DELCATH SYSTEMS INC
Form S-3
August 17, 2005

As filed with the Securities and Exchange Commission on August 17, 2005.

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
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1100 Summer Street
3rd Floor
Stamford, Connecticut 06905
(203) 323-8668

Copies to:

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New Haven, Connecticut 06503-0704
(203) 772-7726

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. [ ]

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	Proposed maximum aggregate offering price	A reg
Common Stock, par value $0.01 per share, issuable upon exercise of warrants issued in 2005 in an exchange offer	1,200,000	$2.75 (1)	$3,300,000	

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

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 COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

Subject to Completion. Dated August 17, 2005

DELCATH SYSTEMS, INC.

Up to 1,200,000 Shares of Common Stock

By means of this prospectus, we are offering up to 1,200,000 shares that may be issued upon the exercise of warrants that we may issue in 2005 in exchange for the warrants that we issued in 2000 in connection with our initial public offering (such warrants that may be issued in 2005, the "Exchange Warrants"). We will receive the proceeds of any exercise of the Exchange Warrants. If all of the Exchange Warrants are issued and are exercised, we would receive net proceeds of approximately $3,260,000 (after our estimated expenses of the offering of $40,000).

Our common stock is currently traded on the Nasdaq SmallCap Market and the Boston Stock Exchange under the symbols "DCTH" and "DCT," respectively. On August 15, 2005, our common stock had a closing price of $3.02 on the Nasdaq SmallCap Market.

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 _____ __, 2005.

THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. WE MAY NOT SELL THESE SECURITIES UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IT IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

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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. 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 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.

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 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. If we are not successful in that development and commercialization, or if we are unable to market and sell the product, we will not generate operating revenue or become profitable.

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 had 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 minimal revenues over the next few years. From our inception on August 5, 1988 through December 31, 2004, we have incurred cumulative losses of $21.5 million which were principally incurred in connection with our product development efforts. For the years ended December 31, 2003 and December 31, 2004, we incurred net losses of $2.3 million and $3.3 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 the detailed discussion of our various sales of securities described in Note 2 to our 2004 financial statements that are included in our Annual Report on Form 10-KSB for the year ended December 31, 2004. In addition, we received proceeds of approximately $5.6 million from private placements we completed in 2004, approximately $2.2 on exercise of warrants and options in 2004 and approximately $3.1 million on exercise of warrants and options in 2005 to the date hereof.

If we continue to incur losses we may exhaust our capital resources resulting in our being unable to complete the development and commercialization of our product. As we incur additional losses, our accumulated deficit will further increase. As of December 31, 2004, we had cash and cash equivalents and short term investments of $7.3 million.

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

Before we can obtain approval to sell our product commercially, we will need premarket approval from the FDA which, in turn, requires that we complete clinical trials to establish the effectiveness of our system. We will likely need additional funding to complete the required clinical trials, and we may not be able to raise additional funds on reasonable terms or at all.

Many of the costs incurred in conducting clinical trials are due to uncertainties that are not within our control, including (i) the possibility that the FDA may require additional trials and the number of trials that may be required; (ii) the charges payable to each current or prospective clinical test site which may be a flat fee for a certain time period or a fee based on the number of participants in the trial; (iii) the amount of the fee per participant which is individually negotiated with each test site; (iv) the number of patients that may be required to be enrolled in any particular trial; (v) the location of the test site which can affect our other costs, including the costs of retaining a clinical research organization and out of pocket costs such as travel; (vi) the actual number of treatments per patient in each clinical trial; and (vii) the possible reduction in trial costs billed to the Company where a patient's insurer agrees to cover treatment expenses. As a result, we are unable to estimate the total costs we will incur in completing the clinical trials. In

addition, completion of the clinical trials does not guarantee that the FDA will give us the required approvals in a timely manner or will give them to us at all.

- 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 or to complete clinical trials using melphalan 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.

- Even if the FDA grants premarket approval for use of the Delcath system for the treatment of melanoma that has metastasized to the liver with doxorubicin, our ability to market the device would be limited to that use. Separate FDA approval would be needed to market the system for use with other drugs or to treat other diseases. Lack of such specific approvals will limit our ability to market our product.

If the FDA grants premarket approval for use of the Delcath system in the treatment of melanoma that has metastasized to the liver with doxorubicin, our ability to market the system would be limited to its use with that drug in treating that disease. Thereafter, physicians could use the system for the treatment of other cancers or using other drugs ("off label" use), but we could not market it for such uses. This would limit our ability to market our product and could result in substantially reduced sales.

- 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 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. If we do not have such approval, we will not be eligible to use a simplified registration process for the Delcath system in a number of countries including the members of the European Union, Great Britain and Australia. 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 clinical trials and obtaining FDA premarket approval could be delayed.

We have experienced and may continue to experience delays in conducting and completing required clinical trials, caused by many factors, including our limited experience:

- in arranging for clinical trials;
- 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 may 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 since the population of appropriate subjects (i.e., patients with melanoma that has metastasized to the liver) is limited. 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, resulting in lower sales even if FDA premarket approval is granted.

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 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.

Currently the Delcath system kit is being manufactured domestically by the OEM division of B. Braun Medical, Inc. of Germany which also supplies the other catheters and accessories and assembles the Delcath system kit. Medtronic USA, Inc. currently manufactures the components of the blood filtration circuit located outside of the body, including the medical tubing through which the patient's blood flows and various connectors and the blood filtration pump head. Historically, the Company purchased activated charcoal filters used in the Delcath system from Asahi Medical Products of Japan. Because Asahi has discontinued manufacturing these filters, we are currently testing an alternative filter from a domestic manufacturer.

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. Notwithstanding our best efforts, we may not be able to find an alternate source of comparable components. 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 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.

We have employment agreements with our President and Chief Executive Officer and our Chief Technical Officer whom we believe are important to our efforts to commercialize the Delcath system. The unavailability of the services of either of them could delay our successful commercial introduction of the Delcath system.

We have entered into employment agreements with M. S. Koly, our President and Chief Executive Officer, and Samuel Herschkowitz, M.D., our Chief Technical Officer, each of whom has played an important role in our efforts to obtain FDA

premarket approval of our product. We maintain a life insurance policy on Mr. Koly. The loss of the services of either of them could delay our completing the clinical trials, our obtaining FDA premarket approval, our introducing the Delcath system commercially and our generating revenues and profits.

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 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, a court might find such consents and waivers of liability to be ineffective or invalid. Were such a claim asserted and even if we prevail on the merits, we would likely incur substantial legal and related expenses. In connection with our clinical trials in Australia, we have obtained a liability policy providing both an aggregate limit and a per occurrence limit of $5 million coverage for claims that might be asserted by participants in those trials. 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 relatively limited public float of our common stock and of our publicly-traded 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 has historically been volatile. During the three years ended December 31, 2004, the range of the high and low sales prices of our common stock have ranged from a high of $4.37 (during the quarter ended March 31, 2004) to a low of $0.31 (during the quarter ended December 31, 2002).

Of our outstanding common stock, approximately 90% (including the shares that could be sold by the selling security holders named in other registration statements we have filed under the Securities Act of 1933 covering the resale of shares of our common stock) can be considered to be in the public float. The term "public float" refers to shares freely and actively tradeable on the Nasdaq SmallCap 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. However, because of the relatively significant number of shares held by the investors in our private placements in 2004, the sale of shares by one or more of such investors could 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 by a limited number of institutional investors may cause the market price of our common stock to be below the level it otherwise would be.

The Company sold approximately 2.8 million shares and issued warrants to purchase approximately 2.5 million additional shares in private placements in 2004 to 11 institutional investors. All of these shares are eligible for resale. The sales of substantial amounts of our common stock by such investors or the perception that such sales could occur, often called "equity overhang," could adversely affect the market price of our common stock.

In addition, we may issue substantial amounts of common stock upon exercise of options outstanding under our stock option plans which are designed principally to retain the services of our key employees. As of December 31, 2004, there were options to purchase approximately 1.0 million shares outstanding under our option plans and an additional 3.0 million shares reserved for issuance under our 2004 Stock Incentive Plan. As of that date, there were also outstanding warrants to purchase approximately 4.4 million shares.

Sales of substantial amounts of common stock 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,

and certain provisions of our certificate of incorporation and by-laws and of our stockholders rights plan could make it more difficult for the Company's stockholders to replace management.

Provisions of our certificate of incorporation, by-laws and Delaware law and of our stockholders rights agreement 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. Certain provisions of our certificate of incorporation and by-laws and of our stockholders rights agreement could have the effect of making it more difficult for the Company's stockholders to replace management at a time when a substantial number of our stockholders would favor a change in management. These include provisions:

- providing for a classified board and permitting the removal of a director only for cause;

- authorizing the board of directors to fill vacant directorships or increase the size of our board of directors; and

- 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 that company for a period of three years from the date the person or entity became an interested stockholder unless (a) prior to such time the board of directors of the corporation 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 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. We were notified by the Nasdaq SmallCap Market on one occasion that we failed to meet the minimum bid price requirement and on two occasions that we did not meet the requirement that we meet one of the following conditions: that the market value of our common stock be at least $35 million; that we have stockholders' equity of not less than $2.5 million; or that we meet certain income tests. 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 our common stock 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 institutions. The additional burdens imposed upon broker-dealers by such requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such 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 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.

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 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, 2004. 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

Terms of our Common Stock

As of August 8], 2005, there were 16,573,965 shares of our common stock outstanding. Assuming (a) that all 1,116,689 of the warrants that we issued in connection with private placements we completed in 2004 and that remain

outstanding (including those issued to the placement agents in connection with the private placements and certain warrants that become exercisable only if other warrants are exercised) (the "2004 Warrants"), (b) that 1,200,000 shares are issued upon exercise of the Exchange Warrants or the warrants that we issued in 2000 which are not exchanged for Exchange Warrants and (c) that none of the unit warrants we issued to the underwriters of our initial public offering in 2000 are exercised, there would be 18,890,654 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 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 Exchange Warrants

As of the date hereof, there are no Exchange Warrants outstanding because the offer to exchange Exchange Warrants for the warrants we issued in 2000 in connection with our initial public offering has not expired. Upon expiration of the exchange offer, we may issue up to 1,200,000 Exchange Warrants. Each Exchange Warrant will entitle the holder thereof to purchase one share of common stock at a price of $2.75, subject to adjustment. The Exchange Warrants will expire on December 31, 2005. The Exchange Warrants will be redeemable at any time at a price of $0.10 per warrant, upon 30 days' notice.

The Exchange Warrants will be issued in registered form under a warrant agreement between Delcath and American Stock Transfer & Trust Company, as warrant agent. Reference is made to the warrant agreement which was filed as an exhibit to our Quarterly Report on Form 10-QSB for the quarter ended June 30, 2004 for a complete description of the terms and conditions thereof.

Terms of the 2004 Warrants

As of the date hereof, there remain outstanding 1,116,689 of the warrants that we issued in connection with private placements of our securities in 2004, i.e. the 2004 Warrants. The 2004 Warrants were issued in several different transactions.

- In connection with a private placement in March and April of 2004, we issued warrants to purchase a total of 446,626 shares (including warrants issued to the placement agents) with an exercise price of $3.01 per share and a five-year term.

- In connection with a private placement in November 2004, we issued three classes of warrants, two of which remain outstanding. The Series A Warrants consist of warrants to purchase a total of 499,306 shares, and have an exercise price of $2.78 per share and a term expiring on November 24, 2009. The Series C Warrants consist of warrants to purchase a total 427,809 shares, and have an exercise price of $2.60 and a term expiring on November 24, 2009.

- In connection with a private placement in December 2004, we issued Series D Warrants to purchase a total of 94,787 shares, having an exercise price of $3.26 and a term expiring on December 7, 2009.

Terms of the 2000 Warrants

Following the expiration of the offer to exchange Exchange Warrants for 2000 Warrants, each 2000 Warrant that is not exchanged for an Exchange Warrant would remain outstanding. 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 would be $10.50 per share. The 2000 Warrants are redeemable at a redemption price of $0.10 per warrant, upon 30 days' notice, at any time, provided that the closing bid quotation of our common stock on all 20 trading days ending on the third day prior to the day on which we give notice has been at least 150% of the then effective exercise price of the 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.

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

Transfer Agent

The transfer agent for our common stock is American Stock Transfer & Trust Company.

USE OF PROCEEDS

In the event that all 1,200,000 of the 2000 Warrants are exchanged for Exchange Warrants and all of the Exchange Warrants 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 $3,250,000. However, the actual number of Exchange Warrants exercised will depend on numerous factors beyond our control, including, without limitation, the market price of our common stock. We cannot estimate with reasonable accuracy the number of Exchange 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 Exchange Warrants for working capital purposes.

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

PLAN OF DISTRIBUTION

The common stock offered by us hereby is issuable by us upon the exercise of some or all of the Exchange Warrants.

In order to comply with the securities laws of certain states, if applicable, the common stock offered hereby may be resold 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.

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.

EXPERTS

Our financial statements as of December 31, 2004 and for each of the two years in the period ended December 31, 2004 and cumulative from inception (August 5, 1988) to December 31, 2004, appearing in our Annual Report on Form 10-KSB for the year ended December 31, 2004 have been audited by Eisner LLP, an independent registered public accounting firm, as set forth in their report thereon dated February 25, 2005, 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 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 stock offered by this prospectus.

This prospectus does not contain all the information set forth in the registration statement and the exhibits 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 filed therewith. The registration statement and the exhibits forming a part thereof may be inspected without charge at the public reference facilities maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549 and copies of such materials can be obtained from the Public Reference Section of the SEC at 100 F Street, N.E., 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 thereto. 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 SEC are incorporated in this Prospectus by reference:

1. Our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2004, filed on March 21, 2005;

2. Our Current Report on Form 8-K dated March 22, 2005, filed on March 23, 2005;

3. Our Current Report on Form 8-K dated April 5, 2005, filed on April 7, 2005;

4. Our Current Report on Form 8-K dated April 25, 2005, filed on May 2, 2005, as amended by an amendment filed on May 2, 2005;

5. Our Current Report on Form 8-K dated May 11, 2005, filed on May 11, 2005;

6. Our definitive proxy statement dated April 29, 2005, filed on April 29, 2005, relating to our 2005 Annual Meeting of Stockholders;

7. Our Quarterly Report on Form 10-QSB for the quarter ended March 31, 2005, filed on May 16, 2005;

8. Our Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005, filed on August 11, 2005; and

9. 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.

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 hereof and prior to the filing of a post-effective amendment to this registration statement 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 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 independent accountants audit and report on our financial statements issued at future dates, and consent to the use of their reports thereon, such financial statements shall also be incorporated by reference in this prospectus 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 of such person, a copy of any or all of the documents incorporated by reference herein, other than exhibits to such documents, or any other documents required to be delivered pursuant to Rule 428(b) under the 1933 Act. Written requests should be addressed to: M. S. Koly, President and Chief Executive Officer, Delcath Systems, Inc., 1100 Summer Street, Stamford, Connecticut 06905. Telephone requests may be directed to Mr. Koly 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.

Part II

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	$ 353
Legal fees and expenses	34,500
Accounting fees and expenses	4,500
Printing expenses	500
Miscellaneous	147
Total	$40,000

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:

- breaches of the director's duty of loyalty to the corporation or its stockholders;
- acts or omissions not made in good faith or which involve intentional misconduct of knowing violations of law;
- liability for dividends paid or stock repurchased or redeemed in violation of the Delaware General Corporation Law; or
- 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 time 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. [UPDATE]

Item 16. Exhibits

Number	Description
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 (incorporated by reference to Exhibit 4.8 to Amendment No. 3 to Registrant's Registration Statement on Form SB-2 (No. 333-101661)).
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 (Commission File No. 001-16133)).
4.7	Form of Series A Warrant to Purchase Shares of Common Stock dated as of November 24, 2004 (incorporated by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K dated November 24, 2004 (Commission File No. 001-16133)).
4.8	Form of Series C Warrant to Purchase Shares of Common Stock dated as of November 24, 2004 (incorporated by reference to Exhibit 4.3 to Registrant's Current Report on Form 8-K dated November 24, 2004 (Commission File No. 001-16133)).
4.9	Form of Series D Warrant to Purchase Shares of Common Stock dated as of December 7, 2004 (incorporated by reference to Exhibit 4.10 to Registrant's Registration Statement on Form S-3 (Registration No. 333-121681)).

4.10 Warrant Agreement dated as of July 22, 2005 between the Registrant and American Stock Transfer & Trust Company, as warrant agent, together with the form of 2005 Redeemable Common Stock Purchase Warrants - Series A (incorporated by reference to Exhibit 4 to Registrant's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005 (File No. 001-16133)).

5 Opinion of Murtha Cullina LLP.

23.1 Consent of Eisner LLP.

23.2 Consent of Murtha Cullina LLP (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 By-laws 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.

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 17th day of August, 2005.

Delcath Systems, Inc.

By: 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)	By: M. S. KOLY Attorney-in-Fact
Paul M. Feinstein	Chief Financial Officer (Principal Financial Officer)	
Samuel Herschkowitz	Chairman and Director	Dated: August 17, 2
Mark A. Corigliano	Director	
Daniel Isdaner	Director	
Victor Nevins	Director	

EXHIBIT INDEX

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4.8	Form of Series C Warrant to Purchase Shares of Common Stock dated as of November 24, 2004 (incorporated by reference to Exhibit 4.3 to Registrant's Current Report on Form 8-K dated November 24, 2004 (Commission File No. 001-16133)).
4.9	Form of Series D Warrant to Purchase Shares of Common Stock dated as of December 7, 2004 (incorporated by reference to Exhibit 4.10 to Registrant's Registration Statement on Form S-3 (Registration No. 333-121681)).
4.10	Warrant Agreement dated as of July 22, 2005 between the Registrant and American Stock Transfer & Trust Company, as warrant agent, together with the form of 2005 Redeemable Common Stock Purchase Warrants - Series A (incorporated by reference to Exhibit 4 to Registrant's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005 (File No. 001-16133)).
5	Opinion of Murtha Cullina LLP.

Number	Description
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23.2	Consent of Murtha Cullina LLP (included in Exhibit 5).
24	Power of Attorney.