other 2003 Warrants except that the exercise price of such warrants is \$1.28 per share. The 2003 Warrants are redeemable as described above under "The Offering."

Assuming that the registration statement of which this prospectus is a part becomes effective by May 20, 2004 and that the average closing price of our common stock for the 20 trading days ending on May 20, 2004 is at least \$1.24, we anticipate that we would send a notice of redemption to all the holders of the 2003 Warrants. Under those circumstances any holder of a 2003 Warrant who does not exercise his 2003 Warrant by the date specified in the notice of redemption would receive a cash payment of \$0.01 per 2003 Warrant and would not thereafter be able to exercise the 2003 Warrant.

The 2003 Warrants were issued in registered form under a warrant agent agreement by and between Delcath and American Stock Transfer & Trust Company, as warrant agent. Reference is made to the warrant agent agreement, dated as of May 20, 2003, which was filed as Exhibit 4.8 to Amendment No. 3 to the Company's Registration Statement on Form SB-2 (No. 333-101661) for a complete description of the terms and conditions thereof.

Terms of the 2000 Warrants

As of the date hereof, there were 1,200,000 outstanding 2000 Warrants. Each 2000 Warrant entitles the holder thereof to purchase one share of common stock at a price of \$6.60 per share, subject to adjustment, at any time up to October 15, 2005. Each unit warrant held by Whale Securities Co., L.P., the underwriter for our 2000 initial public offering, entitles Whale Securities to purchase one share of common stock and one 2000 Warrant at a price of \$6.60. The 2000 Warrants issuable upon exercise of the unit warrant would have the same provisions as the other 2000 Warrants except that the exercise price of such warrants is \$10.50 per share. The 2000 Warrants are redeemable as described above under "The Offering."

The 2000 Warrants were issued in registered form under a warrant agreement between and among Delcath, Whale Securities Co., L.P. and American Stock Transfer & Trust Company, as warrant agent. Reference is made to the warrant agreement which was filed as Exhibit 4.2 to Amendment No. 5 to the

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Company's Registration Statement on Form SB-2 (No. 333-333-39470) for a complete description of the terms and conditions thereof.

Transfer Agent

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

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for the 2004 Warrants and the unit warrants issued to Roan/Meyers Associates, L.P. and to Whale Securities Co., L.P.

USE OF PROCEEDS

In the event that all of our outstanding 2004 Warrants, 2003 Warrants and 2000 Warrants, including those warrants held by the placement agents for our 2004 private placements and unit warrants held by the underwriters of our 2003 and 2000 public offerings, are exercised, we estimate that the net proceeds from the sale by us of shares of our common stock being offered by this prospectus, after deducting the estimated expenses of this offering will be approximately \$_____. However, the actual number of warrants exercised will depend on numerous factors beyond our control, including, without limitation, the market price of our common stock. Based on the recent trading prices of our common stock, we believe it is reasonable to assume that, if we call the 2003 Warrants for redemption in accordance with their terms, a substantial portion of the 2003 Warrants and the unit warrants issued to the managing underwriter of our 2003 public offering will be exercised. Whether other warrants are likely to be issued will probably depend on the market prices of our common stock between the date hereof and the expiration date of the particular warrant. We cannot estimate with reasonable accuracy the number of such warrants which may be exercised and the amount of proceeds to be received therefrom.

We expect that we would use any proceeds we receive upon exercise of any of the 2004 Warrants, the 2003 Warrants and the 2000 Warrants (including any exercise by the managing underwriters or placement agents) for working capital purposes.

Prior to expenditure, proceeds will be invested principally in high grade, short-term, interest-bearing instruments.

SELLING SHAREHOLDERS

The following table sets forth the number and percentage of shares that are being registered by this Prospectus for the account of the entities listed below (the "Selling Shareholders"). The shares may be sold by the Selling Shareholders, or any of their assigns, pursuant to the exercise of some or all of our currently outstanding 2004 Warrants, 2003 Warrants and 2000 Warrants from time to time in the public marketplace. The Selling Shareholders are not obligated to exercise any of their warrants. All information contained in the table below is based on information provided to us by the Selling Shareholders, and we have not independently verified this information. The Selling Shareholders are not making any representation that the shares covered by this prospectus will be offered for sale. The Selling Shareholders may from time to time offer and sell pursuant to this prospectus any or all of the shares being registered for resale.

The applicable percentages of ownership are based on an aggregate of _____, shares of our common stock issued and outstanding as of April 15, 2004 plus, in the case of each Selling Shareholder, the number of shares such Selling Shareholder could acquire within 60 days on exercise of warrants. None of the Selling Shareholders has had a material relationship with us, or with our predecessors or affiliates, at any time during the past three years.

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| Shareholder ----- | Shares Beneficially Owned Prior to the Offering(1) ----- | | Shares Being Offered(2) ----- | Shares Beneficially Own After the Offering Number Percent (%) ----- | |
|---|--|------|-------------------------------------|---|----|
| | | | | | |
| Whale Securities Co., L.P. | 240,000 | (3) | 240,000 | 0 | 0% |
| Yenom Partners | 20,265 | | 20,265 | 0 | 0% |
| Roan/Myers Associates, L.P. | 417,410 | (4) | 417,410 | 0 | 0% |
| Brian Herman | 77,000 | (5) | 77,000 | 0 | 0% |
| James St. Clair | 10,000 | (6) | 10,000 | 0 | 0% |
| Robert Dombrowski | 4,000 | (7) | 4,000 | 0 | 0% |
| Zohar Hod | 4,000 | (8) | 4,000 | 0 | 0% |
| Carlos Corzine | 12,500 | (9) | 12,500 | 0 | 0% |
| Sterling Financial Investment Group | 12,500 | (10) | 12,500 | 0 | 0% |
| Imtiaz Khan | 110,000 | (11) | 110,000 | 0 | 0% |
| Pryor, Counts & Co., Inc. | 30,000 | (12) | 30,000 | 0 | 0% |
| AS Capital Partners, LLC | 60,957 | (13) | 60,975 | 0 | 0% |
| Basso Equity Opportunity Fund Ltd. | 125,000 | (14) | 125,000 | 0 | 0% |
| Basso Multi-Strategy Holding Fund Ltd | 125,000 | (15) | 125,000 | 0 | 0% |
| Bristol Investment Fund, Inc. DKR Sound Shore Oasis Holding Fund Ltd. | 194,503 | (16) | 194,503 | 0 | 0% |
| Enable Growth Partners LP | 259,340 | (17) | 259,340 | 0 | 0% |
| Iroquois Capital LP | 129,670 | (18) | 129,670 | 0 | 0% |
| OTAPE Investments LLC | 103,735 | (19) | 103,735 | 0 | 0% |
| SRG Capital, LLC | 77,805 | (20) | 77,805 | 0 | 0% |
| Truk International Fund, LP | 155,605 | (21) | 155,605 | 0 | 0% |
| Truk Opportunity Fund, LP | 23,216 | (22) | 23,216 | 0 | 0% |
| Vertical Ventures LLC | 28,275 | (23) | 28,275 | 0 | 0% |
| H. C. Wainwright & Co., Inc. | 285,270 | (24) | 285,270 | 0 | 0% |
| John R. Clarke | 29,926 | (25) | 29,926 | 0 | 0% |
| Scott F. Koch | 9,260 | (26) | 9,260 | 0 | 0% |
| Jimmie Sundstrom | 9,260 | (27) | 9,260 | 0 | 0% |
| Robert Nathan | 645 | (28) | 645 | 0 | 0% |
| | 9,260 | (29) | 9,260 | 0 | 0% |

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| Shareholder ----- | Shares Beneficially Owned Prior to the Offering(1) ----- | | Shares Being Offered(2) ----- | Shares Beneficially Own After the Offering Number Percent (%) ----- | |
|----------------------|--|------|-------------------------------------|---|----|
| | | | | | |
| Ari J. Fuchs | 1,500 | (30) | 1,500 | 0 | 0% |
| Stonestreet LP | 155,601 | (31) | 155,601 | 0 | 0% |

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| | | | | | |
|------------------------|---------|------|---------|---|----|
| Omicron Master Trust | 207,470 | (32) | 207,470 | 0 | 0% |
| MZM Capital Management | 14,523 | (33) | 14,523 | 0 | 0% |

- (1) Unless otherwise noted, all of the shares shown are held by individuals or entities possessing sole voting and investment power with respect to such shares. Shares not outstanding but deemed beneficially owned by virtue of the right of a person to acquire them within 60 days, by the exercise of options or warrants or conversion of preferred stock, are deemed outstanding in determining the number of shares beneficially owned by such person. Because the Selling Shareholders may choose not to sell any of the shares offered by this prospectus, and because there are currently no agreements, arrangements or undertakings with respect to the sale of any of the shares of common stock, we cannot estimate the number of shares that the Selling Shareholders will hold after completion of the offering. For purposes of this table, we have assumed that the Selling Shareholders will have sold all of the shares covered by this prospectus upon the completion of the offering.

- (2) Assumes the sale of all shares of common stock issuable upon the exercise of the 2004 Warrants, the 2003 Warrants and the 2000 Warrants issued to the Selling Shareholders in connection with our 2004 private placements (including the warrants issued to the placement agents) and our 2003 and 2000 public offerings (including the unit warrants issued to the managing underwriters).

- (3) Consists of 120,000 shares that could be purchased upon exercise of unit warrants and 120,000 shares that could be purchased on exercise of the 2000 Warrants issuable on exercise of the unit warrants.

- (4) Consists of 208,705 shares that could be purchased upon exercise of unit warrants and 208,705 shares that could be purchased on exercise of the 2003 Warrants issuable on exercise of the unit warrants.

- (5) Consists of 38,500 shares that could be purchased upon exercise of unit warrants and 38,500 shares that could be purchased on exercise of the 2003 Warrants issuable on exercise of the unit warrants.

- (6) Consists of 5,000 shares that could be purchased upon exercise of unit warrants and 5,000 shares that could be purchased on exercise of the 2003 Warrants issuable on exercise of the unit warrants.

- (7) Consists of 2,000 shares that could be purchased upon exercise of unit warrants and 2,000 shares that could be purchased on exercise of the 2003 Warrants issuable on exercise of the unit warrants.

- (8) Consists of 2,000 shares that could be purchased upon exercise of unit warrants and 2,000 shares that could be purchased on exercise of the 2003 Warrants issuable on exercise of the unit warrants.

- (9) Consists of 6,250 shares that could be purchased upon exercise of unit warrants and 6,250 shares that could be purchased on exercise of the 2003 Warrants issuable on exercise of the unit warrants.

- (10) Consists of 6,250 shares that could be purchased upon exercise of unit warrants and 6,250 shares that could be purchased on exercise of the 2003 Warrants issuable on exercise of the unit warrants.

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- (11) Consists of 55,000 shares that could be purchased upon exercise of unit warrants and 55,000 shares that could be purchased on exercise of the 2003 Warrants issuable on exercise of the unit warrants.
- (12) Consists of 15,000 shares that could be purchased upon exercise of unit warrants and 15,000 shares that could be purchased on exercise of the 2003 Warrants issuable on exercise of the unit warrants.
- (13) Includes 12,195 shares that could be purchased upon exercise of 2004 Warrants.
- (14) Includes 25,000 shares that could be purchased upon exercise of 2004 Warrants.
- (15) Includes 25,000 shares that could be purchased upon exercise of 2004 Warrants.
- (16) Includes 30,900 shares that could be purchased upon exercise of 2004 Warrants.
- (17) Includes 51,868 shares that could be purchased upon exercise of 2004 Warrants.
- (18) Includes 25,934 shares that could be purchased upon exercise of 2004 Warrants.
- (19) Includes 20,747 shares that could be purchased upon exercise of 2004 Warrants.
- (20) Includes 15,561 shares that could be purchased upon exercise of 2004 Warrants.
- (21) Includes 31,121 shares that could be purchased upon exercise of 2004 Warrants.
- (22) Includes 4,643 shares that could be purchased upon exercise of 2004 Warrants.
- (23) Includes 5,655 shares that could be purchased upon exercise of 2004 Warrants.
- (24) Includes 57,054 shares that could be purchased upon exercise of 2004 Warrants.
- (25) Consists of shares that could be purchased upon exercise of 2004 Warrants issued to a placement agent. H. C. Wainwright & Co., Inc. ("HCW") received these securities as compensation for its services as placement agent in connection with the 2004 private placement.
- (26) Consists of shares that could be purchased upon exercise of 2004 Warrants. Mr. Clarke, President of HCW, received these warrants from HCW in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them. HCW had received these securities as compensation for its services as placement agent in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them.

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- (27) Consists of shares that could be purchased upon exercise of 2004 Warrants. Mr. Koch, a Managing Director of HCW, received these warrants from HCW in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them. HCW had received these securities as compensation for its services as placement agent in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them.
- (28) Consists of shares that could be purchased upon exercise of 2004 Warrants. Mr. Sundstrom, a Managing Director of HCW, received these warrants from HCW in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them. HCW had received these securities as compensation for its services as placement agent in the ordinary course of business and at the time of receiving the

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securities had no agreements or understandings, directly or indirectly, with any person to distribute them.

- (29) Consists of shares that could be purchased upon exercise of 2004 Warrants. Mr. Nathan, Senior Vice President of HCW, received these warrants from HCW in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them. HCW had received these securities as compensation for its services as placement agent in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them.
- (30) Consists of shares that could be purchased upon exercise of 2004 Warrants. Mr. Fuchs, an employee of HCW, received these warrants from HCW in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them. HCW had received these securities as compensation for its services as placement agent in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them.
- (31) Includes 31,120 shares that could be purchased upon exercise of 2004 Warrants.
- (32) Includes 41,494 shares that could be purchased upon exercise of 2004 Warrants.
- (33) Consists of shares that could be purchased upon exercise of 2004 Warrants issued to a placement agent.

PLAN OF DISTRIBUTION

The common stock offered by us hereby is issuable by us upon the exercise of some or all of our currently outstanding 2004 Warrants, 2003 Warrants and 2000 Warrants. The common stock offered hereby may be offered for sale and sold from time to time by the persons or entities described in this prospectus under the heading "Selling Shareholders," or by pledgees, donees, transferees or other

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successors in interest after the effective date of the registration statement of which this prospectus is a part.

The Selling Shareholders, or their pledgees, donees, transferees or other successors in interest, will act independently of us and of each other in making decisions with respect to the timing, manner and size of each sale. Such sales may be made on the Nasdaq SmallCap Market or otherwise, at prevailing prices and on terms then prevailing or at prices related to the then market price, or in negotiated transactions.

The manner in which the common stock offered hereby may be sold by the Selling Shareholders include, without limitation, the following:

- o block trades in which the broker-dealer(s) engaged by any of the Selling Shareholders will attempt to sell common stock as agent but may position or resell a portion of the block as principal to facilitate the transaction;
- o purchases by the broker-dealer(s) as principals and resale by such broker-dealer(s) for their account pursuant to this prospectus;
- o ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- o negotiated transactions;

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- o a combination of any such methods of sale;
- o through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or
- o any other method permitted pursuant to applicable law.

In effecting sales, broker-dealers engaged by the Selling Shareholders may arrange for other broker-dealers to participate.

In order to comply with the securities laws of certain states, if applicable, the common stock offered hereby may be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the common stock offered hereby may not be sold unless it has been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with by us and the Selling Shareholders.

The Selling Shareholders and any brokers, dealers, agents or underwriters who participate in the sale of the common stock offered hereby may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act, and the commissions paid or discounts allowed to any such brokers, dealers, agents or underwriters, in addition to any profits received on resale of the common stock offered hereby, if any such broker, dealer or agent should purchase any common stock offered hereby as a principal, may be deemed to be underwriting discounts or commissions under the Securities Act.

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Under applicable rules under the Securities Exchange Act, any person engaged in the distribution of the common stock may not simultaneously engage in market making activities with respect to our common stock for a period of one business day prior to the commencement of such distribution. In addition and without limiting the foregoing, the Selling Shareholders will be subject to applicable provisions of the Securities Exchange Act, and the rules thereunder, including without limitation Regulation M, which provisions may limit the timing of purchases and sales of common stock by the Selling Shareholders.

Although we will receive the proceeds of the exercise of the 2004 Warrants, 2003 and the 2000 Warrants (see "Use of Proceeds," described above), we will not receive any part of the proceeds from the sale of the common stock offered hereby by the Selling Shareholders. We are required to pay all fees and expenses incident to the registration of the shares. However, we are not obligated to bear, and will not bear, any underwriting discounts or commissions relating to the use by the Selling Shareholders of an underwriter in connection with the disposition of the common stock offered hereby by the Selling Shareholders.

We cannot assure you that the Selling Shareholders will sell any or all of the common stock offered by them hereby. The common stock offered hereby by the Selling Shareholders also may be sold pursuant to an available exemption from the registration requirements of the Securities Act, including without limitation Rule 144 promulgated thereunder. The sale of common stock by "affiliates" (as defined in Rule 144(a) under the Securities Act) are subject to the volume and manner of sale restrictions set forth in Rule 144.

We have agreed to indemnify the Selling Shareholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

LEGAL MATTERS

The validity of the common stock offered hereby has been passed upon for Delcath by Murtha Cullina, LLP, New Haven, Connecticut, counsel for Delcath.

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EXPERTS

Our financial statements as of December 31, 2003 and for each of the two years in the period ended December 31, 2003, and cumulative from inception (August 5, 1988) to December 31, 2003 appearing in our Annual Report on Form 10-KSB for the year ended December 31, 2003 have been audited by Eisner LLP, independent auditors, as set forth in their report thereon dated February 11, 2004 except as to Note 6, the date of which is March 22, 2004, included therein and incorporated herein by reference. Such financial statements are incorporated herein by reference in reliance upon such report given upon the authority of such firm as experts in accounting and auditing.

WHERE CAN YOU 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 U.S. Securities and Exchange Commission in Washington, D.C., a registration statement on Form S-3 under the Securities Act with the respect to the shares of common

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stock offered by this prospectus. The registration statement relates to the common stock offered by the Company upon exercise of the 2004 Warrants, 2003 Warrants and the 2000 Warrants (including the warrants held by the placement agents in our 2004 private placements and the managing underwriters of our public offerings) and the resale of such shares from time to time by the Selling Shareholders.

This prospectus does not contain all the information set forth in the registration statement and the exhibits and schedules thereto. For further information with respect to us and the common stock, we refer you to the registration statement, the documents incorporated herein 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>.

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 hereto. You may read and obtain a copy of the registration statement and its exhibits and schedules from the SEC, as described in the preceding paragraph.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The following documents that we have filed with the Securities and Exchange Commission are incorporated into this prospectus by reference:

1. Our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003, filed on March 30, 2004;
2. Our definitive Proxy Statement dated April 29, 2004 distributed in connection with our Annual Meeting of Shareholders held on June 15, 2004;

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3. The description of our common stock contained under the caption "Description of Our Capital Stock and Other Securities - Units" in the Prospectus included in the Registrant's Registration Statement on Form SB-2 (No. 333-101661), declared effective on May 15, 2003.

4. The description of our 2003 Redeemable Common Stock Purchase Warrants contained under the caption "Description of Our Capital Stock and Other Securities - Warrants - 2003 Warrants" in the Prospectus included in the Registrant's Registration Statement on Form SB-2 (No. 333-101661).

5. The description of our 2000 Redeemable Common Stock Purchase Warrants

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contained under the caption "Description of Our Capital Stock and Other Securities - Warrants - 2000 Warrants" in the Prospectus included in the Registrant's Registration Statement on Form SB-2 (No. 333-101661).

All documents that we file with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 after the date of this prospectus and prior to the filing of a post-effective amendment to the registration statement of which this prospectus is a part that indicates that all the common stock offered has been sold, or which deregisters all common stock then remaining unsold hereunder, shall be incorporated by reference into this prospectus and to be a part hereof (and of the registration statement) from the date of filing of such documents. Any statement contained in this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in any subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

To the extent that an independent auditor audits and reports on our financial statements issued at future dates and consents to the use of its reports thereon, such financial statements shall also be incorporated by reference in this prospectus (and the registration statement) in reliance upon their reports and their authority as experts in accounting and auditing.

We will provide without charge to each person, including any beneficial owner, to whom a copy of this prospectus is delivered, upon written or oral request, a copy of any and all information that has been incorporated by reference herein (other than exhibits to such information, unless such exhibits are specifically incorporated into any such information). Requests should be directed to us at 1100 Summer Street, Stamford, Connecticut 06905, Attention: Paul M. Feinstein, Chief Financial Officer. Mr. Feinstein may also be contacted at (203) 323-8668.

DISCLOSURE OF THE SEC'S POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Our certificate of incorporation provides that we must, to the fullest extent permitted or required by the Delaware General Corporation Law, indemnify any and all persons whom we have the power to indemnify from and against any and all of the expenses, liabilities or other matters referred to in or covered by the Delaware General Corporation Law. The indemnification provided for in our certificate of incorporation is not exclusive of any other rights to which those indemnified may be entitled under any law, agreement, vote of shareholders or disinterested directors or otherwise.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing 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 of 1933 and is, therefore, unenforceable.

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INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

The following table sets forth an itemization of all estimated expenses payable in connection with the distribution of the securities being registered. All of the expenses set forth below are estimates except for the SEC registration fee. All of these expenses will be paid by the Company.

| | |
|------------------------------|---------|
| SEC registration fee | \$2,187 |
| Legal fees and expenses | * |
| Accounting fees and expenses | * |
| Printing expenses | * |
| Miscellaneous | * |
| | ----- |
| Total | * |
| | ===== |

* To be filed by amendment.

Item 15. Indemnification of Directors and Officers

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

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

- o breaches of the director's duty of loyalty to the corporation or its stockholders;
- o acts or omissions not made in good faith or which involve intentional misconduct of knowing violations of law;
- o liability for dividends paid or stock repurchased or redeemed in violation of the Delaware General Corporation Law; or
- o any transaction from which the director derived an improper personal benefit.

Section 102(b) (7) does not authorize any limitation on the ability of the Company or its stockholders to obtain injunctive relief, specific performance or other equitable relief against directors.

As authorized by the Delaware General Corporation Law, Article Seventh of the Company's Certificate of Incorporation provides that the personal liability of the directors of the Company be eliminated to the fullest extent permitted under Section 102(b) of the Delaware General Corporation Law.

Article Eighth of the Company's Certificate of Incorporation and the Company's By-laws provide that all persons whom the Company is empowered to indemnify pursuant to the provisions of Section 145 of the Delaware General Corporation Law (or any similar provision or provisions of applicable law at the

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time

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in effect), shall be indemnified by the Company to the full extent permitted thereby. The foregoing right of indemnification shall not be deemed to be exclusive of any other rights to which those seeking indemnification may be entitled under any by-law, agreement, vote of stockholders or disinterested directors, or otherwise.

The Company maintains a liability and indemnification insurance policy in the amount of \$2,500,000 for a period extending from October 19, 2003 to October 19, 2004 issued by Carolina Casualty Insurance Company covering all our officers and directors, at an annual expense of \$60,000.

Item 16. Exhibits

| Number | Description |
|--------|--|
| 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. 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 | 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. |
| 4.3 | 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)). |
| 4.4 | 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)). |
| 4.5 | 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 to Purchase Shares of Common Stock issued pursuant to the Common Stock Purchase Agreement dated as of March 19, 2004 (incorporated by reference to Exhibit 4 to Registrant's Current Report on Form 8-K dated March 19, 2004). |

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- 5 Opinion of Murtha Cullina LLP (to be filed by amendment).
- 10.1 Common Stock Purchase Agreement dated as of March 19, 2004 by and among Delcath Systems, Inc. and the Purchasers Listed on Exhibit A thereto (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K dated March 19, 2004).
- 10.2 Registration Rights Agreement dated as of March 19, 2004 by and among Delcath Systems, Inc. and the Purchasers Listed on Schedule I thereto (incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K dated March 19, 2004).

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- 23.1 Consent of Eisner LLP.
- 23.2 Consent of Murtha Cullina LLP (to be included in Exhibit 5).
- 24 Power of Attorney.

Item 17. Undertakings

We hereby undertake:

To file, during any period in which offers or sales of securities are made a post-effective amendment to this registration statement to include any additional or changed material information on the plan of distribution;

For determining liability under the Securities Act, to treat each post-effective amendment as a new registration statement of the securities offered and the offering of the securities at that time to be the initial bona fide offering; and

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

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to our directors, officers and controlling persons pursuant to the provisions of our Certificate of Incorporation or Bylaws or applicable Delaware law, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in that Act and is, therefore, unenforceable.

In the event that a claim for indemnification against such liabilities (other than the payment by us of expenses incurred or paid by a director, officer or controlling person of ours in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to 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 for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Stamford, State of Connecticut this 19th day of April, 2004.

Delcath Systems, Inc.

By: /s/ M. S Koly

 Name: M. S Koly
 Title: President and Chief Executive Officer

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

| Name | Title | |
|------------------------|---------------------------------|-------------------------|
| M. S Koly | President and Chief Executive |) |
| ----- | Officer and Director (Principal |) |
| | Executive Officer) |) |
| | |) |
| Paul M. Feinstein | Chief Financial Officer |) |
| ----- | (Principal Financial Officer |) |
| | |) By: /s/ M. S. Koly |
| | | ----- |
| Samuel Herschkowitz, . | |) Attorney-in-Fact |
| M.D | Chairman and Director |) |
| ----- | |) Dated: April 19, 2004 |
| | |) |
| | |) |
| Mark A.Corigliano | Director |) |
| ----- | |) |
| | |) |
| | |) |
| Daniel Isdaner | Director |) |
| ----- | |) |
| | |) |
| | |) |
| Victor Nevins | Director |) |
| ----- | |) |

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| 24 | Power of Attorney. |