DELCATH SYSTEMS, INC.
Form 10-Q
May 09, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2013.

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-16133

DELCATH SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware	06-1245881
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

566 Queensbury Avenue, Queensbury, New York 12804
(Address of principal executive offices)

(518) 743-8892
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o No x

As of May 7, 2013, 96,725,763 shares of the Company's common stock, $0.01 par value, were outstanding.

DELCATH SYSTEMS, INC.

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DELCATH SYSTEMS, INC.

PART I:
FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

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DELCATH SYSTEMS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share data)

	March 31, 2013	December 31, 2012
Assets:		
Current assets		
Cash and cash equivalents	$ 42,804	$ 23,726
Accounts receivables	81	144
Inventories	1,190	1,105
Prepaid expenses and other current assets	1,667	1,457
Total current assets	45,742	26,432
Property, plant and equipment, net	3,766	4,042
Total assets	$ 49,508	$ 30,474
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable	$ 1,511	$ 939
Accrued expenses	4,078	5,790
Warrant liability	5,485	3,427
Total current liabilities	11,074	10,156
Deferred revenue	9	309
Commitments and contingencies	–	–
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2013 and December 31, 2012	–	–
Common stock, $.01 par value; 170,000,000 shares authorized; 91,212,524 and 76,849,033 shares issued and 91,184,424 and 76,820,933 outstanding at March 31, 2013 and December 31, 2012, respectively	912	768
Common stock to be issued	56	–
Additional paid-in capital	248,760	218,063
Accumulated deficit	(211,653)	(198,808)
Treasury stock, at cost; 28,100 shares at March 31, 2013 and December 31, 2012	(51)	(51)
Accumulated other comprehensive income	401	37
Total stockholders' equity	38,425	20,009
Total liabilities and stockholders' equity	$ 49,508	$ 30,474

See accompanying notes to condensed consolidated financial statements.

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DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share data)

	Three months ended March 31,	
	2013	2012
Product revenue	$ 81	$ —
Other revenues	300	—
Total revenue	381	—
Costs of goods sold	(31)	—
Gross profit	350	—
Operating expenses		
Selling, general and administrative	$ 6,083	$ 7,423
Research and development	4,469	7,131
Total operating expenses	10,552	14,554
Operating loss	(10,202)	(14,554)
Change in fair value of warrant liability, net	(2,272)	(338)
Interest income	10	3
Other expense and interest expense	(381)	—
Net loss	$ (12,845)	$ (14,889)
Common share data:		
Basic and diluted loss per share	$ (0.15)	$ (0.31)
Weighted average number of basic and diluted common shares outstanding	85,487,606	48,341,670
Other comprehensive income (loss):		
Foreign currency translation adjustments	$ 364	$ —
Comprehensive loss	$ (12,481)	$ (14,889)

See accompanying notes to condensed consolidated financial statements.

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DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Three months ended March 31,	
	2013	2012
Cash flows from operating activities:		
Net loss	$ (12,845)	$ (14,889)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	467	703
Restricted stock compensation expense	197	230
Depreciation expense	298	322
Warrant liability fair value adjustment	2,272	338
Non-cash interest income	(2)	(3)
Changes in assets and liabilities:		
Increase in prepaid expenses and other current assets	(248)	(111)
Decrease in accounts receivable	85	—
Increase in inventories	(97)	—
Decrease in accounts payable and accrued expenses	(764)	(772)
Decrease in deferred revenue	(300)	—
Net cash used in operating activities	(10,937)	(14,182)
Cash flows from investing activities:		
Purchase of property, plant, and equipment	(34)	(572)
Purchase of short-term investments and marketable equity securities	—	(1,743)
Proceeds from maturities of short-term investments	—	2,988
Net cash (used in) provided by investing activities	(34)	673
Cash flows from financing activities:		
Net proceeds from sale of stock and exercise of stock options and warrants	30,018	4,782
Net cash provided by financing activities	30,018	4,782
Foreign currency effects on cash	31	—
(Decrease) increase in cash and cash equivalents	19,078	(8,727)
Cash and cash equivalents at beginning of period	23,726	25,777
Cash and cash equivalents at end of period	$ 42,804	$ 17,050
Supplemental non-cash activities:		
Fair value of warrants issued	$ —	$ 153
Fair value of warrants exercised	$ 214	$ —

See accompanying notes to condensed consolidated financial statements.

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DELCATH SYSTEMS, INC.
Notes to Condensed Consolidated Financial Statements
for the Three Months Ended March 31, 2013 and 2012

(1) Description of Business

Delcath is a specialty pharmaceutical and medical device company focused on oncology. The Company's proprietary technology is designed to administer high-dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. Its initial focus is on the treatment of primary and metastatic liver cancers. The Company believes that the proprietary technology is a platform that may have broader applicability, including the use of other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body. In 2010, the Company announced that its randomized Phase 3 clinical trial for patients with metastatic melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival. The Company has also completed a multi-arm Phase 2 trial to treat other liver cancers.

Outside of the United States, the Company's proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT Delivery System for Melphalan). In April 2012, the Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT Delivery System for Melphalan. The right to affix the CE Mark allows the Company to market and sell the CHEMOSAT System for Melphalan in Europe.

In the United States, the Company's proprietary system for the administration of melphalan hydrochloride to the liver is considered a combination drug and device product, and is regulated as a drug by the United States Food and Drug Administration (FDA). The Company submitted its New Drug Application (NDA) to the FDA on August 15, 2012, with the proposed trade name Melblez KitTM (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System) (Melblez Kit), and is seeking approval for commercial sale of the Melblez Kit in the treatment of patients with unresectable metastatic ocular melanoma in the liver. The NDA was accepted for filing by the FDA on October 15, 2012. On April 3, 2013 the FDA extended its Prescription Drug User Fee Act (PDUFA) goal date to September 13, 2013. On May 2, 2013, the FDA's Oncologic Drugs Advisory Committee (ODAC) voted 16 to 0 with no abstentions that benefits of treatment with the Melblez Kit (that contains the Clark or Generation 1 filter) do not outweigh the risks associated with the procedure. The company intends to meet with the FDA to discuss and clarify regulatory requirements for approval of the Melblez Kit containing the Generation 2 filter for unresectable metastatic ocular melanoma in the liver or other indications. The FDA is not bound by the recommendation of its advisory committee, but will consider the committee's guidance as it evaluates the Melblez Kit NDA. Delcath will continue to work closely with the FDA throughout its ongoing evaluation of the Melblez Kit. There can be no assurance that the FDA will ultimately approve the Company's NDA.

The Company has incurred losses since inception. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales. Management believes that its capital resources are adequate to fund operations for the next twelve months, but anticipates that additional working capital may be required to continue operations. To the extent additional capital is not available when needed, the Company may be forced to abandon some or all of its development and commercialization efforts, which would have a material adverse effect on the prospects of the business. Operations of the Company are subject to certain risks and uncertainties, including, among others, uncertainty of product development; uncertainty regarding regulatory approval; technological uncertainty; uncertainty regarding patents and proprietary rights; comprehensive government regulations; limited commercial manufacturing, marketing or sales experience; and dependence on key personnel.

(2) Basis of Condensed Consolidated Financial Statement Presentation

The accompanying condensed consolidated financial statements are unaudited and were prepared by the Company in accordance with generally accepted accounting principles in the United States of America (GAAP) and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make assumptions and estimates that impact the amounts reported in the Company's condensed consolidated financial statements. The condensed consolidated financial statements include the accounts of all entities controlled by Delcath. All significant inter-company accounts and transactions are eliminated. The unaudited interim condensed consolidated financial statements, in the opinion of management, reflect all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the Company's results of operations, financial position and cash flows for the interim periods ended March 31, 2013 and 2012.

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The results of operations and cash flows for the interim periods are not necessarily indicative of the results of operations to be expected for the fiscal year. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2012, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2012 as filed with the Securities and Exchange Commission (the "SEC") on March 13, 2013.

(3) Summary of Significant Accounting Policies

Use of Estimates
The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's condensed consolidated balance sheets and the amount of expenses reported for each of its periods presented are affected by estimates and assumptions, which are used for, but not limited to, the accounting for derivative instrument liabilities, stock-based compensation, valuation of inventory, income taxes and operating expense accruals. 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.

Cash Equivalents and Concentrations of Credit Risk
The Company considers investments with original maturities of three months or less at date of acquisition to be cash equivalents. The Company has deposits that exceed amounts insured by the Federal Deposit Insurance Corporation (FDIC), however, the Company does not consider this a significant concentration of credit risk based on the strength of the financial institution.

Accounts Receivable
Accounts receivable, principally trade, are generally due within 30 days and are stated at amounts due from customers. As the Company's commercial activities expand, collections and payments from customers will be monitored and a provision for estimated credit losses will be created based upon historical experience and specific customer collection issues that may be identified. At March 31, 2013 there were no accounts receivable determined to be uncollectable.

Inventories
Inventories are valued at the lower of cost or market value using the first-in, first-out method. The reported net value of inventory includes finished saleable products, work-in-process, and raw materials that will be sold or used in future periods. The Company reserves for expired, obsolete, and slow-moving inventory.

Prior to obtaining authorization to affix the CE Mark to its Generation Two Delcath Hepatic CHEMOSAT® Delivery System in April 2012, the Company expensed all of its inventory costs as research and development. Inventory as of March 31, 2013 includes finished goods and components relating to Generation Two of the Delcath Hepatic CHEMOSAT® Delivery System that have been purchased since April 2012. Therefore, as is common for companies transitioning from the development stage to commercial, to the extent that materials expensed prior to April 2012 are used in manufacturing finished goods for sale, the Company's cost of goods sold will be adjusted accordingly.

Property, Plant and Equipment
Property, plant and equipment are recorded at cost, less accumulated depreciation. The Company provides for depreciation on a straight line basis over the estimated useful lives of the assets which range from three to seven years. Leasehold improvements will be amortized over the shorter of the lease term or the estimated useful life of the related

assets when they are placed into service. Maintenance and repairs are charged to operations as incurred. Expenditures which substantially increase the useful lives of the related assets are capitalized.

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Derivative Instrument Liability
The Company accounts for derivative instruments in accordance with Accounting Standards Codification (ASC) 815, which establishes accounting and reporting standards for derivative instruments and hedging activities, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value, regardless of the hedging relationship designation. Accounting for changes in the fair value of the derivative instruments depends on whether the derivatives qualify as hedge relationships and the types of relationships designated are based on the exposures hedged. At March 31, 2013 and 2012, the Company did not have any derivative instruments that were designated as hedges.

Fair Value Measurements
The Company adopted ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. ASC 820 applies to reported balances that are required or permitted to be measured at fair value under existing accounting pronouncements; accordingly, the standard does not require any new fair value measurements of reported balances.

ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

- Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals.
- Level 3 inputs are unobservable inputs for the asset or liability, which is typically based on an entity's own assumptions, as there is little, if any, related market activity.

In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

Deferred Revenue
Deferred revenue on the accompanying condensed consolidated balance sheets includes payment received for product sales to a distributor. When obligations or contingencies remain after the products are shipped, such as training and certifying the treatment centers, revenue is deferred until the obligations or contingencies are satisfied. The Company will recognize the revenue related to product sales when its obligations under the agreement have been satisfied and will recognize the deferred revenue related to the research and distribution agreement once the milestones are satisfied or over the expected obligation period of the agreement once this amount is reasonably determinable.

Product Revenue Recognition

Revenue from product sales is generally recognized when all of the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred; product price is fixed or determinable; and collection of the resulting receivable is reasonably assured. The company recognizes product revenues derived from either direct sales to end hospital customers or indirect sales to distributors when the end hospital customers have completed trainings and are certified to perform patient treatments using our product.

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Other Revenue
Other revenue is related to the recognition of previously deferred revenue upon the completion of certain requirements under the Research and Distribution Agreement with Chi-Fu Trading Co., Ltd.

Selling, General and Administrative
Selling, general and administrative costs include personnel costs and related expenses for the Company's sales, marketing, general management and administrative staff, recruitment, costs related to the Company's commercialization efforts in Europe, professional service fees, professional license, business development and certain general legal activities.

Research and Development
Research and development costs include the costs of materials used for R&D and clinical trials, personnel costs associated with device and pharmaceutical R&D, clinical affairs, medical affairs, medical science liaisons, and regulatory affairs, costs of outside services and applicable indirect costs incurred in the development of the Company's proprietary drug delivery system. All such costs are charged to expense when incurred.

Stock Based Compensation
The Company accounts for its share-based compensation in accordance with the provisions of ASC 718, which establishes accounting for equity instruments exchanged for employee services and ASC 505-50, which establishes accounting for equity-based payments to non-employees. Under the provisions of ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders' requisite service period (generally the vesting period of the equity grant). The Company is required to record compensation cost for all share-based payments granted to employees based upon the grant date fair value, estimated in accordance with the provisions of ASC 718. Under the provisions of ASC 505-50, measurement of compensation cost related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests. The Company expensed its share-based compensation for share-based payments granted under the accelerated method, which treats each vesting tranche as if it were an individual grant.

The Company periodically grants stock options for a fixed number of shares of common stock to its employees, directors and non-employee contractors, with an exercise price greater than or equal to the fair market value of Delcath's common stock at the date of the grant. The Company estimates the fair value of stock options using an option pricing model. Key inputs used to estimate the fair value of stock options include the exercise price of the award, the expected post-vesting option life, the expected volatility of Delcath's stock over the option's expected term, the risk-free interest rate over the option's expected term, and Delcath's expected annual dividend yield. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

Recently Adopted Accounting Pronouncements
In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2013-02 which requires additional disclosures regarding the reporting of reclassifications out of accumulated other comprehensive income. ASU 2013-02 requires an entity to present, either on the face of the statement where net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under GAAP to be

reclassified to net income in its entirety in the same reporting period. This guidance is effective for reporting periods beginning after December 15, 2012. The Company adopted this guidance effective January 1, 2013. The Company's adoption of this standard did not have a material impact on its consolidated financial statements.

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DELCATH SYSTEMS, INC.
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In March 2013, the FASB issued ASU 2013-05, which permits an entity to release cumulative translation adjustments into net income when a reporting entity (parent) ceases to have a controlling financial interest in a subsidiary or group of assets that is a business within a foreign entity. Accordingly, the cumulative translation adjustment should be released into net income only if the sale or transfer results in the complete or substantially complete liquidation of the foreign entity in which the subsidiary or group of assets had resided, or, if a controlling financial interest is no longer held. The revised standard is effective for fiscal years beginning after December 15, 2013; however, early adoption is permitted. The Company does not expect adoption of this ASU to materially impact its consolidated financial statements.

(4) Inventories

Inventories consist of:

(in thousands)	March 31, 2013	December 31, 2012
Raw materials	$ 283	$ 197
Work-in-process	631	405
Finished goods	276	503
Total	$ 1,190	$ 1,105

(5) Property, Plant, and Equipment

Property, plant, and equipment consists of:

(in thousands)	March 31, 2013	December 31, 2012
Leaseholds	$ 1,715	$ 1,716
Furniture	952	952
Equipment	1,483	1,473
Computers	2,154	2,141
Buildings and land	603	603
	6,907	6,885
Accumulated depreciation	(3,141)	(2,843)
Total	$ 3,766	$ 4,042

Depreciation expense for the three months ended March 31, 2013 and 2012 was $0.3 million and $0.3 million, respectively.

(6) Stock Options Plans

The Company established the 2004 Stock Incentive Plan and the 2009 Stock Incentive Plan (collectively, the “Plans”) under which 3,000,000 and 6,500,000 shares, respectively, were reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. 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 and Stock Option Committee of the Board of Directors which determines the

individuals to whom awards shall be granted as well as the type, terms and conditions of each award, the option price and the duration of each award.

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DELCATH SYSTEMS, INC.
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Options granted under the Plans vest as determined by the Company's Compensation and Stock Option Committee and expire over varying terms, but not more than ten years from the date of grant. Stock option activity for the three months ended March 31, 2013 is as follows:

	Stock Option Activity under the Plans			
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2012	4,788,887	$ 1.23-$15.54	$ 4.79	6.88
Granted	921,220	$ 1.31-$2.13	2.08	
Forfeited	(115,945)	$ 1.82-$8.50	3.62	
Outstanding at March 31, 2013	5,594,162	$ 1.23-$15.54	$ 4.37	7.13

For the three months ended March 31, 2013, the Company recognized compensation expense of approximately $0.5 million relating to stock options granted to employees. For the three months ended March 31, 2012, the Company recognized compensation expense of approximately $0.7 million relating to stock options granted to employees.

The Company uses an option pricing model to determine the fair value of stock options awarded to employees on the date of grant. The Company has expensed its stock-based compensation for share-based payments granted under the ratable method, which treats each vesting tranche as if it were an individual grant.

The Company accounts for stock-based compensation expense for non-employees using the fair-value method which requires the award to be re-measured at each reporting date until the award is vested. The Company estimates the fair value using an option pricing model. The Company has expensed its share-based compensation for non-employees under the ratable method.

The assumptions used in the option pricing model to determine the fair value of stock options awarded to employees are as follows:

	Three Months Ended March 31,	
	2013	2012
Dividend yield	None	None
Expected volatility	86.16% - 86.51%	77.37% - 79.24%
Weighted average volatility	86.20%	78.75%
Risk-free interest rates	1.16% - 1.36%	1.03% - 1.49%
Expected life (in years)	6.8	6.0

No dividend yield was assumed because the Company has never paid a cash dividend on its common stock and does not expect to pay dividends in the foreseeable future. Volatilities were developed using the Company's historical volatility. The risk-free interest rate was developed using the U.S. Treasury yield for periods equal to the expected

life of the stock options on the grant date. The expected option term for grants made prior to June 30, 2012 was developed based on the mid-point between the vesting date and the expiration date of each respective grant as permitted under ASC 718. This method of determining the expected holding period was utilized because the Company did not have sufficient historical experience from which to estimate the period. The expected option term for grants made since July 1, 2012 was calculated based on actual historical results.

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DELCATH SYSTEMS, INC.
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Restricted stock activity for the three months ended March 31, 2013 is as follows:

	Restricted Stock Activity under the Plans	
	Restricted Stock	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2012	501,468	$ 3.26
Granted	11,850	1.42
Vested	(85,378)	4.99
Forfeited	(17,123)	3.70
Non-vested at March 31, 2013	410,817	$ 2.82

For each of the three months ended March 31, 2013 and March 31, 2012, the Company recognized compensation expense of $0.2 million relating to restricted stock granted to employees.

(7) Assets and Liabilities Measured at Fair Value

Derivative Warrant Liability
The Company allocated part of the proceeds of a private placement and a public offering of the Company's common stock to warrants issued in connection with such transactions. The Company determined that these warrants should be classified as liabilities rather than equity. The valuation of the warrants is determined using an option pricing model. This model uses inputs such as the underlying price of the common stock on the date of valuation, the exercise price of the warrant, volatility, risk free interest rate and expected life of the instrument. The Company has determined that the warrant derivative liability should be classified within Level 3 of the fair-value hierarchy by evaluating each input for the model against the fair-value hierarchy criteria and using the lowest level of input as the basis for the fair-value classification as called for in ASC 820-10-35. There are six inputs: the closing price of the Company's common stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of Delcath's stock over that term; annual rate of dividends; and the riskless rate of return. Of those inputs, the exercise price of the warrants and the remaining term are readily observable in the warrant agreements. The annual rate of dividends is based on our historical practice of not granting dividends. The closing price of the Company's common stock would fall under Level 1 of the fair-value hierarchy as it is a quoted price in an active market (ASC 820-10-35-40). The riskless rate of return is a Level 2 input as defined in ASC 820-10-35-48, while the historical volatility is a Level 3 input as defined in ASC 820-10-55-22. Since the lowest level input is a Level 3, the Company determined the warrant derivative liability is most appropriately classified within Level 3 of the fair value hierarchy.

In June 2009, the Company completed the sale of 0.9 million shares of its common stock and the issuance of warrants to purchase approximately 1.0 million common shares (the "2009 Warrants") pursuant to a subscription agreement with a single investor. The Company received gross proceeds of $3.0 million, with net cash proceeds after related expenses from this transaction of approximately $2.7 million. Of those proceeds, the Company allocated an estimated fair value of $2.2 million to the 2009 Warrants. As required by the 2009 Warrant agreement, the exercise price of the warrants was adjusted following the Company's December 2012 sale of common stock. At March 31, 2013, the 2009 Warrants were exercisable at $1.20 per share with approximately 1.0 million warrants outstanding. The 2009 Warrants have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3

(333-143280 and 333-159857).

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for the Three Months Ended March 31, 2013 and 2012

In May 2012, the Company completed the sale of 15.3 million shares of its common stock and the issuance of warrants to purchase 4.6 million common shares (the "2012 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $21.5 million, with net cash proceeds after related expenses from this transaction of approximately $21.1 million. Of those proceeds, the Company allocated an estimated fair value of $3.4 million to the 2012 Warrants. As required by the 2012 Warrant agreement, the exercise price of the warrants was adjusted following the Company's December 2012 sale of common stock. At March 31, 2013, the 2012 Warrants were exercisable at $1.20 per share with approximately 4.4 million warrants outstanding. The 2012 Warrants have a three-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3 (333-178819).

For the three months ended March 31, 2013, the Company recorded pre-tax derivative instrument expense of $2.3 million. The resulting derivative instrument liabilities totaled $5.5 million at March 31, 2013. Management expects that the warrants will either be exercised or expire worthless. The fair value of the Warrants at March 31, 2013 was determined by using an option pricing model assuming the following:

	2012 Warrants	2009 Warrants
Expected volatility	83.33%	83.43%
Risk-free interest rates	0.27%	0.16%
Expected life (in years)	2.25	1.25

Money Market Funds

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of March 31, 2013, aggregated by the level in the fair value hierarchy within which those measurements fall:

Assets and Liabilities Measured at Fair Value on a Recurring Basis at March 31, 2013
(in thousands)

	Level 1	Level 2	Level 3	Balance at March 31, 2013
Assets				
Money market funds	$ 1,956	$ —	$ —	$ 1,956
Liabilities				
Warrant liability	$ —	$ —	$ 5,485	$ 5,485

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
(in thousands)

	Warrant Liability
Beginning balance as of December 31, 2012	$ 3,427
Total change in the liability included in earnings	2,272
Fair value of warrants exercised	(214)
Ending balance as of March 31, 2013	$ 5,485

(8) Common Stock

In December 2012, the Company entered into a Common Stock Purchase Agreement (Purchase Agreement) with Terrapin Opportunity, L.P. (Terrapin) for a committed equity financing facility (CEFF) program. The Purchase Agreement provides that Terrapin is committed to purchase up to $35,000,000 of our common stock over the 24-month term of the Purchase Agreement. During the three months ended March 31, 2013, the Company sold approximately 5.6 million shares of its common stock through the program for proceeds of approximately $9.0 million. Net proceeds after related expenses were approximately $8.9 million. Due to the timing of the transaction settlement, the funds related to the sale of the Company's common stock were received prior to the end of the quarter, but the shares were not issued until April 1, 2013. The shares were issued pursuant to an effective registration statement on Form S-3 (333-183675) and are reported on the condensed consolidated balance sheet in Common Stock to be Issued. These shares are appropriately excluded from shares issued and outstanding at March 31, 2013. The net proceeds will be used for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital. In addition to the $9.0 million raised during the three months ended March 31, 2013, the Company previously raised $2.1 million under the CEFF program. As a result, there was approximately $23.9 million available under this CEFF program as of March 31, 2013.

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DELCATH SYSTEMS, INC.
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During the three months ended March 31, 2013, the Company sold approximately 14.2 million shares of its common stock under a Sales Agreement with Cowen and Company, LLC through an "at the market" equity offering program for net proceeds of approximately $20.9 million before related expenses. The net proceeds will be used for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital. There are no shares of common stock of the company remaining for sale under the program or registered pursuant to registration statement 333-165677.

On March 13, 2013, the Company entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC to sell shares of the Company's common stock, par value $.01 per share, having aggregate sales proceeds of $50,000,000, from time to time, through an "at the market" equity offering program under which Cowen and Company, LLC will act as sales agent. The net proceeds will be used for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital.

During the three months ended March 31, 2013, the Company issued 0.2 million shares of its common stock upon the exercise of 2012 Warrants for proceeds of approximately $0.2 million.

(9) Net Loss

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. For the periods presented, basic and diluted net loss per common share are identical. Potentially dilutive securities from stock options and warrants would be antidilutive as the Company incurred a net loss. The number of shares of common stock potentially issuable at March 31, 2013 and 2012 upon exercise or conversion that were not included in the computation of net loss per share totaled 11,038,233 and 7,760,087 shares, respectively.

(10) Taxes

As discussed in Note 11 to the Company's audited financial statements contained in the 2012 Annual Report on Form 10-K, the Company has a valuation allowance against the full amount of its net deferred tax assets. The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion or all of its deferred tax assets will not be realized. The Company has not recognized any unrecognized tax benefits in its balance sheet.

The Company is subject to income tax in the United States, the Republic of Ireland, and certain state jurisdictions. The Company has not been audited by the United States Internal Revenue Service (the "IRS"), international tax authorities, or any states in connection with income taxes. The periods from December 31, 2009 to December 31, 2012 remain open to examination by the IRS and state tax authorities. The periods from December 31, 2011 to December 31, 2012 remain open to examination by the Republic of Ireland. Also note that the federal, state, and international tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations.

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(11) Subsequent Events

The Company completed an evaluation of the impact of any subsequent events through the date financial statements were issued and determined there were no subsequent events requiring disclosure in or adjustment to these financial statements.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of the Company's financial condition and results of operations should be read in conjunction with the unaudited interim condensed consolidated financial statements and notes thereto contained in Item 1 of Part I of this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2012 included in the Company's 2012 Annual Report on Form 10-K to provide an understanding of its results of operations, financial condition and cash flows.

Disclosure Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q for the period ended March 31, 2013 contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "could," "would," "will," "may," "can," "continue and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this Quarterly Report on Form 10-Q for the period ending March 31, 2013 that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this Quarterly Report on Form 10-Q for the period ended March 31, 2013 in Part II, Item 1A under "Risk Factors" as well as in Part I, Item 3 "Quantitative and Qualitative Disclosures About Market Risk," our Annual Report on Form 10-K for the period ended December 31, 2012 in Item 1A under "Risk Factors" as well as in Item 7A "Quantitative and Qualitative Disclosures About Market Risk," and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- the progress and results of our research and development programs;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of the system and enter into supplier contracts;
- our ability to successfully manufacture the CHEMOSAT/Melblez Kit system;
- our ability to successfully commercialize the CHEMOSAT/Melblez Kit system and successfully obtain reimbursement;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners; and
- our estimates of potential market opportunities and our ability to successfully realize these opportunities.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

Overview

The following section should be read in conjunction with Part I, Item 1: Condensed Consolidated Financial Statements of this report and Part I, Item 1: Business; and Part II, Item 8: Financial Statements and Supplementary Data of the

Company’s 2012 Annual Report on Form 10-K.

Delcath is a specialty pharmaceutical and medical device company focused on oncology. The Company’s proprietary technology is designed to administer high-dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. The Company believes that its proprietary technology is a platform that may have broader applicability, including the use of other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body. In 2010, the Company announced that its randomized Phase 3 clinical trial for patients with metastatic melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival. The Company has also completed a multi-arm Phase 2 trial to treat hepatocellular carcinoma (HCC, or primary liver cancer), metastatic adenocarcinomas, and neuroendocrine tumors in the liver and patients with metastatic ocular and cutaneous melanoma.

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The Company is currently focused on three main goals:

- Securing U.S. Food & Drug Administration (FDA) approval of its New Drug Application (NDA) for Melblez TM Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System) (Melblez Kit) for an initial indication in the treatment of patients with unresectable metastatic ocular melanoma in the liver. The Company believes approval for this first indication in the United States will serve as a platform for the technology that may lead to broader indications for treating cancers in the liver.
- European commercialization of the Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT Delivery System for Melphalan). In 2013 the Company is focused on expanding clinical usage of the CHEMOSAT system and obtaining compelling reimbursement for CHEMOSAT procedures in certain markets in Europe.
- The Company plans to pursue a pivotal trial for its CHEMOSAT/Melblez Kit system with melphalan to support a regulatory application for labeling for hepatocellular carcinoma (HCC or primary liver cancer).

About the CHEMOSAT/Melblez Kit Systems

The CHEMOSAT/Melblez Kit systems administer concentrated regional chemotherapy to the liver. This “whole organ” therapy is performed by first isolating the circulatory system of the liver, infusing the liver with chemotherapeutic agent, and filtering the blood prior to returning it to the patient. During the procedure, three catheters are placed percutaneously through standard interventional radiology techniques. The catheters temporarily isolate the liver from the body’s circulatory system, administer a 30-minute infusion of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and collect blood exiting the liver for filtration by proprietary filters. The filters reduce the concentration of chemotherapeutic agent in the blood, thereby minimizing systemic exposure to the drug and related toxic side-effects before the filtered blood is returned to the patient’s circulatory system. Through March 31, 2013, the CHEMOSAT/Melblez Kit system has been used on approximately 200 patients through clinical development and early commercial experience in Europe.

Treatment with the CHEMOSAT/Melblez Kit System

Currently there are few effective treatment options for cancers in the liver. Traditional treatment options include surgery, chemotherapy, radiation therapy, thermal therapy and chemoembolization as well as cryosurgery, percutaneous ethanol injection, implanted infusion pumps, isolated hepatic perfusion and liver transplant. Based on the results of its Phase 1, Phase 2 and Phase 3 trials, the Company believes the CHEMOSAT/Melblez Kit system may address the limitations of traditional treatments for metastatic and primary liver cancers.

The most advanced application for which the CHEMOSAT/Melblez Kit system was evaluated is treatment of metastatic melanoma in the liver. During the Company’s clinical trials, the procedure typically took approximately two to three hours. Patients remained in the intensive care unit overnight for observation after undergoing treatment with the CHEMOSAT/Melblez Kit system. Treatment with CHEMOSAT/Melblez Kit system is a repeatable procedure, and during clinical trials patients received an average of three procedures at approximately four to six week intervals. A new disposable CHEMOSAT/Melblez Kit system is used for each treatment.

Regulatory Status

United States

In the United States, the Delcath Melblez Kit is subject to regulation as a combination product composed of both a drug product and device product. In August 2012, the Company submitted its NDA for the Melblez Kit under Section 505(b)(2) of the FFDCA seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver, and subsequently amended the indication it is seeking to ocular melanoma metastatic to the liver. The Company’s NDA was accepted for filing by the FDA on

October 15, 2012.

On May 2, 2013 the Company announced that the FDA Oncologic Drugs Advisory Committee (ODAC) voted 16 to 0 with no abstentions that benefits of treatment with Delcath's Melblez Kit (containing the Clark or generation 1 filter) do not outweigh the risks associated with the procedure. The FDA is not bound by the recommendation of its advisory committee, but will consider the committee's guidance as it evaluates the Melblez Kit NDA. Delcath will continue to work closely with the FDA throughout its ongoing evaluation of the Melblez Kit.

On April 3, 2013, the FDA extended its PDUFA goal date to September 13, 2013. On March 18, 2013 the Company supplied certain information in response to an FDA request. The information related to clarification regarding the bridging studies that were performed between the filter generations that were used throughout the development program. As the information was requested and supplied within 90 days of the previous PDUFA goal date of June 15, 2013, the agency exercised its option to extend the PDUFA goal date to provide adequate time for completion of its review. The three-month extension to September 13, 2013 is the standard extension cycle granted.

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There can be no assurance that the FDA will ultimately approve the Company's NDA.

Europe

In April 2012, the Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT Delivery System for Melphalan. In the EEA, the CHEMOSAT Delivery System for Melphalan is regulated as a Class IIb medical device indicated for the intra-arterial administration of chemotherapeutic agent (melphalan hydrochloride) to the liver with additional extracorporeal filtration of the venous blood return. As a Class IIb medical device, the Company must continue to comply with the essential requirements of the EU Medical Devices Directive (Directive 93/42 EC) and is subject to a conformity assessment procedure requiring the intervention of a Notified Body. The conformity assessment procedure for Class IIb medical devices requires the manufacturer to apply for the assessment of its quality system for the design, manufacture and inspection of its medical devices by a Notified Body. The Notified Body will audit the system to determine whether it conforms to the provisions of the Medical Devices Directive. If the Notified Body's assessment is favorable it will issue a Full Quality Assurance Certificate, which enables the manufacturer to draw a Declaration of Conformity and affix the CE Mark to the medical devices covered by the assessment. Thereafter, the Notified Body will carry out periodic audits to ensure that the approved quality system is applied by the manufacturer.

Other International Regulations

The Company received regulatory approval for the CHEMOSAT System for Melphalan in Australia and completed the product notification process in New Zealand. The Company has also submitted applications for regulatory approval as a device for the CHEMOSAT System for Melphalan in Argentina, Taiwan, Hong Kong and Singapore, and intends to submit regulatory applications in Israel, Turkey, Mexico, Brazil, and Japan. In China, the Company intends to pursue a drug registration for the CHEMOSAT Delivery System for Melphalan. The Company's Delcath Systems Limited facility in Galway, Ireland has obtained certificates of free sale from the Irish Medicines Board as many markets require country of origin manufacturing, such as Mexico, Argentina, Brazil, Japan, China, and Taiwan, as a prerequisite to obtain regulatory approval. In Canada, the Company's application for approval as a device was rejected by the Canadian health authority, with the recommendation that it resubmit its application as a drug, similar to the process being followed in the United States. The Company is currently evaluating this option for seeking regulatory approval in Canada.

Sales and Marketing

European Economic Area

Outside of the United States, the Company's proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT Delivery System for Melphalan). In April 2012, the Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT Delivery System for Melphalan. The right to affix the CE Mark allows the Company to market and sell the CHEMOSAT System for Melphalan in Europe.

The Company began European commercialization in February 2012 when the first CHEMOSAT procedures performed outside of a clinical trial setting were performed at the European Institute of Oncology in Milan, Italy. In April 2012, the Company obtained CE Mark for its Generation Two CHEMOSAT System, allowing it to market and sell the CHEMOSAT Delivery System for Melphalan in the European Economic Area (EEA). Since obtaining the right to affix the CE Mark to the Generation Two CHEMOSAT system, all procedures performed in Europe have been done using the Generation Two system.

The Company's initial efforts are focused on seven target markets including Germany, United Kingdom, France, the Netherlands, Italy, Spain and Ireland. The Company believes these countries represent a majority of the total potential liver cancer market in EEA countries. The Company uses a combination of direct and indirect sales channels to market and distribute the CHEMOSAT Delivery System for Melphalan in the EEA. The Company has also retained a

contract field-based team of medical science liaisons (MSL) to educate the medical oncology community in all seven target markets.

Since launching the CHEMOSAT Delivery System for Melphalan, the Company entered into training and marketing agreements with 16 leading European cancer centers located in all seven of its target markets. As of March 31, 2013, nine of these centers have been trained and activated to provide treatment with the CHEMOSAT System. Physicians in Europe have used CHEMOSAT to treat patients with a variety of cancers in the liver, primarily ocular melanoma liver metastases, as well as HCC, Cholangeocarcinoma, and liver metastases from CRC, breast, cutaneous melanoma and other tumor types.

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To support commercialization efforts in the EEA, the Company has established its European Headquarters in Galway, Ireland.

European Reimbursement

A critical driver of utilization growth for CHEMOSAT in Europe will be the expansion of compelling reimbursement mechanisms for the procedure in each of the seven markets we are targeting. In Europe, there is no centralized pan-European medical device reimbursement body. Reimbursement is administered on a regional and national basis, and the Company has engaged a third party reimbursement specialist to support efforts in filing for reimbursement coverage. Medical devices are typically reimbursed under diagnosis related groups (DRG) as part of a procedure. Prior to obtaining permanent DRG reimbursement codes, in certain jurisdictions, the Company is actively seeking interim reimbursement from existing mechanisms that include specific interim reimbursement schemes, new technology payment programs as well as existing DRG codes.

Germany

In February 2013, the Company announced that the Institut f r das Entgeltsystem im Krankenhaus (InEk), the German federal reimbursement agency, established a reimbursement pathway for the treatment of patients with liver metastases with the CHEMOSAT System for Melphalan. The Value 4 status given to procedures with the CHEMOSAT System for Melphalan, while not mandating reimbursement, allows participating cancer centers to negotiate reimbursement coverage for the CHEMOSAT procedure with all insurers serving their region. Reimbursement pathways will potentially be available for treatment with CHEMOSAT regardless of primary cancer origin. Some of the participating cancer centers in Germany are pursuing reimbursement under the NUB scheme, and have begun negotiations with private payers.

United Kingdom

In the United Kingdom, leading cancer centers are seeking to gain Primary Care Trust (PCT) funding for procedures with the CHEMOSAT Delivery System, which we hope will be granted in the second quarter of 2013. PCT funding would allow CHEMOSAT procedures to be performed at those centers that apply, with referrals possible nationwide. The Company is working closely with five of the key melanoma centers in the United Kingdom to achieve this interim funding. Due to current healthcare reforms in the United Kingdom, in April 2013 interim funding for oncological procedures will move away from local PCTs to a centralized body, which may offer an opportunity to gain nationwide interim funding more quickly. The timeframe for completing this change is currently unknown. The Company is also engaged with the Healthcare Resource Groups (HRG) that decide on new HRG codes with a view to gaining a dedicated and permanent reimbursement code. At the same time, the National Institute for Clinical Excellence (NICE) may decide to conduct a review of the CHEMOSAT procedure at any time, the outcome of which would determine the long term reimbursement status. However, the Company does not anticipate an assessment from NICE until a significant number of CHEMOSAT procedures are conducted regularly in the United Kingdom.

Italy

In Italy, the Company identified an existing DRG code that may be used by hospitals to submit for partial reimbursement of the CHEMOSAT device and related procedure. Additionally, the Company is assisting hospitals in applying for supplemental new technology payments from certain regions, and is hopeful the authorities in the Lombardy region will issue their decision soon. Furthermore, in conjunction with the European Institute of Oncology in Milan, we are evaluating the potential application for a new dedicated DRG code specific to the CHEMOSAT procedure.

The Netherlands

The Netherlands is currently reforming its healthcare system, and in the process has moved to a procedure code driven DRG system, referred to as “DOT” in the Netherlands. The process of obtaining a DOT code specific to the CHEMOSAT Delivery System for Melphalan requires that Delcath publishes its Phase 3 data, which the Company

anticipates submitting for publication in the Spring of 2013. Following publication, the application for reimbursement will be submitted. In the meantime, the Company is in close contact with the Dutch committee which sanctions new oncological treatments (BOM) and we believe that the CHEMOSAT Delivery System for Melphalan will have a positive review. Until that time the Company is pursuing the possibility of conducting a limited amount of cases through extraordinary insurance funding at the National Cancer Institute in Amsterdam and at the University Hospital in Leiden. The first CHEMOSAT procedures performed in the Netherlands were done at the National Cancer Institute (NKI) in Amsterdam in March 2013.

Permanent, compelling reimbursement in remaining EU markets will require additional time to secure. In the interim period, the Company is seeking payment through various avenues, including new technology programs. In France, in order to obtain a permanent DRG code, the level of required data both in terms of clinical trials and healthcare economics is extremely high compared to other countries in the EU. The Company believes we will need the published Phase 3 trial manuscript, supported by investigator initiated trial data before submitting its application. The Company anticipates submitting its application in late 2013, and in the meantime is targeting the private market in France. Phase 3 publication is also a gating item for reimbursement in Ireland.

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United States

In the United States, the Company's proprietary system for the administration of melphalan hydrochloride to the liver is considered a combination drug and device product, and is regulated as a drug by the FDA. The Company submitted its New Drug Application (NDA) to the FDA on August 15, 2012, with the proposed trade name Melblez KitTM (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System) (Melblez Kit), and is seeking approval for commercial sale of the Melblez Kit in the treatment of patients with unresectable metastatic ocular melanoma in the liver.

In the United States, if granted FDA approval by the PDUFA goal date of September 13, 2013, the Company intends to begin marketing the Melblez Kit in the first quarter of 2014. Initial marketing efforts will be focused on the hospitals that participated in the Company's Phase 3 clinical trial, which provide an existing base of experienced procedure teams trained in the use of the Melblez Kit. The focus will then expand to include other member hospitals of the National Comprehensive Cancer Network (NCCN)—centers of excellence for cancer care in the United States which see a majority of advanced metastatic ocular melanoma patients. To address this market, the Company plans to deploy a direct sales force supported by MSLs, which will provide clinical-based education to the healthcare professionals (medical oncologists, surgical oncologists, and interventional radiologists) that make up the procedure team utilizing the Melblez Kit.

With an anticipated initial indication in ocular melanoma metastasized to the liver, the Company has begun a comprehensive pricing analysis for this "ultra-orphan" disease state. There are currently no approved or effective treatment options for ocular melanoma metastasized to the liver, so there is a clear unmet clinical need among patients suffering from this disease. The pricing analysis is aimed at optimizing value for treatment with the Melblez Kit, establishing the economic basis for reimbursement, and ensuring patient access to treatment.

U.S. Reimbursement

Assuming the Company's NDA is approved by the FDA, it will seek to have payers establish policy coverage and payment of the cost of the Melblez Kit and the associated procedures. Following FDA approval, the Company intends to apply for a Current Procedural Terminology (CPT) code. A CPT code accurately describes medical, surgical, and diagnostic services, and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers for administrative, financial, and analytical purposes. The Company anticipates submitting an application for a CPT-Category I code in October 2013, if its NDA is approved by the PDUFA goal date. Category I codes represent procedures considered consistent with contemporary medical practice, Category II codes are used for supplemental tracking and Category III codes are used for new and emerging technologies. Assuming an October 2013 submission, the CPT would become effective in January 2015. In the interim, the Company intends to assist hospitals in the utilization of existing procedure related codes to obtain reimbursement for treatments utilizing the Melblez Kit.

Clinical Development Program

The goal of the Company's Clinical Development Program (CDP) is to expand its U.S. label indication beyond the initial indication it is seeking in ocular melanoma liver metastases. The CDP includes plans to evaluate the CHEMOSAT/Melblez Kit system with melphalan for use in the treatment of hepatocellular carcinoma (HCC or primary liver cancer). The Company held productive discussions with the FDA on a trial design for a Phase 3 clinical trial in patients with HCC during the first quarter. Subject to agreement with the FDA, the Company intends to initiate this study by the end of 2013.

In Europe, the Company has initiated a retrospective data collection trial and plans to initiate a Patient Registry, which will prospectively collect data from EU commercial experience, and expects to support other Investigator Initiated Trials (IIT) globally as suitable opportunities present. The Company believes IITs will serve to build clinical

experience at key cancer centers, and will support efforts to obtain compelling reimbursement in Europe.

In Asia, the Company plans to collaborate with its strategic partner Chi-Fu Trading Co., Ltd, on a pivotal trial for CHEMOSAT with melphalan for HCC in Taiwan.

Beyond its near-term CDP for CHEMOSAT/Melblez Kit system with melphalan, the Company also has long-term plans to evaluate other chemotherapeutic agents for use with its technology to treat other liver cancers, as well as other organs and body regions.

In June 2012, the Company amended its Investigational New Drug (IND) application, which permits the use of the Generation Two CHEMOSAT/Melblez Kit system in the clinical trials planned in its CDP.

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Expanded Access Program
In June 2012, the Company amended its Expanded Access Program (EAP) in the United States to include the use of the Generation Two hemofiltration cartridge of the Melblez Kit system. The amendment filed with the FDA permits physicians at experienced U.S. cancer centers to use the Generation Two Melblez Kit system in expanded access and compassionate use cases. Under the EAP's protocol, eligible patients will be able to receive treatment through enrollment at participating cancer centers upon receipt of each center's institutional review board (IRB) approval. As of March 31, 2013, treatments under the EAP have begun at the Sky Ridge Medical Center in Lone Tree, Colorado and the Moffitt Cancer Center in Tampa, Florida. The Company anticipates that up to six cancer centers will participate in the EAP.

Results of Operations for the Three Months Ended March 31, 2013; Comparisons of Results of Operations for the Three Months Ended March 31, 2012

Revenue

The Company recorded approximately $0.4 million in total revenue during the three months ended March 31, 2013, of which $0.3 million is related to the recognition of previously deferred revenue as a result of satisfying certain requirements of the Company's agreement with Chi-Fu Trading Co. Ltd. The remainder of the revenue is related to product sales. During the three months ended March 31, 2012, Delcath had not yet transitioned to a commercial enterprise and no revenue was recorded for the period.

Cost of Goods Sold

During the period ended March 31, 2013, the Company recognized cost of goods sold of approximately $31,000. As Delcath continues to expand its commercialization in Europe and other parts of the world, the Company expects to see a certain amount of volatility in both the average selling price and gross margin for the next several years. This volatility will be related to several factors, including: the expected use of third party distributors, whose purchase prices will be lower than direct to end user customer prices; the gradual increase in cost of goods sold as the Company exhausts raw materials that were purchased and expensed in prior periods and begins to recognize the actual costs of materials, labor and overhead; and an improvement in efficiencies as the Company increases its production of the CHEMOSAT system.

Operating Expenses

Selling, General and Administrative Expenses
For the three months ended March 31, 2013, selling, general and administrative expenses decreased to $6.1 million from $7.4 million for the three months ended March 31, 2012. The decrease reflects the Company's efforts to increase organizational efficiencies, including a workforce restructuring initiated early in 2013. During the first three months of 2012, the Company incurred certain expenses related to the early stages of its European expansion, including creating the appropriate subsidiaries, and the hiring of staff for sales and support positions across Europe, leading to a reduction in expenses for the first three months of 2013.

Research and Development Expenses
For the three months ended March 31, 2013, research and development expenses decreased to $4.5 million from $7.1 million for the three months ended March 31, 2012. The decrease is primarily due to a significant reduction in expenses related to the Company's NDA submission to the FDA. Additionally, the Company transitioned from a development stage company to a commercial organization in 2012. As a result, purchases of inventory are now capitalized rather than being expensed as research and development materials as they were for the first three months of 2012.

Interest Income

Interest income is from a money market account and interest earned on operating accounts. For the three months ended March 31, 2013, the Company had interest income of $10,036 as compared to interest income of $3,234 for the same period in 2012. For the three months ended March 31, 2013, the Company invested its cash in interest bearing accounts which yielded higher returns than in the same period of 2012.

Other Expense and Interest Expense

Other expense is primarily related to foreign currency exchange gains and losses. Interest expense is related to an ongoing Revolving Line Facility Fee as required by the Loan and Security Agreement signed with Silicon Valley Bank in 2012 and discussed in Note 9 to the Company's audited financial statements contained in the 2012 Annual Report on Form 10-K.

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Net Loss

The Company had a net loss for the three months ended March 31, 2013, of $12.9 million, a decrease of $2.0 million, or 14%, compared to the net loss from continuing operations for the same period in 2012. This decrease is primarily due to a $4.0 million decrease in operating expenses, which was partially offset by a $1.9 million increase in the change in the fair value of the warrant liability, which is a non-cash expense. As detailed above, the decrease in operating expenses reflects a significant decrease in costs related to the Company's NDA filing and overall operations.

Liquidity and Capital Resources

The Company's future results are subject to substantial risks and uncertainties. Delcath has operated at a loss for its entire history and anticipates that losses will continue over the coming years. There can be no assurance that Delcath will ever generate significant revenues or achieve profitability. The Company expects to use cash, cash equivalents and investment proceeds to fund its operating activities. Delcath's future liquidity and capital requirements will depend on numerous factors, including the progress of research and product development programs, obtaining approvals and complying with regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments.

At March 31, 2013, the Company had cash and cash equivalents totaling $42.8 million, as compared to cash, cash equivalents and certificates of deposit totaling $23.7 million and $20.8 million at December 31, 2012 and March 31, 2012, respectively. During the three months ended March 31, 2013, the Company used $10.9 million of cash in its operating activities, which compares to $14.2 million used for operating activities during the comparable three month period in 2012. The decrease of $3.3 million is primarily driven by a reduction in NDA submission related costs and a reduction in expenses related to the Company's ongoing commercialization efforts in Europe. The Company believes it has access to sufficient capital to fund operating activities for the next twelve months. Assuming Delcath receives FDA approval in 2013, the Company anticipates additional resources will be required to support full U.S. commercialization in 2014.

Because Delcath's business does not generate positive cash flow from operating activities, the Company will need to raise additional capital in order to fully commercialize the product or to fund development efforts relating to additional indications. The company's ability to raise capital may be limited in the near term due to the decline in its stock price following the decision from the FDA's ODAC panel discussed earlier in this filing. However, the Company continues to believe it will be able to raise additional capital in the event it is in its best interest to do so. The Company anticipates raising such additional capital by either borrowing money, selling shares of Delcath's capital stock, or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when needed, the Company may be forced to abandon some or all of its development and commercialization efforts, which would have a material adverse effect on the prospects of our business. Further, the Company's assumptions relating to its cash requirements may differ materially from its actual requirements because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the focus and direction of clinical trials and costs related to commercializing the product.

The Company has funded its operations through a combination of private placements of its securities, public offerings in 2000, 2003, 2009, 2010, 2011 and 2012, registered direct offerings in 2007 and 2009, an "at the market" equity offering program initiated in 2012, and a committed equity financing facility program initiated in 2012. For a detailed discussion of the Company's various sales of securities and the "at the market" equity offering program see Note 8 to the Company's condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

During the three months ended March 31, 2013, the Company sold approximately 14.2 million shares of our common stock under a Sales Agreement through an "at the market" equity offering program for net proceeds of approximately

$20.9 million before related expenses. The net proceeds will be used for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital. There are no shares of common stock of the Company remaining for sale under the program or registered pursuant to registration statement 333-165677. Following successful completion of the "at the market" equity offering program initiated in December 2011, on March 13, 2013 the Company entered into a new Sales Agreement with Cowen and Company, LLC to sell shares of the Company's common stock having aggregate sales proceeds of $50,000,000, from time to time, through an "at the market" equity offering program. The Securities will be issued pursuant to a shelf registration statement on Form S–3 (333-187230) which was filed with the Securities and Exchange Commission on March 13, 2013.

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In December 2011, the Company filed a registration statement on Form S-3 with the SEC, which allowed the Company to offer and sell, from time to time in one or more offerings, up to $100,000,000 of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deemed prudent or necessary to raise capital at a later date. The registration statement became effective on February 13, 2012. The Company used this registration statement for its May 2012 public offering detailed in Note 8 to the Company's audited financial statements contained in the 2012 Annual Report on Form 10-K. The Company subsequently filed a new shelf registration statement on Form S-3 with the SEC which became effective on October 9, 2012. This new shelf replaces the shelf registration filed in December 2011 and allows the Company to offer and sell, from time to time in one or more offerings, up to $100,000,000 of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deems prudent or necessary to raise capital at a later date. The Company used this registration statement for its Common Stock Purchase Agreement with Terrapin Opportunity, L.P. detailed in Note 8 to the Company's audited financial statements contained in the 2012 Annual Report on Form 10-K. During the three months ended March 31, 2013, the Company sold approximately 5.6 million shares of its common stock under the Common Stock Purchase Agreement for proceeds of $9.0 million before related expenses. As of March 31, 2013, Delcath had approximately $88.1 million available under this registration statement, of which approximately $6.5 million is reserved for the potential issuance of shares upon the exercise of warrants.

The Company intends to use the net proceeds from any future offerings for general corporate purposes, including, but not limited to, obtaining regulatory approvals, commercialization of its products, funding of clinical trials, capital expenditures and working capital.

Application of Critical Accounting Policies

The Company's financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP). Certain accounting policies have a significant impact on amounts reported in the financial statements. A summary of those significant accounting policies can be found in Note 1 to the Company's audited financial statements contained in the 2012 Annual Report on Form 10-K. During 2012, Delcath transitioned from a development stage company to a commercialization organization. At this early commercial stage, the Company has limited choices 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 GAAP.

Additionally, the Company devotes substantial resources to obtaining regulatory approvals for the CHEMOSAT/Melblez Kit system as well as its research and development activities, 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 ASC 740 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. Management believes the Company does not have any uncertain tax positions.

The Company has adopted the provisions of ASC 718, which establishes accounting for equity instruments exchanged for employee services. Under the provisions of ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders' requisite service period (generally the vesting period of the equity grant). The Company expenses its share-based compensation under the ratable method, which treats each vesting tranche as if it were an individual grant.

The Company has adopted the provisions of ASC 505-50, which establishes accounting for equity-based payments to non-employees. Measurement of compensation cost related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. Each transaction is reviewed to determine the more reliably measurable basis for the valuation. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests. Non-employee stock-based compensation charges are amortized over the vesting period or period of performance of the services.

The Company has adopted the provisions of ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity’s own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

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Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability which are typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability. See Note 5 to the Company's condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q for assets and liabilities the Company has evaluated under ASC 820.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

The Company may be minimally exposed to market risk through changes in market interest rates that could affect the interest earned on its cash balances.

The Company measures all derivatives, including certain derivatives embedded in contracts, at fair value and recognizes them on the balance sheet as an asset or a liability, depending on the Company's rights and obligations under the applicable derivative contract.

In June 2009, the Company completed the sale of 0.9 million shares of its common stock and the issuance of warrants to purchase 1.0 million common shares (the "2009 Warrants") pursuant to a subscription agreement with a single investor. The Company received proceeds of $3.0 million, with net cash proceeds after related expenses from this transaction of approximately $2.7 million. Of those proceeds, the Company allocated an estimated fair value of $2.2 million to the warrant liability. The fair value of the 2009 Warrants on June 15, 2009 was determined by using an option pricing model assuming a risk free interest rate of 2.75%, volatility of 72.93% and an expected life equal to the contractual life of the 2009 Warrants (June 2014). As required by the 2009 Warrant agreement, the exercise price of the warrants was adjusted following the Company's December 2012 sale of common stock. At March 31, 2013, the 2009 Warrants were exercisable at $1.20 per share with 1.0 million shares outstanding. The 2009 Warrants have a five-year term.

In May 2012, the Company completed the sale of 15.3 million shares of its common stock and the issuance of warrants to purchase 4.6 million common shares (the "2012 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $21.5 million, with net cash proceeds after related expenses from this transaction of approximately $21.1 million. Of those proceeds, the Company allocated an estimated fair value of $3.4 million to the 2012 Warrants. The fair value of the 2012 Warrants on May 31, 2012 was determined by using an option pricing model assuming a risk free interest rate of 0.35%, volatility of 80.64% and an expected life equal to the contractual life of the 2012 Warrants (May 2015). As required by the 2012 Warrant agreement, the exercise price of the warrants was adjusted following the Company's December 2012 sale of common stock. At March 31, 2013, the 2012 Warrants were exercisable at $1.20 per share with 4.4 million warrants outstanding. The 2012 Warrants have a three-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3. During the three months ended March 31, 2013, 0.2 million 2012 Warrants were exercised for net proceeds of approximately $0.2 million.

The $3.4 million in proceeds allocated to the 2012 Warrants and the $2.2 million in proceeds allocated to the 2009 Warrants are classified as derivative instrument liabilities. The terms of the warrants provide for potential adjustment

in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As a result, for the three month period ended March 31, 2013, the Company recorded pre-tax derivative instrument expense of $2.2 million. The resulting derivative instrument liabilities totaled $5.5 million at March 31, 2013. Management expects that the warrants will either be exercised or expire worthless. The fair value of the Warrants at March 31, 2013 was determined by using an option pricing model assuming the following:

	2012 Warrants	2009 Warrants
Expected volatility	83.33%	83.43%
Risk-free interest rates	0.27%	0.16%
Expected life (in years)	2.25	1.25

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Delcath's management, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) of the Exchange Act. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that Delcath's disclosure controls and procedures as of March 31, 2013 (the end of the period covered by this Quarterly Report on Form 10-Q), have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in the Company's reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including the Company's Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Controls

There was no change in our internal control over financials reporting that occurred during the quarter ended March 31, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II:
OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

Delcath's 2012 Annual Report on Form 10-K, in Part 1, Item 1A. "Risk Factors," contains a detailed discussion of factors that could materially adversely affect our business, operating results and/or financial condition. There have been no material changes in these risk factors since such disclosure.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not Applicable.

Item 3. Defaults upon Senior Securities

Not Applicable.

Item 5. Other Information

Not Applicable.

Item 6. Exhibits

Exhibit
No. Description

31.1	**	Certification by Principal executive officer Pursuant to Rule 13a 14.
31.2	**	Certification by Principal financial officer Pursuant to Rule 13a 14.
32.1	***	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	***	Certification of Principal financial officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS		XBRL Instance Document
101.SCH		XBRL Taxonomy Extension Schema Document
101.CAL		XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF		XBRL Taxonomy Extension Definition Linkbase Document
101.LAB		XBRL Taxonomy Extension Label Linkbase Document
101.PRE		XBRL Taxonomy Extension Presentation Linkbase Document

** Filed herewith.

*** Furnished herewith.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

May 8, 2013

DELCATH SYSTEMS, INC.
(Registrant)

/s/Graham G. Miao
Graham G. Miao
Chief Financial Officer
(Principal Financial Officer)

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101.LAB		XBRL Taxonomy Extension Label Linkbase Document
101.PRE		XBRL Taxonomy Extension Presentation Linkbase Document

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