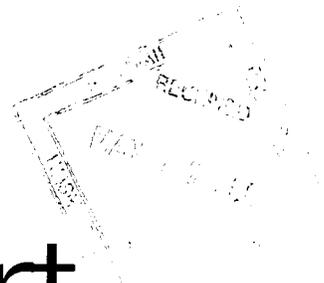
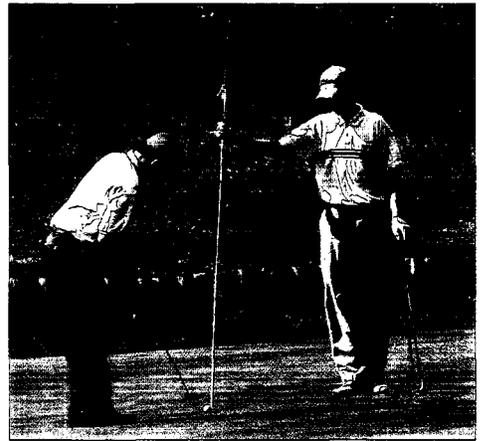
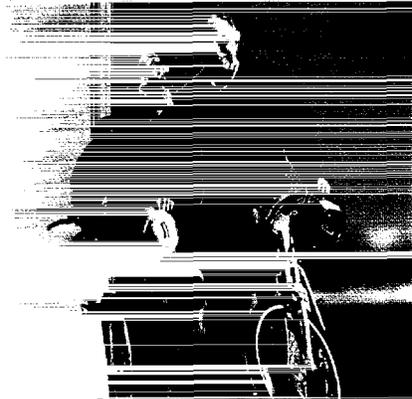




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# 2004 Annual Report



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THOMSON  
FINANCIAL



The Future of Targeted Drug Delivery

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# OUR MISSION

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To become the leading provider of systems for organ specific and regional delivery of drugs — using FDA-approved anticancer agents.

## OVERVIEW OF THE DELCATH SYSTEM

- Organ or regional specific drug delivery
- Outpatient procedure, minimally invasive
- Permits higher drug doses
- Filtration minimizes systemic toxicity
- Repeatable procedure increases utility of FDA-approved drugs
- Safety, efficacy demonstrated for certain cancers in the liver
- Systems protected by multiple patents



## BOARD OF DIRECTORS

*From left to right:*

Mark A. Corigliano, Victor Nevins, M.S. Koly—President, Chief Executive Officer & Treasurer,  
Daniel L. Isdaner and Samuel Herschkowitz, M.D. —Chairman & Chief Technical Officer

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# TO OUR SHAREHOLDERS

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Delcath experienced substantial progress in most key areas of corporate and clinical development during the past year, including:

Initiation of enrollment in our Phase III trial, start of a multiple histology Phase II clinical trial at the National Cancer Institute, two private placement financings, several professional society presentations of Delcath data by the National Cancer Institute (NCI), and the commencement of discussions with the FDA concerning possible protocol revisions to accelerate the clinical study of our device and facilitate a more rapid market introduction.

All of the clinical studies with Delcath technology completed thus far, including those undertaken at the NCI, have provided confirmatory evidence of the Delcath system's ability to shrink tumors and prolong the survival of some patients with inoperable tumors in the liver. These results have been achieved with organ specific delivery of two well known and widely used cancer agents, doxorubicin and melphalan.

Although the Delcath system is a platform technology (it can be used with practically any drug for multiple types of cancers in different organs) its current clinical development is focused specifically on cancers in the liver. For this application, the Delcath system delivers high-dose chemotherapy directly to the liver via the hepatic artery. As blood exits the liver through the Delcath system's double-balloon catheter, special filters trap the chemotherapy, protecting the rest of the body from excessive toxicity. The procedure is repeatable and is less invasive than a surgical technique that was previously the only way to perform isolated perfusion to effect dose-directed therapy of specific body organs or regions. Since more than 80 percent of cancerous tumors in the liver cannot be surgically removed at the time of diagnosis, the Delcath system is designed to isolate the organ to allow aggressive chemotherapy while limiting the serious side effects that typically restrict dosing of toxic-but-therapeutic cancer chemicals.

The Phase III clinical trial using the Delcath system with the cancer drug doxorubicin will continue in Australia, treating patients who suffer from metastatic melanoma in the liver. Because of the high incidence of melanoma in Australia, we are currently negotiating with other clinical trial facilities in Australia. We are also in discussion with several US trial sites, and we are optimistic about one or more becoming active with our technology in the near future. While the initiation of these sites has frustratingly taken longer than we hoped or expected, we remain committed to this goal.

*continued on page 2*

Company  
founded by  
a team of  
physicians

1988

Company  
commences  
Phase I  
clinical trials

1990

Delcath  
receives  
first  
U.S. patent

1991

Company  
receives  
Canadian and  
European patents

1995

Company  
receives  
Japanese  
patents

1998

Company receives  
FDA approval  
for conducting  
Phase III clinical trials

1999

Two years ago, the company began working with the NCI to expand the human clinical studies of Delcath's technology for inoperable liver cancers using melphalan, another effective chemotherapeutic agent. A Phase 1 dose finding study has been completed and its results have been reported at several professional society conferences, the most recent being the March 2005 meeting of The Society of Surgical Oncology in Atlanta, GA.

NCI researchers reported that survival times were longer than expected, and that two-thirds of the patients experienced positive anti-tumor activity ranging from stabilization to a complete response.

The NCI researchers also assessed how liver tumors originating from different types of cancers responded to the Delcath experimental therapy. The findings formed the basis for advanced clinical studies to evaluate the Delcath system in treating diseases other than metastatic melanoma in the liver. Phase II trials at NCI have begun, and in these trials the Delcath system will be used to treat patients with primary liver cancer as well as neuro-endocrine tumors and adenoid carcinomas that metastasize to the liver.

It was the success and positive results of the NCI's Phase I trial that led H. Richard Alexander, MD, head of NCI's Surgical Metabolism Section, and his staff to design and propose the Phase II study with melphalan and the Delcath system. This study is currently enrolling and treating patients.

In addition to tumor response and survival time endpoints, Dr. Alexander will also measure quality of life outcomes, comparing Delcath patients to the conventionally treated control group.

As part of our ongoing internal review of Delcath clinical programs and study protocols we have begun discussions with the FDA on a wide range of topics that could contribute to improving clinical trial enrollment rates and facilitate market introduction of Delcath's technology.

The Company completed two private placements of shares and warrants to accredited investors during 2004 that resulted in our raising over \$5.0 million of working capital to continue clinical trials and product development. Additionally, the exercise by shareholders of previously issued warrants resulted in our raising an additional \$2.2 million for clinical procedures. Delcath's clinical programs are growing in scope and our cash position is the strongest it's been since our IPO five years ago. We expect to make substantial progress in 2005 toward becoming the premier developer and marketer of technology for high-dose delivery of drugs to specific body organs or regions. On behalf of the Board of Directors, I would like to extend our appreciation and thanks to our employees, our advisors, our outside clinical investigators, and our loyal shareholders for your continued support of our programs. We look forward to a successful year ahead.



M.S. Koly  
President, Chief Executive Officer and Treasurer

Delcath completes Initial Public Offering of Common Stock

2000

Company commences Phase I clinical trial study with melphalan at the National Cancer Institute

2001

NCI presentation to medical symposium concerning the positive results of the Delcath System

2003

Company commences Phase III clinical trial study with doxorubicin at the Sydney Melanoma Unit. Phase I clinical trial using melphalan completed at the NCI.

2004

# RECENT PRESENTATIONS BY INVESTIGATORS

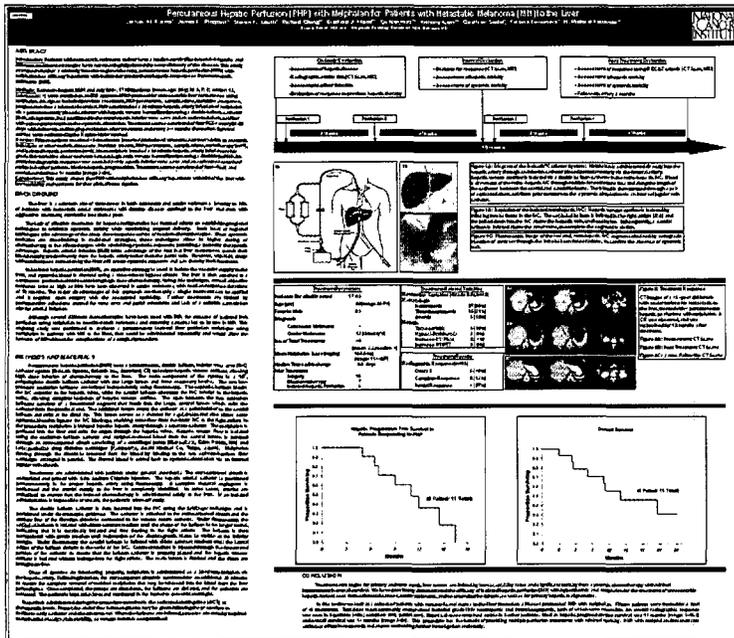
Dr. Jeffrey Farma, a colleague of the Principal Investigator, Dr. Richard Alexander, presented an academic poster (pictured below) before the 2005 Gastrointestinal Cancers Symposium. The clinical investigators have discussed their experience with the Delcath system at numerous meetings and in publications. A few presentations that focused solely on the Delcath system include:

The Royal Australasian College of Surgeons Annual Scientific Meeting in Auckland, New Zealand, September 8 - 10, 2004

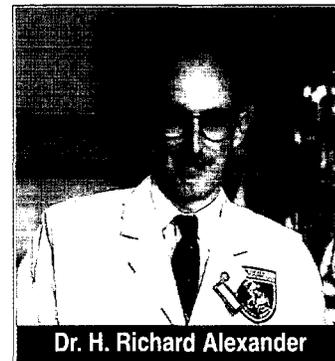
The Gastrointestinal Cancers Symposium in Hollywood, Florida  
January 27 - 29, 2005

The Society of Surgical Oncology's 58th Annual Cancer Symposium, in Atlanta, Georgia  
March 3 - 6, 2005

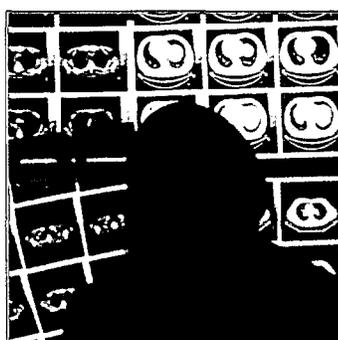
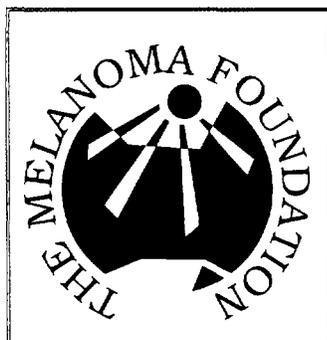
In addition, a major medical journal has accepted a paper by Dr. Alexander for publication. These presentations and publications not only demonstrate peer review by the leaders in the field, they also help educate physicians around the world regarding the benefits of the treatment and encourage patient referrals.



Poster presented by Dr. Farma discussing the observed tumor responses in the completed Phase I trial



Dr. H. Richard Alexander



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# PLAN OF OPERATION

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## DELCATH SYSTEMS, INC. (A DEVELOPMENT STAGE COMPANY)

Since our founding in 1988 by a team of physicians, we have been a development stage company engaged primarily in developing and testing the Delcath system for the treatment of cancer in the liver. A substantial portion of our historical expenses have been for the development of our medical device and the clinical trials of our product, and the pursuit of patents worldwide. We expect to continue to incur significant losses from costs for product development, clinical studies, securing patents, regulatory activities, manufacturing and establishment of a sales and marketing organization without any significant revenues. A detailed description of the cash used to fund historical operations is in the financial statements and the notes thereto. Without an FDA-approved product and commercial sales, we will continue to be dependent upon existing cash and the sale of equity or debt to fund future activities. While the amount of future net losses and time required to reach profitability are uncertain, our ability to generate significant revenue and become profitable will depend on our success in commercializing our device.

During 2001, Delcath initiated the clinical trial of the system for isolated liver perfusion using the chemotherapeutic agent, melphalan. The Phase I trial at the National Cancer Institute marked an expansion in the potential labeled usage beyond doxorubicin, the chemotherapeutic agent used in our initial clinical trials. Enrollment of new patients in the Phase I trial was completed in 2003 and following the 2004 presentation and adoption of a Phase II clinical trial protocol, patients are being enrolled and treated.

During 2004, we commenced a Phase III clinical trial study at the Sydney Melanoma Unit to proceed with study of the Delcath drug delivery system for inoperable cancer in the liver using doxorubicin. We are currently identifying, recruiting and treating patients and are in discussions with other sites worldwide.

Over the next 12 months, we expect to continue to incur substantial expenses related to the

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

### **Liquidity and Capital Resources**

Our available funds will be sufficient to meet our anticipated needs for working capital and capital expenditures at least through 2006. The Company is not projecting any capital expenditures that will significantly affect the Company's liquidity during the next 12 months. The Company is projecting the hiring of one additional employee.

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

### **Future Capital Needs; Additional Future Funding**

The Company's future results are subject to substantial risks and uncertainties. The Company has operated at a loss for its entire history and there can be no assurance of its ever achieving consistent profitability. The Company believes its capital resources are adequate to fund operations for at least the next twelve months but anticipates that it will

require additional working capital after 2006. There can be no assurance that such working capital will be available on acceptable terms, if at all.

### **Forward Looking Statements**

Certain statements in this report, including statements of our and management's expectations, intentions, plans, objectives and beliefs, including those contained in or implied by "Management's Discussion and Analysis or Plan of Operation," are "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, that are subject to certain events, risks and uncertainties that may be outside our control. These forward-looking statements may be identified by the use of words such as "expects," "anticipates," "intends," "plans" and similar expressions. They include statements of our future plans and objectives for our future operations and statements of future economic performance, information regarding our expansion and possible results from expansion, 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 report 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 without limitation, those described in the context of such forward-looking statements, our expansion strategy, 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, and other risk factors described from time to time in our other documents and reports filed with the Securities and Exchange Commission (the "Commission"). We do not assume any responsibility to publicly 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-QSB, Form 8-K and Form 10-KSB reports filed with the Commission.

### **Application of Critical Accounting Policies**

The Company's financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The notes to financial statements included in Item 7 contain a summary of the significant accounting policies and methods used in the preparation of Delcath's financial statements. The Company is still in the development stage and has no revenues, trade receivables, inventories, or significant fixed or intangible assets and therefore has very limited opportunities to choose among accounting policies or methods. In many cases, the Company must use an accounting policy or method because it is the only policy or method permitted under accounting principles generally accepted in the United States of America.

Additionally, the Company devotes substantial resources to clinical trials and other research and development activities relating to obtaining FDA and other approvals for the Delcath system, the cost of which is required to be charged to expense as incurred. This further limits the Company's choice of accounting policies and methods. Similarly, management believes there are very limited circumstances in which the Company's financial statement estimates are significant or critical.

The Company considers the valuation allowance for the deferred tax assets to be a significant accounting estimate. In applying SFAS No. 109, "Accounting for Income Taxes," management estimates future taxable income from operations and tax planning strategies in determining if it is more likely than not that the Company will realize the benefits of its deferred tax assets.

# BALANCE SHEET

DELCATH SYSTEMS, INC. (A DEVELOPMENT STAGE COMPANY)

December 31, 2004

## Assets

### Current assets:

Cash and cash equivalents	\$	202,335
Certificate of deposit		7,055,129
Interest receivable		32,886
Prepaid insurance		47,816
Total current assets	\$	<u>7,338,166</u>

Furniture and fixtures, net		<u>13,606</u>
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Total assets	\$	<u>7,351,772</u>
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## Liabilities and Stockholders' Equity

### Current liabilities:

Accounts payable and accrued expenses	\$	564,626
Total current liabilities		<u>564,626</u>

### Stockholders' equity:

Preferred stock, \$.01 par value; 10,000,000 shares authorized; no shares issued and outstanding		—
Common stock, \$.01 par value; 70,000,000 shares authorized; 15,243,185 shares issued and 15,215,085 outstanding		152,151
Additional paid-in capital		29,605,543
Deficit accumulated during development stage		<u>(22,970,548)</u>

Total stockholders' equity		<u>6,787,146</u>
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Total liabilities and stockholders' equity	\$	<u>7,351,772</u>
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# STATEMENTS OF OPERATIONS

DELCATH SYSTEMS, INC. (A DEVELOPMENT STAGE COMPANY)

	Year ended December 31,		Cumulative from inception (August 5, 1988) to December 31, 2004
	2004	2003	
<b>Costs and expenses:</b>			
General and administrative	\$ 1,059,815	\$ 707,737	\$ 7,070,861
Research and development	2,306,733	1,598,615	15,316,229
Total costs and expenses	<u>3,366,548</u>	<u>2,306,352</u>	<u>22,387,090</u>
Operating loss	(3,366,548)	(2,306,352)	(22,387,090)
<b>Other income (expense):</b>			
Interest income	100,216	55,941	1,086,620
Interest expense	—	—	(171,473)
Net loss	<u>\$ (3,266,332)</u>	<u>\$ (2,250,411)</u>	<u>\$ (21,471,943)</u>
<b>Common share data:</b>			
Basic and diluted loss per share	\$ (0.28)	\$ (0.30)	
Weighted average number of basic and diluted common shares outstanding	<u>11,543,256</u>	<u>7,453,349</u>	

See accompanying notes to financial statements.

# STATEMENTS OF CASH FLOWS

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

	Year ended December 31,		Cumulative from inception (August 5, 1988) to December 31, 2003
	2004	2003	
<b>Cash flows from operating activities:</b>			
Net loss	\$ (3,266,332)	\$ (2,250,411)	\$ (21,471,943)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	5,222	—	2,525,392
Stock and warrant compensation expense issued for consulting services	—	—	236,286
Depreciation expense	5,526	4,990	31,692
Amortization of organization costs	—	—	42,165
Rent expense attributable to lease deposit	24,000	—	—
Changes in assets and liabilities:			
(Increase) decrease in prepaid expenses	(316)	49,083	(47,816)
Increase in interest receivable	(18,611)	(8,865)	(32,883)
Increase in accounts payable and accrued expenses	304,425	85,030	564,625
Net cash used in operating activities	(2,946,086)	(2,120,173)	(18,152,482)
<b>Cash flows from investing activities:</b>			
Purchase of furniture and fixtures	(5,347)	(5,029)	(45,300)
Purchase of short-term investments	(6,052,383)	(2,017,321)	(10,969,704)
Proceeds from maturities of short-term investments	1,014,575	370,000	3,914,575
Organization costs	—	—	(42,165)
Net cash used in investing activities	(5,043,155)	(1,652,350)	(7,142,594)
<b>Cash flows from financing activities:</b>			
Net proceeds from sale of stock and exercise of stock options and warrants	7,877,961	3,022,487	24,343,085
Repurchases of outstanding common stock	—	—	(51,103)
Dividends paid	—	—	(499,535)
Proceeds from short-term borrowings	—	—	1,704,964
Net cash provided by financing activities	7,877,961	3,022,487	25,497,411
(Decrease) increase in cash and cash equivalents	(111,280)	(750,035)	202,335
Cash and cash equivalents at beginning of period	313,615	1,063,650	—
Cash and cash equivalents at end of period	\$ 202,335	\$ 313,615	\$ 202,335
Cash paid for interest	\$ —	\$ —	\$ 171,473
<b>Supplemental non-cash activities:</b>			
Conversion of debt to common stock	\$ —	\$ —	\$ 1,704,964
Common stock issued for preferred stock dividends	\$ —	\$ —	\$ 999,070
Conversion of preferred stock to common stock	\$ —	\$ —	\$ 24,167
Common stock issued as compensation for stock sale	\$ —	\$ —	\$ 510,000

See accompanying notes to financial statements.

# STATEMENTS OF STOCKHOLDERS' EQUITY

Years ended December 31, 2004 and 2003 and

	Issued		Common stock \$.01 par value In treasury		Outstanding	
	No. of shares	Amount	No. of shares	Amount	No. of shares	Amount
Shares issued in connection with the formation of the Company as of August 22, 1988	621,089	\$ 6,211	—	\$ —	621,089	\$ 6,211
Sale of preferred stock, August 22, 1988	—	—	—	—	—	—
Shares returned as of March 8, 1990	—	—	(414,059)	(4,141)	(414,059)	(4,141)
Sale of stock, October 2, 1990	—	—	17,252	173	17,252	173
Sale of stock, January 23, 1991	—	—	46,522	465	46,522	465
Sale of stock, August 30, 1991	—	—	1,353	14	1,353	14
Sale of stock, December 31, 1992	—	—	103,515	1,035	103,515	1,035
Sale of stock, July 15, 1994	—	—	103,239	1,032	103,239	1,032
Sale of stock, December 19, 1996	—	—	39,512	395	39,512	395
Shares issued in connection with conversion of short-term borrowings as of December 22, 1996	58,491	585	98,388	984	156,879	1,569
Sale of stock, December 31, 1997	53,483	535	—	—	53,483	535
Exercise of stock options	13,802	138	3,450	35	17,252	173
Shares issued as compensation	2,345	23	828	8	3,173	31
Shares issued in connection with exercise of warrants	21,568	216	—	—	21,568	216
Sale of stock, January 16, 1998	34,505	345	—	—	34,505	345
Sale of stock, September 24, 1998	3,450	35	—	—	3,450	35
Shares returned, April 17, 1998	(3,450)	(35)	—	—	(3,450)	(35)
Exercise of stock options	8,626	86	—	—	8,626	86
Sale of stock, June 30, 1999	46,987	470	—	—	46,987	470
Shares issued in connection with exercise of warrants	2,300	23	—	—	2,300	23
Sale of stock, April 14, 2000	230,873	2,309	—	—	230,873	2,309
Dividends paid on preferred stock	690,910	6,909	—	—	690,910	6,909
Conversion of preferred stock	833,873	8,339	—	—	833,873	8,339
Sale of stock, October 19, 2000	1,200,000	12,000	—	—	1,200,000	12,000
Shares issued as compensation for stock sale	85,000	850	—	—	85,000	850
Stock options issued as compensation	—	—	—	—	—	—
Sum of fractional common shares cancelled after year 2000 stock splits	(36)	(1)	—	—	(36)	(1)
Stock warrants issued as compensation	—	—	—	—	—	—
Sale of stock on April 3, 2002	243,181	2,432	—	—	243,181	2,432
Repurchases of stock, November and December 2002	—	—	(28,100)	(281)	(28,100)	(281)
Amortization since inception of compensatory stock options	—	—	—	—	—	—
Forfeiture since inception of stock options	—	—	—	—	—	—
Deficit accumulated from inception to December 31, 2002	—	—	—	—	—	—
Balance at December 31, 2002	4,146,997	\$41,470	(28,100)	\$ (281)	4,118,897	\$ 41,189
Sale of stock on May 20, 2003 including underwriter's exercise of over-allotment option	3,895,155	38,952	—	—	3,895,155	38,952
Proceeds from sale of unit option	—	—	—	—	—	—
Exercise of 2003 Warrants	1,730,580	17,305	0	0	1,730,580	17,305
Net Loss for year ended December 31, 2003	—	—	—	—	—	—
Balance at December 31, 2003	9,772,732	\$ 97,727	(28,100)	\$ (281)	9,744,632	\$ 97,446
Sale of stock March, 2004	1,197,032	11,970	—	—	1,197,032	11,970
Sale of stock April, 2004	290,457	2,905	—	—	290,457	2,905
Exercise of 2002 Warrants	20,265	203	—	—	20,265	203
Stock options issued as compensation	—	—	—	—	—	—
Exercise of 2003 Warrants	2,160,163	21,602	—	—	2,160,163	21,602
Sale of stock November, 2004	1,069,520	10,695	—	—	1,069,520	10,695
Sale of stock December, 2004	236,966	2,370	—	—	236,966	2,370
Exercise of 2003 Representative's Unit Warrants	282,025	2,820	—	—	282,025	2,820
Exercise of Representative's Common Stock Warrants	152,025	1,520	—	—	152,025	1,520
Exercise of stock options	62,000	620	—	—	62,000	620
Net loss for year ended December 31, 2004	—	—	—	—	—	—
	15,243,185	\$152,432	(28,100)	\$ (281)	15,215,085	\$ 152,151

See accompanying notes to financial statements.

DELCATH SYSTEMS, INC. (A DEVELOPMENT STAGE COMPANY)

cumulative from inception (August 5, 1988) to December 31, 2004

Preferred Stock \$.01 par value		Class A Preferred stock \$.01 par value		Class B Preferred stock \$.01 par value		Additional paid-in capital	Deficit accumulated during development stage	Total
No. of shares	Amount	No. of shares	Amount	No. of shares	Amount			
—	\$ —	—	\$ —	—	\$ —	\$ (5,211)	\$ —	\$ 1,000
—	—	2,000,000	20,000	—	—	480,000	—	500,000
—	—	—	—	—	—	4,141	—	—
—	—	—	—	—	—	24,827	—	25,000
—	—	—	—	416,675	4,167	1,401,690	—	1,406,322
—	—	—	—	—	—	9,987	—	10,001
—	—	—	—	—	—	1,013,969	—	1,015,004
—	—	—	—	—	—	1,120,968	—	1,122,000
—	—	—	—	—	—	999,605	—	1,000,000
—	—	—	—	—	—	1,703,395	—	1,704,964
—	—	—	—	—	—	774,465	—	775,000
—	—	—	—	—	—	30,827	—	31,000
—	—	—	—	—	—	34,454	—	34,485
—	—	—	—	—	—	234,182	—	234,398
—	—	—	—	—	—	499,655	—	500,000
—	—	—	—	—	—	56,965	—	57,000
—	—	—	—	—	—	(4,965)	—	(5,000)
—	—	—	—	—	—	67,414	—	67,500
—	—	—	—	—	—	775,722	—	776,192
—	—	—	—	—	—	24,975	—	24,998
—	—	—	—	—	—	499,516	—	501,825
—	—	—	—	—	—	992,161	(1,498,605)	(499,535)
—	—	(2,000,000)	(20,000)	(416,675)	(4,167)	15,828	—	—
—	—	—	—	—	—	5,359,468	—	5,371,468
—	—	—	—	—	—	(850)	—	—
—	—	—	—	—	—	3,800	—	3,800
—	—	—	—	—	—	1	—	—
—	—	—	—	—	—	198,000	—	198,000
—	—	—	—	—	—	265,068	—	267,500
—	—	—	—	—	—	(50,822)	—	(51,103)
—	—	—	—	—	—	3,760,951	—	3,760,951
—	—	—	—	—	—	(1,240,780)	—	(1,240,780)
—	—	—	—	—	—	—	(15,955,200)	(15,955,200)
0	\$ 0	0	\$ 0	0	\$ 0	\$ 19,049,406	\$ (17,453,805)	\$ 1,636,790
—	—	—	—	—	—	1,453,696	—	1,492,648
—	—	—	—	—	—	68	—	68
0	0	0	0	0	0	1,273,895	0	1,291,200
—	—	—	—	—	—	—	(2,250,411)	(2,250,411)
0	\$ 0	0	\$ 0	0	\$ 0	\$ 21,777,065	\$ (19,704,216)	\$ 2,170,295
—	—	—	—	—	—	2,660,625	—	2,672,595
—	—	—	—	—	—	635,130	—	638,035
—	—	—	—	—	—	26,547	—	26,750
—	—	—	—	—	—	5,222	—	5,222
—	—	—	—	—	—	1,652,524	—	1,674,126
—	—	—	—	—	—	1,829,305	—	1,840,000
—	—	—	—	—	—	497,630	—	500,000
—	—	—	—	—	—	284,383	—	287,203
—	—	—	—	—	—	193,072	—	194,592
—	—	—	—	—	—	44,040	—	44,040
—	—	—	—	—	—	—	(3,266,332)	(3,266,332)
0	\$ 0	0	\$ 0	0	\$ 0	\$ 29,605,543	\$ (22,970,548)	\$ 6,787,146

# NOTES TO FINANCIAL STATEMENTS

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

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

### (A) Description of Business

Delcath Systems, Inc. (the "Company") is a development stage company which was founded in 1988 for the purpose of developing and marketing a proprietary drug delivery system capable of introducing and removing high dose chemotherapy agents to a diseased organ system while greatly inhibiting their entry into the general circulation system. It is hoped that the procedure will result in a meaningful treatment for cancer. In November 1989, the Company was granted an IDE (Investigational Device Exemption) and an IND status (Investigational New Drug) for its product by the FDA (Food and Drug Administration). The Company is seeking to complete clinical trials in order to obtain separate FDA pre-market approvals for the use of its delivery system using doxorubicin and melphalan, chemotherapeutic agents, to treat malignant melanoma that has spread to the liver.

### (B) Basis of Financial Statement Presentation

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

### (C) Furniture and Fixtures

Furniture and fixtures are recorded at cost and are being depreciated on a straight line basis over the estimated useful lives of the assets of five years. Accumulated depreciation amounted to \$31,692 at December 31, 2004.

### (D) Income Taxes

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

### (E) Stock Option Plan

The Company has historically accounted for its employee stock option plans in accordance with the provisions of Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. As such, compensation cost is measured on the date of grant only if the

current fair market value of the underlying stock exceeds the exercise price. Fair market values of the Company's Common Stock at the dates options were granted, prior to the Company's stock becoming publicly traded, were based on third party sales of stock at or around the dates options were granted, or in the absence of such transactions, based on a determination by the board of directors based on current available information. Such cost is then recognized over the period the recipient is required to perform services to earn such compensation. If a stock option does not become vested because an employee fails to fulfill an obligation, the estimate of compensation expense recorded in previous periods is adjusted by decreasing compensation expense in the period of forfeiture.

The Company has adopted Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock-Based Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure," which permits entities to recognize as expense over the vesting period the fair value of all stock-based awards on the date of grant. Alternatively, SFAS No. 123 also allows entities to continue to apply the provisions of APB Opinion No. 25 and provide pro forma net income (loss) and pro forma earnings (loss) per share disclosures for employee stock option grants as if the fair-value-based method defined in SFAS No. 123 had been applied. The Company has elected to continue to apply the provisions of APB Opinion No. 25 and provide the pro forma disclosure in accordance with the provisions of SFAS No. 123.

Had compensation cost for the Company's stock option grants been determined based on the fair value at the grant dates consistent with the methodology of SFAS No. 123, the Company's net loss and net loss per share for the years ended December 31, 2004 and 2003 would have been increased to the pro forma amounts indicated as follows:

	2004	2003
Net loss	\$ (3,266,332)	\$ (2,250,411)
Stock-based employee compensation expense included in net loss, net of related tax effects	0	0
Stock-based employee compensation determined under the fair value based method, net of related tax effects	(93,793)	(82,568)
Pro forma net loss	\$ (3,360,125)	\$ (2,332,979)
Loss per share (basic and diluted):		
As reported	\$ (0.28)	\$ (0.30)
Pro forma	(0.29)	(0.31)

The per share weighted average fair value of stock options granted during 2003 was \$.32, estimated on the date of grant using the Black-Scholes option-pricing model with the weighted-average assumption of a risk free interest rate of 3.49% and volatility of 29%, with no dividend yield and an expected life of five years. No options were granted in 2004.

# NOTES TO FINANCIAL STATEMENTS (continued)

## **(F) Loss Per Share**

The Company follows the provisions of SFAS No. 128, "Earnings Per Share", which requires presentation of both basic and diluted earnings per share (EPS) on the face of the Statements of Operations. Basic EPS excludes dilution and is computed using the weighted average number of common shares outstanding during the period. The diluted EPS calculation assumes all dilutive stock options or contracts to issue Common Stock were exercised or converted into Common Stock at the beginning of the period.

For the years ended December 31, 2004 and 2003, the following potential common shares were excluded from the computation of diluted EPS because their effects would be antidilutive:

	2004	2003
Shares issuable upon exercise of options	1,017,020	1,520,678
Shares issuable upon exercise of warrants	<u>4,417,748</u>	<u>4,628,970</u>
	<u>5,434,768</u>	<u>6,149,648</u>

In addition, Common Stock purchase rights issuable only in the event that a non-affiliated person or group acquires 15% of the Company's then outstanding Common Stock have been excluded from the computation.

## **(G) Research and Development Costs**

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

## **(H) Cash Equivalents**

The Company considers highly liquid debt instruments with maturities of three months or less at date of acquisition to be cash equivalents.

## **(I) Stock Splits**

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

## **(2) Stockholders' Equity**

### **(A) Stock Issuances**

BGH Medical Products, Inc. (name later changed to Delcath Systems, Inc.), a Delaware corporation (BGH - Delaware), was formed on August 5, 1988. As of August 22, 1988, BGH Medical Products, Inc., a Connecticut corporation (BGH - Conn.), was merged into BGH - Delaware, the surviving corporation. As of the merger date, the authorized capital stock of BGH - Conn. consisted of 5,000 shares of common stock, par value \$.01 per share, of which 1,000 shares were issued and outstanding. Upon the merger, each BGH - Conn. Common Share outstanding was converted into 621.089 BGH - Delaware Common Shares. As a result of the conversion, BGH - Delaware issued 621,089 shares of Common Stock at \$.01 par value. The aggregate amount of the par value of all Common Shares issued as a result of the exchange, \$6,211, was credited as the Common Stock capital of

BGH - Delaware, and the difference in respect of the capital account deficiency was charged to additional paid-in capital.

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

On March 8, 1990, 414,059 shares of Common Stock were returned to the Company by certain stockholders as treasury stock due to relevant technology milestones not being fully achieved within the specified time period, in accordance with provisions of a stockholders' agreement.

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

On October 2, 1990, the Company sold 17,252 shares of Common Treasury Stock, \$.01 par value, for an aggregate amount of \$25,000.

On January 23, 1991, the Company offered in a private placement shares of Common Stock and/or Class B Preferred Stock at \$7.39 and \$2.55 per share respectively for an aggregate maximum amount of \$2,000,000. Under the terms of the private placement, 46,522 shares of Common Treasury Stock and 416,675 shares of Class B Preferred Stock were sold, yielding net proceeds to the Company of \$1,406,322. The Common Stock and Class B Preferred Stock sold each has a par value of \$.01, resulting in an increase in additional paid-in capital of \$1,401,690. The two affiliated venture capital funds that owned the Class A Preferred Shares purchased 117,650 of the Class B Preferred Shares sold in the private placement.

On August 30, 1991, the Company sold an additional 1,353 shares of Common Treasury Stock at \$7.39 per share, yielding proceeds to the Company of \$10,001. The shares have a par value of \$.01, resulting in an additional paid-in capital amount of \$9,987.

In a December 1992 private placement, the Company sold 103,515 shares of Common Stock held in its treasury at \$10.14 per share for a total placement of \$1,050,000 (\$1,015,004 after expenses). The shares issued have a par value of \$.01, resulting in an additional paid-in capital amount of \$1,048,965 (\$1,013,969 after expenses). The two affiliated venture capital funds that owned the Class A Preferred Shares purchased 27,604 of the Common Treasury Shares sold.

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

During the first quarter of 1994, the Company increased its authorized number of Common Shares from 5,000,000 to 15,000,000.

On July 15, 1994, the Company sold through a private placement offering, units at a price of \$51,000 per unit. Each unit consisted of 4,693 Common Shares and 469 Warrants,

# NOTES TO FINANCIAL STATEMENTS (continued)

each of which entitled the holder to purchase one share of Common Stock for \$10.87. In connection therewith, the Company sold twenty-two (22) units (103,239 Common Shares and 10,324 Warrants expiring August 30, 1997) for total proceeds of \$1,122,000. The two affiliated venture capital funds that owned the Class A Preferred Shares purchased six (6) of the units sold. During August 1997, the holders of Warrants exercised 8,916 Warrants to purchase 8,916 Common Shares at \$10.87 each for total proceeds of \$96,900. The remaining Warrants expired unexercised.

Effective January 1, 1995, the Company issued 1,725 shares of Common Treasury Stock at \$1.45 per share for a total price of \$2,500 upon the exercise of stock options by an employee of the Company.

Effective January 1, 1996, the Company issued 828 shares of Common Stock, valued at \$10.87 per share for a total of \$9,000, as compensation for consulting services.

On December 19, 1996, the Company sold through a private transaction 39,512 shares of Common Stock for total proceeds of \$1,000,000. In connection with the offering, the purchaser obtained sole distribution rights for the Company's products in Japan, Korea, China, Taiwan, and Hong Kong through December 31, 2004. No value was attributed to the distribution rights. In addition, under certain conditions, the purchaser would have been required to buy certain products from the Company.

On April 26, 1996, the Company entered into short-term borrowing agreements with 26 investors under which it borrowed \$1,704,964 bearing interest at 10.25% per annum. Under the terms of the agreements, on December 22, 1996, the short-term borrowings were converted into 156,879 shares of Common Stock, based on a conversion price of \$10.87 per share, and 78,438 Warrants, expiring April 25, 1999, entitling the holders to purchase 78,438 additional shares of Common Stock at \$10.87 per share. The two affiliated venture capital funds discussed above provided \$250,000 of the short-term loan, converting that debt into approximately 23,003 shares of Common Stock and 11,502 Warrants. From April 26, 1996 through December 22, 1996, interest of \$114,948 accrued on the borrowings. Such interest was paid in January 1997. During September 1997, the holders of Warrants exercised 1,150 Warrants to purchase 1,150 Common Shares at \$10.87 each for total proceeds of \$12,499. During December 1997, the two affiliated venture capital funds exercised their 11,502 Warrants to purchase 11,502 Common Shares at \$10.87 each for total proceeds of \$124,999. During April 1999, the holders of Warrants exercised 2,300 Warrants to purchase 2,300 Common Shares at \$10.87 each for total proceeds of \$24,998. The remaining Warrants expired unexercised.

In 1997, the Company issued 2,345 shares of Common Stock, valued at \$10.87 per share based on a 1996 agreement, for a total cost of \$25,485, as compensation for consulting services.

From September 1997 through December 31, 1997, the Company received \$775,000 and issued 53,483 shares of

Common Stock. During January 1998, the Company received an additional \$500,000 and issued another 34,505 shares of Common Stock. In April 1998, under the terms of restricted stock sale agreements, the Company issued to the purchasers of the 87,988 shares of Common Stock 11,732 three-year Warrants entitling the holders to purchase 11,732 Common Shares at \$10.87 per share. These Warrants expired unexercised in April 2001.

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

In April 1998, a venture capital firm exercised 8,626 non-incentive stock options to purchase 8,626 restricted Common Shares at \$7.83 each for total proceeds of \$67,500.

In April 1998, in connection with the settlement of a dispute with a former director, the Company cancelled 3,450 shares of Common Stock previously held by the former director in return for \$1.45 per share, the price originally paid by the former director.

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

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

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

The Company completed an initial public offering ("IPO") on October 19, 2000 of 1,200,000 units for \$6.00 per unit, each unit consisting of one share of Common Stock and one redeemable Warrant to purchase one share of Common Stock at a price of \$6.60 until October 18, 2005. In connection with the initial public offering, the Company received \$7,200,000 before offering costs (\$5,371,468 after expenses). The Company also issued to the underwriter Warrants to purchase 120,000 units for \$6.60 per unit, each unit consisting of one Common Share and one redeemable Warrant to purchase one share of Common Stock at a price of \$10.50 until October 18, 2005. The Company also issued 85,000 shares of Common Stock valued at \$510,000 for legal services provided in connection with the offering.

Also, in connection with the initial public offering, the holders of the 2,000,000 outstanding shares of the Company's Class A Preferred Stock and the 416,675 outstanding shares of the Company's Class B Preferred Stock agreed to convert their shares into Common Stock prior to the closing of the offering. Upon the conversion of the Company's Class A Preferred Stock and the Company's Class B Preferred Stock into 833,873 shares of Common Stock, the holders of the Class A and Class B shares received an aggregate of \$499,535 in cash and 690,910 shares of Common Stock valued at \$999,070 in payment of declared dividends.

# NOTES TO FINANCIAL STATEMENTS (continued)

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

The Company issued the following common stock warrants in 2001 for consulting services:

(1) 150,000 fully vested warrants to purchase 150,000 units at \$7.00 per unit, through January 4, 2005, each unit consisting of one fully-paid and non-assessable share of common stock, and one Common Stock Purchase Warrant entitling the holder to purchase one share of Common Stock for \$6.60 per share. None of these warrants has been exercised as of December 31, 2004. Such warrants, valued at \$175,000, were recognized as an expense in the first quarter of 2001.

(2) 150,000 warrants to purchase up to 150,000 shares of Common Stock, through April 30, 2005, for \$6.60 per share. 25,000 of such warrants vested in 2001 and the remaining 125,000 warrants would have vested if the share price of the Company's Common Stock exceeded certain share price levels above the IPO price by May 2002. As of May 2002, none of the thresholds had been met, and the 125,000 remaining warrants did not vest and were forfeited. None of the 25,000 vested warrants had been exercised as of December 31, 2004. The 25,000 vested, non-contingent warrants have been valued at \$23,000, and were recognized as an expense in the first quarter of 2001. The expenses, as noted in (1) and (2) above, recognized with these two warrant issues are non-cash expenses.

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

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

On October 30, 2001, the Company entered into a Rights Agreement with American Stock Transfer & Trust Company (the "Rights Agreement") in connection with the implementation of the Company's stockholder rights plan (the "Rights Plan"). The purposes of the Rights Plan are to deter, and protect the Company's shareholders from, certain coercive and otherwise unfair takeover tactics and to enable the Board of Directors to represent effectively the interests of shareholders in the event of a takeover attempt. The Rights Plan does not deter negotiated mergers or business combinations that the Board of Directors determines to be in the best interests of the Company and its shareholders. To implement

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

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

On January 31, 2003, the stockholders approved an amendment to the Company's certificate of incorporation to increase the authorized number of shares of Common Stock from 15 million to 35 million.

On May 20, 2003, the Company completed the sale of 677,419 units of its securities at a selling price of \$3.10 per unit. Each unit consisted of five shares of common stock and five warrants (the "2003 Warrants") each to purchase one share of common stock. The 2003 Warrants are exercisable at \$0.775, and they expire on May 20, 2008. A total of 3,387,095 shares of common stock and 2003 Warrants each were issued, and the Company received gross proceeds of \$2,099,999. In addition, the Company granted the underwriters an option to purchase at \$3.10 per unit up to an aggregate of an additional 15% of the total units sold in the public offering. On June 10, 2003 the underwriters exercised their option for the full allotment of additional units, and the Company issued 508,060 shares of its common stock and 2003 Warrants each, and received gross proceeds of \$314,997. The Company received \$68 for granting the underwriters an option to purchase until May 14, 2008, 67,741 units at 165% of the offering price. As a result of the foregoing, the Company received \$2,415,064 of proceeds (\$1,492,716 after underwriting fees and other expenses).

As of December 31, 2003, the Company had received \$1,291,200 of net proceeds from the exercise of 2003 Warrants for which it issued 1,730,580 shares of its common stock.

Costs of \$238,571 incurred through December 31, 2002 in connection with the May 2003 sale of units, which had been deferred at December 31, 2002, were charged to additional paid-in capital upon completion of the sale in 2003.

In March 2004 proceeds of \$26,750 were received (\$1.32 per share) as 20,265 warrants the Company issued in a private placement in 2002 were exercised.

# NOTES TO FINANCIAL STATEMENTS (continued)

In March 2004 the Company completed the sale of 1,197,032 shares of its common stock and the issuance of warrants to purchase 299,258 common shares at \$3.01 per share in a private placement to institutional and accredited investors. The Company received net proceeds of \$2,672,595 in this transaction and agreed to register the shares of common stock and the shares issuable upon exercise of the warrants under the Securities Act of 1933.

In April 2004 the Company completed an additional private placement of 290,457 shares of common stock and an aggregate of 72,614 warrants to purchase shares of its common stock, under the same terms and conditions as those sold in March 2004 for which it received net proceeds of \$638,035.

On June 15, 2004, the stockholders approved an amendment to the Company's certificate of incorporation to increase the authorized number of shares of Common Stock from 35 million to 70 million.

In November 2004 the Company completed the sale of 1,069,520 shares of its common stock at \$1.87 per share and the issuance of warrants to purchase 1,996,635 common shares in a private placement to institutional and accredited investors. The Company received net proceeds of \$1,840,000 in this transaction and agreed to register the shares of common stock and the shares issuable upon exercise of the warrants under the Securities Act of 1933.

In December 2004 the Company completed the sale of 236,966 shares of its common stock at \$2.11 per share and the issuance of warrants to purchase 94,787 common shares in a private placement to institutional and accredited investors. The Company received net proceeds of \$500,000 in this transaction and agreed to register the shares of common stock and the shares issuable upon exercise of the warrants under the Securities Act of 1933.

During 2004 the Company received net proceeds of \$1,674,126 (\$0.775 per share) as 2,160,163 of the 2003 Warrants were exercised and for which it has issued shares of its common stock. 1,893,658 warrants were exercised following a notice of redemption issued on October 1, 2004 in accordance with the terms of the warrant and as all such warrants have now been redeemed, trading therein has ceased.

During 2004 the Company received net proceeds of \$287,203 (\$1.022 per share) upon the exercise of 56,405 of the Representative Unit Purchase Warrants that were issued to underwriters as part of the 2003 public offering. This resulted in the issuance of 282,025 shares of common stock together with a similar amount of Representative's Common Stock Warrants. 152,025 Representative's Common Stock Warrants were exercised (\$1.28 per share) with a similar amount of common stock being issued and receipt of net proceeds of \$194,592.

The Company received a net amount of \$44,660 upon the exercise of 62,000 in stock options during the last quarter. 60,000 options were exercised at a price of \$0.71 per share and 2,000 were exercised at a price of \$1.03 per share.

## **(b) Common Stock Repurchases**

Pursuant to a stock repurchase plan approved in 2002 by the Company's Board of Directors, the Company repurchased 28,100 shares of common stock for \$51,103 during 2002. The Company has been authorized by the Board of Directors to purchase up to seven percent of its then outstanding common stock (290,289).

## **(c) Stock Option Plans**

The Company established an Incentive Stock Option Plan, a Non-Incentive Stock Option Plan, the 2000 Stock Option Plan, the 2001 Stock Option Plan and the 2004 Stock Incentive Plan (collectively, the "Plans") under which stock options may be granted. A stock option grant allows the holder of the option to purchase a share of the Company's Common Stock in the future at a stated price. The Plans are administered by the Compensation Committee of the Board of Directors which determines the individuals to whom the options shall be granted as well as the terms and conditions of each option grant, the option price and the duration of each option.

The Company's Incentive and Non-Incentive Stock Option Plans were approved and became effective on November 1, 1992. During 2000, 2001 and 2004, respectively, the 2000 and 2001 Stock Option Plans and the 2004 Stock Incentive Plan, became effective. Options granted under the Plans vest as determined by the Company and expire over varying terms, but not more than five years from the date of grant. Stock option activity for the period January 1, 2003 through December 31, 2004 is as follows:

	<b>The Plans</b>	
	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2002	1,145,678	2.43
Granted during 2003	475,000	1.03
Forfeited during 2003	(86,500)	.96
Expired during 2003	(13,500)	1.23
Outstanding at December 31, 2003	1,520,678	\$ 2.09
Expired during 2004	(441,664)	4.14
Exercised during 2004	(62,000)	.72
Outstanding at December 31, 2004	1,017,020	\$ 1.28

# NOTES TO FINANCIAL STATEMENTS (continued)

(c) **Stock Option Plans** *(continued from page 14)*

The following summarizes information about shares subject to option at December 31, 2004

Number Outstanding	Range of Exercise Prices	Options outstanding		Options exercisable	
		Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Number Exercisable	Average Exercise Price
100,000	\$ .60		1.92	100,000	
160,000	.71		2.75	130,000	
120,000	.85		2.00	120,000	
473,000	1.03		3.67	223,500	
164,020	3.31		0.95	164,020	
<u>1,017,020</u>	<u>\$ .60 — \$3.31</u>	<u>\$1.28</u>	<u>2.72</u>	<u>737,520</u>	<u>\$ 1.30</u>

At December 31, 2003, options for 935,678 shares were exercisable at a weighted average exercise price of \$2.79 per share.

**Income Taxes**

As of December 31, 2004, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$17,702,000. A portion of that amount, \$13,420,000, is subject to an annual limitation of approximately \$123,000 as a result of a change in the Company's ownership through May 2003, as defined by federal income tax regulations (Section 382). The balance of \$4,282,000 is available to offset future federal taxable income, if any, through 2024. The available net operating loss carryforwards after applying the annual limitation under Section 382 resulted in a deferred tax asset of approximately \$2,295,000 at December 31, 2004 (\$1,280,000 at December 31, 2003). Management does not expect the Company to have taxable income in the near future and established a 100% valuation allowance against the deferred tax asset created by the available net operating loss carryforwards at December 31, 2004 and 2003. The valuation allowance increased \$1,015,000 during the year ended December 31, 2004, and decreased \$3,100,000 during the year ended December 31, 2003.

**(4) Related Party Transactions**

The Company sublet office space from a corporation controlled by an officer of the Company whose lease with the landlord expired in August 1997. Thereafter, the Company's occupancy of the premises continued pursuant to an informal arrangement, under which the Company remitted monthly rental payments directly to the landlord. The informal arrangement was replaced as of January 1, 2002 with a lease agreement between the Company and the landlord which expired on December 22, 2003. In connection with its occupancy, the Company paid the affiliate \$24,000 which the affiliate then paid to the landlord as a deposit on the lease. Since the Company has occupied its office space on a month-to-month basis since December 22, 2003, and has not executed a new lease agreement for the premises, it believes recovery of the lease deposit is uncertain and has charged the aforementioned \$24,000 to rent expense in December 2004.

During the year ended December 31, 2004, the Company incurred \$61,720 for consulting services to the affiliate of an officer referred to above.

**(5) Rents**

The Company currently occupies its office space on a month-to-month basis. Rent expense totaled \$111,376 and \$87,376 for the years ended December 31, 2004 and 2003, respectively.

**(6) Recent Accounting Pronouncements**

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." SFAS No. 149 is effective for derivative contracts entered into or modified after June 30, 2003. The Company does not currently have any derivative instruments. This new standard did not have an impact on the Company's financial statements.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This new standard requires an issuer to classify certain financial instruments as liabilities or, in some instances, assets. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003. This new standard did not have an impact on the Company's financial statements.

FASB Statement 123 (Revision 2004), "Share – Based Payment," was issued in December 2004 and is effective for the Company on January 1, 2006. The new statement requires all share-based payments to employees to be recognized in the financial statements based on their fair values. The Company currently accounts for its share-based payments to employees under the intrinsic value method of accounting set forth in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees." Additionally, the Company complies with the stock-based employer compensation disclosure requirements of SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure, an amendment of FASB Statement No. 123." The Company plans to adopt the new statement in its financial statements as of January 1, 2006.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Nonmonetary Assets (an amendment of APB Opinion No. 29)." This new standard requires an issuer to measure and recognize nonmonetary exchanges which are anticipated to have an impact on future cash flows. SFAS No. 153 will be effective for the Company in the fourth quarter of 2005 and is not expected to have any impact on the Company's financial statements.

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# INDEPENDENT AUDITORS' REPORT

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The Board of Directors  
Delcath Systems, Inc.:

We have audited the accompanying balance sheet of Delcath Systems, Inc. (a development stage company) as of December 31, 2004, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2004 and for the period from August 5, 1988 (inception) to December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements enumerated above present fairly, in all material respects, the financial position of Delcath Systems, Inc. (a development stage company) as of December 31, 2004, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2004 and for the period from August 5, 1988 (inception) to December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

Eisner LLP

New York, NY  
February 25, 2005

# MANAGEMENT, BOARD OF DIRECTORS, KEY SCIENTIFIC & TECHNICAL ADVISORS

## MANAGEMENT TEAM

M. S. Koly | President, Chief Executive Officer & Treasurer  
Samuel Herschkowitz, M.D. | Chairman & Chief Technical Officer  
Paul M. Feinstein, Esq. | Chief Financial Officer

## BOARD OF DIRECTORS

M. S. Koly  
Samuel Herschkowitz, M.D.  
Mark A. Corigliano | Managing Director, Coast Cypress Associates  
Daniel L. Isdaner | Owner & Director, Camp Mataponi, Inc.  
Victor Nevins | CEO, Max Abramson Enterprises  
Former Trustee, Flushing Hospital & Medical Center

## KEY SCIENTIFIC AND TECHNICAL ADVISORS

Seymour H. Fein, M.D. | President, Fein & Associates  
Regulatory & Medical Oncology  
Morton G. Glickman, M.D. | Professor Emeritus, Diagnostic  
Radiology and Surgery, Yale University School of Medicine  
Cardiovascular and Interventional Radiology (Founder)  
Craig Hammes, J.D. | Principal, Hammes Consulting, Inc.  
Regulatory  
William N. Hait, M.D., Ph.D. | Director, The Cancer Institute  
of New Jersey  
Medical Oncology and Pharmacology (Founder)  
T. S. Ravikumar, M.D., F.A.C.S. | Chairman, Department of Surgery,  
Montefiore Medical Center  
Surgical Oncology (Principal Investigator)  
Harvey J. Ellis, C.C.P. | Chief of Cardiac Perfusion, Bridgeport Hospital  
Perfusion Consultant  
Durmus Koch | President, Bipore, Inc.  
Manufacturing Consultant  
James H. Muchmore, M.D. | Assoc. Professor of Surgery, Tulane  
University School of Medicine  
Oncology and Perfusion Consultant  
John Quiring, Ph.D. | Principal, QST Consulting  
Biostatistician

## ADVISORS

Patent Counsel | Steven E. Feldman, P.C.  
Transfer Agent | American Stock Transfer & Trust, New York, NY

## INVESTOR INFORMATION

Shareholders, analysts and others interested in additional  
information may contact:  
Redington, Inc.  
49 Richmondville Ave. | Westport, CT 06880  
(203) 222-7399

## ANNUAL MEETING

The Annual Meeting of shareholders will be held on  
Tuesday, June 14, 2005 at 11:00 AM  
at the Holiday Inn Select  
700 Main Street | Stamford, CT 06901

## FINANCIAL INFORMATION AND REPORTS

A copy of the Company's 10-KSB report will be furnished to  
shareholders without charge upon written request to the  
Company. Your request should be mailed to:  
Mr. Paul M. Feinstein | Chief Financial Officer  
Delcath Systems, Inc.  
1100 Summer St. | Stamford, CT 06905

## STOCK PRICES

The Company's Common Shares trade on the Nasdaq  
Small Cap market under the symbol "DCTH" and on the  
Boston Stock Exchange under the symbol "DCT." The  
redeemable common stock purchase warrants we issued in  
2000 are listed on the Nasdaq Small Cap market and the  
Boston Stock Exchange under the symbols "DCTHW" and  
"DCT&W," respectively.

The following table sets forth the per share range of high  
and low sales prices of our Common Stock for the periods  
indicated as reported on the Nasdaq Small Cap Market:

Common Stock Price Range	2004	
	High	Low
Quarter ended March 31, 2004	\$4.37	\$0.92
Quarter ended June 30, 2004	3.43	1.75
Quarter ended September 30, 2004	2.32	1.46
Quarter ended December 31, 2004	3.12	1.86
2003		
Quarter ended March 31, 2003	\$1.79	\$0.94
Quarter ended June 30, 2003	2.35	0.56
Quarter ended September 30, 2003	1.55	1.00
Quarter ended December 31, 2003	1.39	0.86

## DIVIDEND POLICY

We have never paid cash dividends on our Common Stock  
and anticipate that we will continue to retain our earnings, if  
any, to finance the growth of our business.



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1100 Summer Street  
Stamford, CT 06905

203-323-8668  
[www.delcath.com](http://www.delcath.com)

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