Chelsea Therapeutics International, Ltd. Form 10-Q May 04, 2010 Table of Contents

# 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, 2010

or

" 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: 000-51462

# CHELSEA THERAPEUTICS INTERNATIONAL, LTD.

(Exact name of Registrant as specified in its charter)

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Delaware (State or other jurisdiction of

20-3174202 (I.R.S. Employer

incorporation or organization)

Identification No.)

3530 Toringdon Way, Suite 200, Charlotte, North Carolina 28277

(Address of principal executive offices, including zip code)

(704) 341-1516

 $(Registrant \ \ s \ telephone \ number, including \ area \ code)$ 

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 ...

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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES "NO"

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 definition of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer Accelerated Filer Accelerated Filer

Non-accelerated Filer  $\,^{\circ}\,$  (Do not check if smaller reporting company) Smaller Reporting Company  $\,^{\circ}\,$  Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES  $\,^{\circ}\,$  NO  $\,$ x

As of May 3, 2010 there were 40,200,406 shares of registrant s Common Stock outstanding.

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#### PART I FINANCIAL INFORMATION

# Item 1. Financial Statements CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY

(A Development Stage Company)

# CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2010 (unaudited)	December 31, 2009 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 31,596,730	\$ 22,294,649
Short-term investments	11,400,000	11,450,000
Prepaid contract research and manufacturing	189,808	293,886
Other prepaid expenses and other current assets	405,307	129,687
Total current assets	43,591,845	34,168,222
Property and equipment, net	86,556	103,795
Other assets	77,500	76,950
	\$ 43,755,901	\$ 34,348,967
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 2,650,925	\$ 2,842,566
Accrued compensation and related expenses	355,820	894,696
Accrued contract research and manufacturing	4,883,328	5,501,329
Other accrued expenses	575,028	792,458
Line of credit payable	11,400,000	11,466,012
Total liabilities	19,865,101	21,497,061
Commitments		
Stockholders equity:		
Preferred stock, \$0.0001 par value, 5,000,000 shares authorized, no shares issued and outstanding		
Common stock, \$0.0001 par value, 60,000,000 shares authorized, 40,200,406 and 33,500,406		
shares issued and outstanding, respectively	4,020	3,350
Additional paid-in capital	125,662,056	108,391,823
Deficit accumulated during the development stage	(101,775,276)	(95,543,267)
Total stockholders equity	23,890,800	12,851,906
	\$ 43,755,901	\$ 34,348,967

# CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY

(A Development Stage Company)

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

	For	the three montl	Period from April 3, 2002		
		2010		2009	(inception) to March 31, 2010
Operating expenses:					
Research and development	\$	4,880,473	\$	6,506,906	\$ 82,499,633
Sales and marketing		410,547		305,300	6,890,920
General and administrative		975,587		1,042,473	16,768,170
Total operating expenses		6,266,607		7,854,679	106,158,723
Operating loss		(6,266,607)		(7,854,679)	(106,158,723)
Interest income		67,551		115,674	4,604,359
Interest expense		(32,953)		(26,754)	(220,912)
Other income (expense)				337,492	
Net loss	\$	(6,232,009)	\$	(7,428,267)	\$ (101,775,276)
100 1035	Ψ	(0,232,007)	Ψ	(7,420,207)	φ (101,773,270)
Net loss per basic and diluted share of common stock	\$	(0.18)	\$	(0.25)	
Weighted average number of basic and diluted common shares outstanding		35,435,962		30,111,479	

# CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY

(A Development Stage Company)

# CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

(unaudited)

	Common	stock	Additional paid-in	Deficit accumulated during the development	Total stockholders
	Shares	Amount	capital	stage	
Balance at January 1, 2010	33,500,406	\$ 3,350	\$ 108,391,823	\$ (95,543,267)	\$ 1 <b>2</b> ,851,906
Stock-based compensation			510,043		510,043
Sale and issuance of common stock with detachable warrants in March 2010 at approximately \$2.50 per					
share, net of issuance costs	6,700,000	670	16,760,190		16,760,860
Net loss				(6,232,009)	(6,232,009)
Balance at March 31, 2010	40,200,406	\$ 4,020	\$ 125,662,056	\$ (101,775,276)	\$ 23,890,800

# CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY

(A Development Stage Company)

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	For	For the three months ended March 31,					
	2010			2009		(inception) to March 31, 2010	
Operating activities:		2010		2009	141	arcii 31, 2010	
Net loss	\$	(6,232,009)	\$	(7,428,267)	\$	(101,775,276)	
Adjustments to reconcile net loss to net cash used in operating activities:		(0,202,000)		(,,,==,==,)		(,,,	
Non-cash stock-based compensation		510,043		406,134		4,865,203	
Depreciation and amortization		17.239		18,939		247,143	
Stock issued for license agreement		17,209		10,505		575,023	
Non-cash interest expense						34,020	
Gain on recovery of other-than-temporary impairment of short-term and						5 1,020	
long-term investments				(337,492)			
Gain on disposition of assets				(337,172)		(2,208)	
Fair value of warrants for finder s agreement						433,750	
Changes in operating assets and liabilities:						733,730	
Prepaid contract research and manufacturing expenses, other prepaid							
expenses and other assets		(171,542)		126,474		(595,115)	
Accounts payable, accrued contract research and manufacturing expenses		(171,342)		120,474		(393,113)	
		(1.027.072)		(1 100 155)		9 100 292	
and other accrued expenses		(1,027,072)		(1,108,155)		8,109,282	
Accrued compensation and related expenses		(538,876)		(298,361)		355,820	
Net cash used in operating activities		(7,442,217)		(8,620,728)		(87,752,358)	
Investing activities:							
Acquisitions of property and equipment				(1,731)		(335,169)	
Proceeds from sale of assets						3,677	
Purchases of investments						(49,538,336)	
Redemptions and sales of investments		50,000		2,375,000		38,138,336	
Security deposits		(550)				(77,500)	
Net cash provided by (used in) investing activities		49,450		2,373,269		(11,808,992)	
Financing activities:							
Proceeds from borrowings from affiliate						1,745,000	
Borrowings from (repayments of) line of credit		(66,012)		4,281,877		11,400,000	
Proceeds from exercise of stock options						80,729	
Proceeds from exercise of common stock warrants						299,080	
Recapitalization of the Company						(400,000)	
Proceeds from sales of equity securities, net of issuance costs		16,760,860				118,028,646	
Receipt of cash for stock subscription receivable						4,625	
		16 604 040		4.201.055		121 150 000	
Net cash provided by financing activities		16,694,848		4,281,877		131,158,080	
N. C.		0.202.001		(1.065.500)		21 507 722	
Net increase (decrease) in cash and cash equivalents		9,302,081		(1,965,582)		31,596,730	
Cash and cash equivalents, beginning of period		22,294,649		21,532,553			
Cash and cash equivalents, end of period	\$	31,596,730	\$	19,566,971	\$	31,596,730	

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Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 32,953	\$ 26,754	\$ 186,892

#### CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY

(A Development Stage Company)

#### CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

#### (UNAUDITED)

#### Supplemental disclosure of non-cash investing and financing activities:

During 2002, the Company issued 5,428,217 shares of its \$0.0001 par value common stock for a subscription receivable of \$4,625.

During 2004, the Company converted a loan with an affiliate for aggregate principal of \$1,745,000 and accrued interest of \$34,020 into shares of the Company s \$0.0001 par value common stock, issuing 677,919 shares, at approximately \$2.62 per share in lieu of repayment of this obligation.

In December 2004, in conjunction with and as compensation for activities related to the December 2004 sale of equity securities, the Company issued warrants to purchase 483,701 shares of its \$0.0001 par value common stock, with a purchase price of approximately \$2.88 per share and an aggregate fair value of \$14,400.

In conjunction with the merger and recapitalization of the Company dated February 11, 2005, the Company issued 11,911,357 shares of its \$0.0001 par value common stock in exchange for all of the issued and outstanding shares of Chelsea Therapeutics, Inc. In addition, in conjunction with and as compensation for facilitating the merger, the Company issued warrants for the purchase of 105,516 shares of its \$0.0001 par value common stock at an exercise price of \$2.62 per share and an aggregate fair value of \$26,700.

In February 2006, in conjunction with and as compensation for activities related to the February 2006 sale of equity securities, the Company issued warrants to purchase 716,666 shares of its \$0.0001 par value common stock, with a purchase price of \$3.30 per share and an aggregate fair value of approximately \$705,000.

In May 2006, in conjunction with and as compensation for activities related to a licensing agreement and under a Finder s Agreement, the Company issued warrants to purchase 250,000 shares of its \$0.0001 par value common stock, with an exercise price of \$4.31 per share. The exercise of these warrants was conditioned on an event that occurred in January 2007 and, accordingly, the Company recorded a charge based on the warrants fair value determined at January 2007 of \$433,750.

#### CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY

(A Development Stage Company)

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### **AS OF MARCH 31, 2010**

(Unaudited)

# NOTE 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND NATURE OF OPERATIONS $\it The Company$

Chelsea Therapeutics International, Ltd. ( Chelsea Ltd. or the Company ) is a development stage, specialty pharmaceutical company focused on the acquisition, development and commercialization of innovative pharmaceutical products. The Company s currently licensed compounds target a variety of medical conditions, particularly rheumatoid arthritis, psoriasis, cancer, other immunological disorders, neurogenic orthostatic hypotension and other norepinephrine-related autonomic disorders. The Company s operating subsidiary, Chelsea Therapeutics, Inc. ( Chelsea Inc. ), was incorporated in the State of Delaware on April 3, 2002 as Aspen Therapeutics, Inc., with the name changed in July 2004. In February 2005, Chelsea Inc. merged with a wholly-owned subsidiary of our predecessor company, Ivory Capital Corporation ( Ivory ), a Colorado public company with no operations (the Merger ). The Company reincorporated into the State of Delaware in July 2005, changing its name to Chelsea Therapeutics International, Ltd.

As a result of the Merger of Ivory and Chelsea Inc. in February 2005, and the reincorporation in Delaware in July 2005, Chelsea Ltd. is the reporting company and is the 100% owner of Chelsea Inc. The separate existence of Ivory ceased in connection with the Delaware reincorporation in July 2005. Except where the context provides otherwise, references to the Company and similar terms mean Ivory, Chelsea Ltd. and Chelsea Inc.

#### Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of the Company and its operating subsidiary, which shall collectively be referred to as the Company . These statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial reporting and the instructions to Form 10-Q and do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of the Company s management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results for the interim periods have been included. Operating results for the three months ended March 31, 2010 are not necessarily indicative of the results for the year ending December 31, 2010 or future periods. The accompanying condensed consolidated financial statements should be read in conjunction with the Company s audited consolidated financial statements and related notes included in the Company s Annual Report on Form 10-K filed on March 10, 2010 and available on the website of the United States Securities and Exchange Commission (<a href="https://www.sec.gov">www.sec.gov</a>). The accompanying condensed consolidated balance sheet as of that date included in the Form 10-K.

Since inception, the Company has focused primarily on organizing and staffing, negotiating in-licensing agreements with its partners, acquiring, developing and securing its proprietary technology, participating in regulatory discussions with the United States Food and Drug Administration, or FDA, the European Medicines Agency, or EMEA, and other regulatory agencies and undertaking pre-clinical trials and clinical trials of its product candidates. The Company is a development stage company and has generated no revenue since inception.

The Company has sustained operating losses since its inception and expects that such losses could continue over the next several years. Management believes that currently available capital resources will be sufficient to meet our operating needs into the first quarter of 2011 and continues to actively pursue additional sources of liquidity in anticipation of ongoing needs for operations. Potential sources of additional liquidity might include strategic relationships, out-licensing of the Company s products, public or private sales of equity or debt and other sources. Such strategic relationships or out-licensing arrangements might require the Company to relinquish rights to certain of its technologies, product candidates or products that the Company would otherwise seek to develop or commercialize itself. If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its development programs or curtail operations.

#### CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY

(A Development Stage Company)

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### **AS OF MARCH 31, 2010**

(Unaudited)

#### Basis of Consolidation

The accompanying financial statements present, on a condensed consolidated basis, the financial position and results of operations of Chelsea Ltd. and its subsidiary. All significant intercompany transactions and balances have been eliminated in consolidation.

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgments. Management bases estimates on its historical experience and on various other factors that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results might differ from these estimates under different assumptions or conditions.

#### Investments

Investments consist of investments in auction rate securities, or ARS. ARS are generally long-term debt instruments for which interest rates are reset through a dutch auction process that occurs at pre-determined calendar intervals, generally each 28 or 35 days. As all of the Company s investments in ARS at March 31, 2010 are currently being held principally for the purpose of selling them in the near term, they are classified as trading securities. The Company has elected the fair value option in accounting for its trading securities and, accordingly, accounts for such investments at their determined fair value.

#### Fair Value Measurements and the Fair Value Option

For financial assets and liabilities and any other assets and liabilities carried at fair value, the Company completes analyses of fair value and provides certain disclosures about fair value measurements. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Under the fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value, the Company performs analyses on a consistent basis and designs its disclosures surrounding such analyses and the fair value determined at the balance sheet date to meet required presentation and disclosure requirements.

#### Recent Accounting Pronouncements

In September 2009, the Financial Accounting Standards Board, or FASB, issued authoritative guidance that modifies the accounting for multiple element arrangements. This guidance requires an entity to allocate revenue to each unit of accounting in multiple deliverable arrangements based on the relative selling price of each deliverable. It also changes the level of evidence of stand-alone selling prices required to separate deliverables by allowing an entity to make its best estimate of the stand-alone selling price of the deliverables when more objective evidence of selling price is not available. Implementation of this guidance is required no later than fiscal years beginning after June 15, 2010 and this guidance may be applied prospectively to new or materially modified arrangements after the effective date or retrospectively. Early application is permitted. As the Company has no active multiple element arrangements, the adoption of this authoritative guidance will have no material impact on its consolidated financial position or results of operations.

#### CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY

(A Development Stage Company)

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### **AS OF MARCH 31, 2010**

(Unaudited)

#### NOTE 2 AUCTION RATE SECURITIES

At March 31, 2010, the Company held investments in student-loan backed ARS with an aggregate par value of \$11.4 million, classified as trading securities based on the terms of a settlement agreement reached during 2008. Trading securities are carried at estimated fair value, based on available information. As the terms of the settlement agreement allows these securities to be redeemed by, at the earliest, June 30, 2010, and it is the Company s intent to redeem those securities at that date, they were classified as short-term investments at March 31, 2010.

The Company s ARS investments at March 31, 2010 represent interests in collateralized debt obligations supported by pools of student loans and none are collateralized by mortgage, credit card or insurance securitizations. All but approximately \$4.4 million of the par value of the Company s investments in ARS were AAA/Aaa rated, fully backed by the Federal Family Education Loan Program, or FFELP, and/or over-collateralized. Of the remaining \$4.4 million of investments at par value, all were collateralized at 100% or greater and, consistent with the Company s investment policy at the time of purchase, \$0.75 million carried an A rating, \$1.15 million carried an Aa3/AAA rating and the remainder carried AAA/Aaa ratings. During the three months ended March 31, 2010, the Company has not been notified of any modification to the credit ratings of the underlying issuing agencies for any of the investments held at March 31, 2010.

On December 31, 2009, the Company held total investments in ARS with a par value of approximately \$11.45 million. During the quarter ended March 31, 2010, the Company received proceeds of \$50,000 from partial redemptions at par.

The par value of the Company s ARS investments, classified as trading securities and held at UBS Financial Services, Inc. (UBS), as of March 31, 2010 was \$11.4 million and as of December 31, 2009 was \$11.45 million. During 2008, the Company finalized the details of its settlement agreement related to those ARS held at UBS and accepted the terms for ARS Rights (the ARS Rights) for the illiquid ARS holdings maintained at UBS as of February 13, 2008. The ARS Rights provide the Company with the ability to sell the ARS, along with the ARS Rights, to UBS at the par value of the ARS no earlier than June 30, 2010 and expire on July 2, 2012. The ARS Rights grant UBS the sole discretion and right to sell or otherwise dispose of ARS at any time up until June 30, 2010, so long as the holder receives a payment of par upon any sale or disposition. The ARS Rights are not transferable, not tradable and will not be quoted or listed on any securities exchange or any other trading network.

UBS also agreed that an affiliate would provide the Company with a no net-cost line of credit. Under the terms of the line of credit agreements the Company received funds in December 2008 and March 2009 and had a remaining liability at March 31, 2010 of \$11.4 million. Though the loan is payable on demand, if the UBS affiliate should exercise its right to demand repayment of any portion of the loan prior to the date the Company can exercise its ARS Rights, UBS and its affiliates would be required to arrange for alternative financing on terms and conditions substantially the same as those contained in the line of credit agreement. If alternative financing cannot be established, then UBS AG, or one of its affiliates, will purchase the Company s pledged UBS ARS at par. As a result, the loan and any alternative financing will not be payable by the Company prior to the time that is it able to exercise its ARS Rights in accordance with its agreement with UBS and, accordingly, the liability is classified as a short-term liability at March 31, 2010. The Company expects to repay the line of credit with the proceeds from the exercise of those ARS Rights. Proceeds of any sales of the Company s UBS ARS will first be applied to repayment of the line of credit with the balance, if any, deposited into its account.

As the ARS Rights represent a separate freestanding contract between the Company and UBS and are not transferable to a subsequent buyer, the existence of the ARS Rights had no effect upon the determination of fair value for the ARS at March 31, 2010. In 2008, recognizing that the ARS Rights act as an economic hedge against any further price movement in those ARS holdings, the Company elected to account for the ARS Rights under the fair value option to mitigate volatility in reported earnings due to the relationship between the ARS Rights and the ARS. The Company adjusts the ARS Rights to fair value at each financial statement date with corresponding changes in fair value reported in earnings. Simultaneously, the Company elected a one-time transfer of the ARS covered under the settlement agreement with UBS from the available-for-sale category to the trading category recognizing the unprecedented failure of the entire market for ARS. This election allows all future movements in the fair value of the ARS to be reported in earnings, creating relative accounting symmetry with the ARS Rights until the settlement is realized. The ARS Rights are recorded at fair value and are classified as short-

#### CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY

(A Development Stage Company)

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### **AS OF MARCH 31, 2010**

(Unaudited)

term investments on the consolidated condensed balance sheet as of March 31, 2010. Finally, based on the terms of the settlement agreement and the earliest exercise date for the ARS Rights, the Company has classified its investments in the UBS ARS as short-term investments at March 31, 2010.

For those ARS held at UBS under the settlement agreement, the Company believes that normal discounted cash flow modeling continues to have limited validity under current market conditions as the interest rates currently associated with the majority of these securities are not truly a factor of value. The ARS continue to pay interest according to their stated terms. However, the application of additional discount factors related to issuer credit ratings, percentage of FFELP or insurance wraps, etc. does make modeling such discounted cash flows feasible and the Company determined that it should review the valuation for the UBS ARS based on those factors. The Company assigned risk component factors, utilized a liquidity discount of 300 basis points to reflect the continuing weakness in the market and utilized a five-year life for these assets. In addition, for establishing the fair value of the ARS Rights as of March 31, 2010, the Company determined that, as the line of credit had been fully funded at 100% of the par value of the Company s ARS holdings at UBS, discount factors should no longer be applied related to counterparty performance risk and the time value of money in a discounted cash flow methodology. Subsequently, the fair value of the ARS Rights of approximately \$2.2 million and the fair value of the ARS of approximately \$9.2 million, in the aggregate, total 100% of the par value of the ARS held at UBS.

As a result of the analysis of fair value, the Company recorded no additional trading loss related to its trading securities nor any corresponding adjustment to the fair value of its ARS rights during the quarter ended March 31, 2010. During the quarter ended March 31, 2009, the Company recorded a gain of approximately \$0.2 million related to the increased value of the ARS rights due to the additional funding received under the line of credit and the resulting elimination of any performance risk associated with the settlement. In addition, the Company also recorded the recovery of \$0.1 million of previously recorded other-than-temporary impairment losses related to the \$0.3 million in partial redemptions at par of its available-for-sale ARS investments during the first quarter of 2009.

#### NOTE 3 FAIR VALUE MEASUREMENTS

In determining fair value, the Company utilizes techniques that optimize the use of observable inputs, when available, and minimize the use of unobservable inputs to the extent possible. As normal trading activity within public markets for ARS ceased during the quarter ended March 31, 2008 and had not resumed with any regularity at March 31, 2010, there continues to be an absence of observable market quotes (level 1 inputs). Trading activity in the secondary markets for ARS is not sufficiently active and the resulting data does not qualify as appropriate level 2 inputs. Data points that are available do not technically qualify as level 2 inputs and have been characterized as unobservable (level 3) inputs, along with other inputs including fair value information provided by UBS on the Company s ARS holdings with UBS (based on percentage of collateralization, assessments of counterparty credit quality, default risk underlying the security, the mix of FFELP loans and private loans) and overall capital market liquidity.

The following fair value hierarchy table categorizes information regarding assets measured at fair value on a recurring basis:

#### CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY

(A Development Stage Company)

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### **AS OF MARCH 31, 2010**

(Unaudited)

#### Assets Measured at Fair Value on a Recurring Basis

(in thousands)

	Quoted prices in active markets for identical assets (Level 1)		Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
As of March 31, 2010					
Cash and cash equivalents	\$	31,597	\$	\$	\$ 31,597
Auction rate securities (1)				9,209	9,209
ARS Rights (Note 2)				2,191	2,191
	\$	31,597	\$	\$ 11,400	\$ 42,997

<sup>(1)</sup> Auction rate securities classified as trading and as short-term investments. The method used to estimate the fair value of these investments is more fully explained in Note 2.

The Company s assets that were measured at fair value on a recurring basis using significant Level 3 inputs as of March 31, 2010 consisted of its investments in ARS and its ARS Rights. The following table summarizes the Company s fair value measurements using significant Level 3 inputs, and changes therein, for the three months ended March 31, 2010:

Balance as of December 31, 2009	\$ 11,450,000
Redemptions	(50,000)
Sales on secondary market	
Increase in fair value of ARS Rights	
Realized losses	
Transfers in and/or out of Level 3	
Balance as of March 31, 2010	\$ 11,400,000

The valuation of the Company s ARS investment portfolio has been sensitive to market conditions and is based on management s best estimate given the facts available at the time of the estimate. The assumptions utilized in the estimate of fair value have been difficult to predict and the resulting fair value estimates have been subject to fluctuation. However, with the Company s success in gaining full liquidity on its remaining ARS holdings at UBS in 2009, the risk of such fluctuations are effectively offset by corresponding changes in the fair value of the ARS Rights.

#### NOTE 4 STOCK-BASED COMPENSATION

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The Company has a stock incentive plan, as amended (the Plan ) under which stock options for 5,000,000 shares of the Company s 0.0001 par value common stock (the common stock ) may be granted. Grants under the Plan may be made to employees (including officers), directors, consultants, advisors or other independent contractors who provide services to the Company or its subsidiary.

During the three months ended March 31, 2010, the Company granted stock options to employees and non-employee directors for the purchase of 793,500 shares of its common stock with a weighted-average exercise price of \$2.94 per share, a weighted average grant date fair value of \$2.14 per share and an aggregate intrinsic value at March 31, 2010 of approximately \$0.5 million. During the three months ended March 31, 2009, the Company granted stock options to employees and non-employee directors for the purchase of 760,400 shares of its common stock with a weighted average

#### CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY

(A Development Stage Company)

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### **AS OF MARCH 31, 2010**

(Unaudited)

exercise price of approximately \$1.71 per share and a weighted average grant date fair value of approximately \$1.11 per share and an aggregate intrinsic value at March 31, 2010 of approximately \$1.4 million.

Each option granted to employees and non-employee directors during the three months ended March 31, 2010 and 2009 vests as to 25% of the shares on each of the first, second, third and fourth anniversary of the vesting commencement date. Following the vesting periods, options are exercisable by employees until the earlier of 90 days after the employee s termination with the Company or the ten-year anniversary of the initial grant, subject to adjustment under certain conditions. Following the vesting periods, options are exercisable by non-employee directors until the earlier of 180 days after they cease to be a member of the Board of Directors or the ten-year anniversary of the initial grant, subject to adjustment under certain conditions.

The Company utilizes the Black-Scholes-Merton valuation model for estimating the fair value of the stock options granted. The table below summarizes the assumptions utilized in estimating the fair value of the stock options granted for the three months ended March 31, 2010 and 2009:

	For the three months er	ided March 31,
	2010	2009
Weighted average risk-free interest rate	2.46%	1.71%
Expected life of options	5 years	5 years
Expected dividend yield	0%	0%
Weighted average expected volatility	94.44%	80.96%

The Company recorded compensation expense for the three months ended March 31, 2010 and 2009 of approximately \$0.5 million and approximately \$0.4 million, respectively, in conjunction with option grants made to employees and non-employee directors. As of March 31, 2010, the Company had total unrecognized compensation expense related to options granted to employees and non-employee directors of approximately \$4.3 million, which it expects to recognize over a remaining average period of 2.1 years.

As of March 31, 2010, there were 4,596,680 options outstanding under the Plan with a weighted average remaining contractual life of 7.5 years and a weighted average exercise price of approximately \$3.65 per share. Of these, options for 2,395,219 shares had vested and were exercisable at March 31, 2010 with a weighted average remaining contractual life of 6.2 years and a weighted average exercise price of approximately \$3.77 per share.

The aggregate intrinsic value is calculated as the difference between the exercise prices of the underlying awards and the quoted closing price of the common stock of the Company as of March 31, 2010 for those awards that have an exercise price below the quoted closing price. As of March 31, 2010, there were options outstanding to purchase an aggregate of 2,907,484 shares with an exercise price below the quoted closing price of the common stock of the Company, resulting in an aggregate intrinsic value of approximately \$3.2 million. Of those, options for 1,419,919 shares had vested and had an exercise price below the quoted closing price of the common stock of the Company, resulting in an aggregate intrinsic value of approximately \$1.5 million.

During the three months ended March 31, 2010 and 2009, no options were exercised. During the three months ended March 31, 2010, unvested options for 9,750 shares were forfeited by a former employee that resigned during that period.

#### NOTE 5 LOSS PER SHARE

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

#### CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY

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diluted net loss per common share are identical. Potentially dilutive securities from stock options and stock warrants would be antidilutive as the Company incurred a net loss. The number of shares of common stock potentially issuable at March 31, 2010 and 2009 upon exercise or conversion that were not included in the computation of net loss per share totaled 11,002,438 and 7,815,489 shares, respectively.

#### NOTE 6 EXERCISE OF COMMON STOCK WARRANTS

No warrants were exercised during the three months ended March 31, 2010 and 2009.

#### NOTE 7 REGISTERED DIRECT SALE OF COMMON STOCK

On March 5, 2010, the Company raised gross proceeds of approximately \$18.2 million through the sale of 6,700,000 shares of its common stock plus warrants for the purchase of 2,345,000 shares of its common stock. The warrants permit the holders to purchase the underlying common shares at \$2.79 each and are exercisable in whole at any time, or in part from time to time, during the period commencing six months after the date of issuance and ending three years from the date of issuance. These shares were offered pursuant to the Company s shelf registration statement as filed with the SEC under which it may offer shares of its common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings, up to a total dollar amount of \$60 million. Such registration statement became effective as of August 20, 2009. In connection with this offering, the Company paid commissions and other offering-related costs of approximately \$1.5 million.

#### NOTE 8 LICENSING AGREEMENTS

In March 2004, the Company entered into a license agreement with Dr. M. Gopal Nair, Ph.D., of the University of South Alabama College of Medicine, for the rights to use, produce, distribute and market products derived from an invention by Dr. Nair, claimed in US Patent # 5,912,251, entitled metabolically inert anti-inflammatory and antitumor antifolates , designated by Chelsea as CH-1504 and related compounds. The license provides the Company exclusive, worldwide (excluding India) rights for CH-1504. The Company made an upfront payment in May 2004 of \$150,000 and milestone payments as required by the agreement of \$100,000 each in March 2006 and 2005. In April 2007, the Company issued 26,643 shares of its common stock, subject to trading restrictions, at a value of approximately \$5.63 per share, in settlement of the \$150,000 annual milestone payment liability. In March 2008, the Company made a milestone payment of \$100,000 related to patient dosing in a Phase 2 study as required by the agreement. In April 2008, the Company issued 30,612 shares of its common stock, subject to trading restrictions, at a value of approximately \$4.90 per share, in settlement of the 2008 anniversary milestone payment. In April 2009, the Company made the 2009 anniversary milestone payment of \$150,000. The Company is required to make additional payments upon the achievement of specific development and regulatory approval milestones. The Company is also obligated to pay royalties under the agreement until the later of the expiration of the applicable patent or the applicable last date of market exclusivity after the first commercial sale, on a country-by-country basis. Future potential milestone payments total approximately \$1.3 million and there are no minimum royalties required under the agreement.

In May 2006, the Company entered into an agreement with Dainippon Sumitomo Pharma Co., Ltd. ( DSP ) for a worldwide, exclusive, sub-licensable license and rights to certain intellectual property and proprietary information (the DSP Agreement ) relating to L-threo-3,4-dihydroxyphenylserine ( L-DOPS or droxidopa ) including, but not limited to all information, formulations, materials, data, drawings, sketches, designs, testing and test results, records and regulatory documentation. As consideration for these rights, the Company paid DSP \$100,000 and issued 63,131 shares of its common stock, with a value of approximately \$4.35 per share, or \$274,621. As additional consideration, the Company agreed to pay DSP and/or its designees (1) royalties on the sales should any compound be approved for commercial sale, and (2) milestone payments, payable upon achievement of milestones as defined in the DSP Agreement. In February 2008, the Company made a milestone payment under the

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agreement of \$500,000 related to patient dosing in a Phase 3 study and has remaining potential future milestone payments, subject to the Company s right to terminate the license agreement, totaling \$3.25

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million. The Company and DSP also initiated, and the Company agreed to fund, activities focused on modifying the manufacturing capabilities of DSP in order to expand capacity and comply with regulations and requirements of the FDA. Based on work performed by DSP as of March 31, 2010, the Company had recorded expense of approximately \$3.3 million and had a remaining liability of \$0.5 million at March 31, 2010.

In conjunction with and as consideration for activities related to the execution of the DSP Agreement, the Company entered into a Finder's Agreement with Paramount BioCapital, Inc. (Paramount). In May 2006, pursuant to the Finder's Agreement, the Company issued warrants for the purchase of 250,000 shares of its common stock at an exercise price of \$4.31 per share. The exercise of these warrants is conditioned on an event that occurred in January 2007 and, accordingly, the Company recorded a charge for the fair value of the warrants at January 2007 of \$433,750. The Company utilized the Black-Scholes-Merton valuation model for estimating the fair value of the warrants at the date the condition lapsed, based on a risk-free interest rate of 4.79%, an expected life of three years, an expected dividend yield of 0%, an expected volatility of 66.01% and no estimated forfeitures. As additional consideration, the Company agreed to (1) make future milestone payments to Paramount, upon achievement of milestones as defined in the Finder's Agreement, (2) pay royalties on sales should any licensed compound become available for commercial sale, and (3) compensate a stated third-party consultant for services rendered in the evaluation of the transaction with DSP. The Company has remaining potential future milestone payments under the Finder's Agreement of \$150,000.

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

The statements contained in this Quarterly Report on Form 10-Q that are not historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the expectations, beliefs, intentions or strategies regarding the future. We intend that all forward-looking statements be subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. In particular, this Management s Discussion and Analysis of Financial Condition and Results of Operations includes forward-looking statements that reflect our current views with respect to future events and financial performance. We use words such as we expect, anticipate, believe, and intend and similar expressions to identify forward-looking statements. A number of important factors could, individually or in the aggregate, cause actual results to differ materially from those expressed or implied in any forward-looking statement, including those set forth under Item 1A. Part 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2009.

#### Overview

We are a development stage pharmaceutical company that seeks to acquire, develop and commercialize innovative products for the treatment of a variety of human diseases. Our strategy is to develop technologies that address important unmet medical needs or offer improved, cost-effective alternatives to current methods of treatment. Specifically, we are developing a novel therapeutic agent for the treatment of symptomatic neurogenic orthostatic hypotension, or NOH, and related conditions and diseases along with our development of prescription products for multiple autoimmune disorders including rheumatoid arthritis, psoriasis, inflammatory bowel disease and cancer.

We are currently focusing the majority of our drug development resources on two clinical stage development projects: droxidopa for NOH and related conditions and our portfolio of non-metabolized antifolate compounds for the treatment of rheumatoid arthritis.

Droxidopa, our most advanced investigational product candidate, is an orally active synthetic precursor of norepinephrine. To be marketed under the brand name Northera , droxidopa is being developed for the treatment of symptomatic NOH and is currently approved and marketed in Japan for the treatment of symptomatic orthostatic hypotension, freezing of gait in Parkinson s disease and intradialytic hypotension, or IDH. During 2007, the U.S. Food and Drug Administration, or FDA, granted orphan drug status to Northera for the treatment of NOH and the European Medicines Agency, or EMEA, granted orphan medicinal product designation for the treatment of patients with Pure Autonomic Failure and patients with Multiple Systems Atrophy. Northera is currently in Phase III clinical trials designed to support its registration in the United States for the treatment of symptomatic NOH.

In September 2009, we announced preliminary data from Study 302, the first of our pivotal double-blind Phase III trials, designed to compare Northera to placebo for the treatment of symptomatic NOH. While statistically significant benefits were shown across six clinically relevant assessment criteria along with positive trends favoring Northera on 16 of the 17 study endpoints, the trial did not meet the primary endpoint of demonstrating a statistically significant improvement relative to placebo on Item 1 (dizziness or light-headedness) of the Orthostatic Hypotension Symptom Assessment, or OHSA, scale during the double-blind phase of the trial.

During the fourth quarter of 2009, we met with the FDA to obtain greater clarity about our options for completing the planned clinical and registration program for Northera after the failure of Study 302. The FDA agreed for us to change the primary endpoint and increase the enrollment of Study 301, our other ongoing pivotal Phase III trial, being conducted under a Special Protocol Assessment, or SPA. The primary endpoint of the trial is now the relative improvement in the Orthostatic Hypotension Questionnaire, or OHQ, composite score between Northera and placebo. The FDA agreed that the revised primary endpoint reflects a more comprehensive global assessment of the clinical benefit of Northera for the treatment of symptomatic NOH in primary autonomic failure, a heterogeneous population consisting of patients suffering from Parkinson s disease, multiple systems atrophy, pure autonomic failure, dopamine-b-hydroxylase deficiency and non-diabetic autonomic neuropathy and would therefore be suitable for supporting a symptomatic claim. Although we had already enrolled 126 patients, exceeding our initial target enrollment of 118 patients, in Study 301 by September 2009, the results were not unblinded. To further de-risk the study and maximize the potential significance of the outcome, we decided to increase the power of the study to greater than 80% by reopening enrollment at select North American centers to randomize an additional 24 patients. Work on recruiting these additional patients was initiated in the first quarter of 2010.

The FDA subsequently confirmed that the SPA originally awarded to Study 301 in 2008 remained in effect following the protocol amendments approved by the FDA in December 2009.

The FDA also recommended that we submit a confirmatory pivotal study to support a new drug application, or NDA, filing and that such study could be contained to a small, highly enriched, homogeneous patient population. Based on this recommendation, we plan to initiate a new clinical trial, Study 306, in the second quarter of 2010. Study 306 is a randomized, double-blind, placebo-controlled, induction-design Phase III trial evaluating up to 84 patients with symptomatic NOH associated with Parkinson s disease. The trial will be approximately 12 weeks in duration and include an initial, blinded dose titration period lasting up to two weeks, after which all patients will continue into an 8-week double-blind treatment period. The primary endpoint of the trial will be the relative improvement versus placebo in the OHQ composite score.

In March 2010, we announced the results from our twenty-four hour blood pressure monitoring study, Study 305. Data from this study indicate that Northera treatment resulted in a consistent and expected increase in systolic blood pressure, or SBP, with patients experiencing a mean increase in average SBP of 7.3 mmHg over 24 hours while on drug. Consecutive nocturnal SBP measurements greater than 180 mmHg lasting 3.5 hours or less were observed in only 2 patients on drug treatment and 1 patient while off drug treatment. No serious adverse events were reported during the conduct of this study.

In addition, at March 31, 2010, our Phase II trial of droxidopa, alone and in combination with carbidopa, for the treatment of fibromyalgia continues. This trial began in early 2009 under approval from the United Kingdom s Medicines and Healthcare Products Regulatory Agency. We also announced that an investigator-led Phase II study of droxidopa in combination with carbidopa for the treatment of adult attention deficit hyperactivity disorder, or ADHD, was initiated during the quarter ended March 31, 2010.

In addition to droxidopa, we are currently developing a portfolio of molecules for the treatment of various autoimmune/inflammatory diseases. The most advanced platform is a portfolio of metabolically inert antifolate molecules engineered to have potent anti-inflammatory and anti-tumor activity to treat a range of immunological disorders, including two clinical stage product candidates designated as CH-1504 and CH-4051. In March 2009, we announced positive results from the completed Phase II head-to-head clinical trial of CH-1504 for the treatment of rheumatoid arthritis, designed to compare the efficacy and tolerability of CH-1504 against methotrexate, currently the leading antifolate treatment and standard of care for a broad range of abnormal cell proliferation diseases. The preliminary analysis showed comparable American College of Rheumatology efficacy criteria, or ACR20/50/70 response rates to patients treated with 0.25mg, 0.50mg and 1.0mg of CH-1504 against patients treated with a standard 20mg oral dose of methotrexate. In addition, the efficacy of CH-1504 was associated with improved tolerability and reduced hepatotoxicity compared with methotrexate. In April 2009, we announced positive findings from our Phase I study of CH-4051, the L-isomer of CH-1504. Data from this single and multiple ascending dose study demonstrated that CH-4051 is safe and well tolerated up to a maximally tolerated dose of 7.5mg.

During the quarter ended March 31, 2010, we finalized the design of our Phase II study to compare CH-4051 to methotrexate in patients who have previously failed to show an adequate therapeutic response to methotrexate in the treatment of rheumatoid arthritis. This Phase II study is a double-blind, multiple-arm randomized study with a primary efficacy endpoint of the ACR hybrid score that combines a continuous scale of percentage improvement with the well known ACR20/50/70. The trial is expected to be initiated in the second quarter of 2010.

Complementing our autoimmune/inflammatory program is a second platform consisting of a portfolio of therapeutics targeting immune-mediated inflammatory disorders and transplantation, known as our I-3D portfolio. We currently have no work underway related to this portfolio.

Since inception we have focused primarily on organizing and staffing our company, negotiating in-licensing agreements with our partners, acquiring, developing and securing our proprietary technology, participating in regulatory discussions with the FDA, the EMEA and other regulatory agencies and undertaking preclinical trials and clinical trials of our product candidates. We are a development stage company and have generated no revenue since inception. We do not anticipate generating any product revenue until and unless we successfully obtain approval from the FDA or equivalent foreign regulatory bodies to begin selling our pharmaceutical candidates although we could potentially generate revenue by entering into strategic agreements including out-licensing, co-development or co-promotion of our drug candidates. Developing pharmaceutical products is a lengthy and expensive process. Even if we do not encounter unforeseen safety issues or timing

or other delays during the course of developing our currently licensed product candidates, we would not anticipate receiving regulatory approval to market any such products until, at the earliest, 2012. Assuming FDA approval of Northera for marketing in the United States, we currently anticipate launching the product and having initial sales or royalty revenue from it in the first quarter of 2012. Currently, development expenses are being funded with proceeds from equity financings completed in December 2004, February 2006, March 2007, November 2007, July 2009 and March 2010. To the extent we move our products into additional clinical trials and expand our commercialization and marketing efforts for droxidopa, our need to finance operating costs will continue. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development and/or commercialization of the products (see Liquidity and Capital Resources ).

#### **Critical Accounting Policies**

Our management s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. Our significant accounting policies are more fully described in Note 1 to the financial statements. The following accounting policies are critical in fully understanding and evaluating our reported financial results.

*Use of Estimates.* The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the financial statements as well as the reported revenue and expenses during the reporting periods. On an ongoing basis, management evaluates its estimates and judgments. Management bases estimates on historical experience and on various other factors that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results might differ from these estimates under different assumptions or conditions.

Research and Development Expense. Research and development costs are expensed as incurred. We often contract with third parties to facilitate, coordinate and perform agreed upon research and development activities. To ensure that research and development costs are expensed as incurred, we measure expense based on work performed for the underlying contract, typically utilizing a percentage-of-completion approach, and record prepaid assets or accrue expenses on a monthly basis for such activities based on the measurement of liability from expense recognition and the receipt of invoices.

These contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain milestones. In the event that we prepay fees for future milestones, we record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed. Most fees are incurred throughout the contract period and are expensed based on their percentage of completion at a particular date.

These contracts generally include pass-through fees. Pass-through fees include, but are not limited to, regulatory expenses, investigator fees, travel costs, and other miscellaneous costs including shipping and printing fees. Because these fees are incurred at various times during the contract term and they are used throughout the contract term, we record a monthly expense allocation to recognize the fees during the contract period. Fees incurred to set up the clinical trial are expensed during the setup period.

Costs related to the acquisition of technology rights and patents for which development work is still in process are expensed as incurred and considered a component of research and development costs.

Accounting for Stock-Based Compensation. We account for our stock options and warrants utilizing a fair value based method of accounting. In determining the fair value of the equity instrument, we consider, among other factors, (i) the risk-free interest rate, (ii) the expected life of the options granted, (iii) the anticipated dividend yield, (iv) the estimated future volatility of the underlying shares and (v) anticipated future forfeitures. To determine the risk-free interest rate, we utilize the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected life of our awards. We estimate the expected life of the options granted based on anticipated exercises in future periods assuming the success of our business model as currently forecasted. The expected dividends reflect our current and expected future policy for dividends on our common stock. To determine the expected stock price volatility for our stock options, we examine historical volatilities for industry peers closely related to the current status of our business, but with sufficient trading history to be able to determine volatility. Utilizing a weighted

average calculation to account for the limited price history of our stock, we analyze the historical volatility of our stock price in combination with the historical volatility of the industry peers selected to determine an appropriate volatility factor. We plan to continue to analyze the expected stock price volatility and expected term assumption at each grant date as more historical data for our common stock becomes available. Given the limited service period for our current employees and the senior nature of the roles for those employees, we had estimated that we would experience no forfeitures or that our rate of forfeiture would be immaterial to the recognition of compensation expense for those options currently outstanding. Our results of operations include non-cash compensation expense as a result of the issuance of stock option grants utilizing this method. We expect to record additional non-cash compensation expense in the future, which might be significant. Due to the limited amount of historical data available to us, particularly with respect to stock-price volatility, employee exercise patterns and forfeitures, actual results could differ from our assumptions.

#### **Results of Operations**

#### Three Months Ended March 31, 2010 and 2009

The table below sets forth, for the periods indicated, certain items in our condensed consolidated statements of operations and other pertinent financial and operating data.

#### (in thousands, except percentages)

	mon Ma	the three ths ended arch 31, 2010	mon Ma	the three ths ended arch 31, 2009	\$ Increase	% Change
Research and development expense	\$	4,880	\$	6,507	\$ (1,627)	-25%
Sales and marketing expense		411		305	106	35%
General and administrative expense		976		1,042	(66)	-6%
Interest income		68		116	(48)	-41%
Interest expense		(33)		(27)	(6)	22%
Other income (expense)				337	(337)	-100%

Research and development expenses decreased in the first quarter of 2010 when compared to the same period of 2009. In December 2009 and February 2010, we announced several updates related to our Phase III clinical and registration program for Northera in symptomatic NOH. Based on the results of our meeting with the FDA in the fourth quarter of 2009, much of our efforts during the first quarter of 2010 were focused on implementing the approved changes to Study 301 and finalizing the plans for Study 306, our newest pivotal study. We did incur expenses associated with these and other NOH programs during the quarter, along with costs related to our ongoing Phase II trial of droxidopa in fibromyalgia, initial costs related to the Phase II trial of our antifolates in rheumatoid arthritis and the costs of manufacturing, packaging and labeling appropriate clinical trial material for these trials. The primary expenditures in 2009 included our then ongoing Phase I trial of CH-4051 in rheumatoid arthritis, significant costs associated with our Phase III trials in symptomatic NOH for Northera and the costs of our Phase II program in IDH for droxidopa. Also contributing to our expenses were compensation and related costs, in both periods. As a percentage of operating expenses, research and development costs were 78% for the three months ended March 31, 2010 and 83% for the three months ended March 31, 2009.

From inception through March 31, 2010, cumulative research and development expenses related to our major research and development projects were approximately \$82.5 million and are detailed as follows:

#### (in thousands)

	For the thre	For the three months ended				
	March	March	Through Marc			
	31,	31,		31,		
	2010	2009	2010			
Antifolates	\$ 1,300	\$ 1,300	\$	27,300		
Droxidopa	3,600	5,200		52,700		
I-3D				2,500		
	\$ 4,900	\$ 6,500	\$	82,500		

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*Droxidopa*. From inception through March 31, 2010, we had spent approximately \$52.7 million in research and development expenses on droxidopa. Assuming we do not enter into an out-license, development or other collaborative agreement with respect to this compound, we estimate that subsequent to that date we will need to incur

approximately \$24 million more, primarily to complete our Phase III clinical trials and submit a new drug application, or NDA, under the brand name Northera, to the FDA. This estimate includes costs related to regulatory activities for Northera but excludes license payments totaling \$2.3 million to be made at the time of NDA filing and approval. Assuming FDA approval of Northera for marketing in the United States, we currently anticipate launching the product and having initial sales or royalty revenue from it in the first quarter of 2012. In addition to the spending requirements above, we plan to spend up to approximately \$2.1 million through the end of 2010 for clinical proof of concept studies of droxidopa in other indications unrelated to the NOH registration and commercialization program.

Antifolates. From inception through March 31, 2010, we had spent approximately \$27.3 million in research and development expenses on our portfolio of antifolates. We currently do not expect to conduct additional trials or make further investments in the development of CH-1504 and plan to focus our clinical resources on further development of CH-4051, the second clinical stage compound in this portfolio and the more potent L-enantiomer of CH-1504. We currently intend to seek a partner to assist us in the development of our antifolates after the completion of Phase II proof-of-concept studies for CH-4051 in rheumatoid arthritis, expected in 2011. We estimate that we will spend approximately \$12 million more in 2010 and 2011 to complete this study. Assuming an approval for marketing, we currently estimate launch of this product and initial royalty revenue from it no sooner than 2014.

*I-3D Portfolio*. From inception through March 31, 2010, we had spent approximately \$2.5 million in research and development expenses on the I-3D portfolio of compounds. We have conducted compound discovery work on the portfolio to try and identify one or more lead compounds. All of the work completed to date was performed before 2008 and we do not expect to incur significant additional expenses for these compounds until we select a partner or obtain additional financing.

Sales and marketing expenses. Although we have no formalized selling activities, sales and marketing expenses increased significantly in the first quarter of 2010 when compared to the same period of 2009 primarily related to compensation and related costs and legal and patent filing expenses related to our intellectual property.

General and administrative expenses. General and administrative expenses decreased slightly due to minor decreases in audit and tax fees, corporate legal costs and travel, offset by a similarly minor increase in compensation and related expenses.

Interest income. At March 31, 2010, we had cash and cash equivalents of \$31.6 million and short-term investments of \$11.4 million. Although the funding received from our March 2010 financing allowed us to maintain a higher average cash level during the first quarter of 2010 when compared to 2009, interest income reflects the redemption of ARS during the second quarter of 2009 and the loss of the premium rates for those investments. Combining the loss of premium rates on short-term investments in 2009 with the soft interest rate market in 2010 and the mix of our holdings in non-interest bearing accounts, money markets, Treasury funds and similar investments, interest earned decreased by \$48,000.

Other income. During the quarter ended March 31, 2009, we recorded a gain of \$0.1 million on the recovery of previously recorded impairment losses on ARS of \$0.3 million that were redeemed at par. In addition, based on a fair value analysis, we recorded a gain on our ARS Rights with UBS of \$0.2 million, reflecting the full funding of those ARS holdings at par value through the amended line of credit agreement. For the same period of 2010, we recorded no adjustment to our previously recorded fair value of ARS.

#### **Liquidity and Capital Resources**

From inception to March 31, 2010, we have incurred an aggregate net loss of approximately \$101.8 million as a result of expenses similar in nature to those described above.

As of March 31, 2010, we had working capital of approximately \$23.7 million including cash and cash equivalents of approximately \$31.6 million, short-term investments of \$11.4 million and liabilities of \$19.9 million. We have financed our operations primarily through sales of our common stock and, to a much lesser extent, through the issuance of our common stock pursuant to option or warrant exercises. Cash on hand results primarily from previous financing activities and proceeds from our line of credit with UBS, offset by funds utilized for operating and investing activities.

On March 5, 2010, we raised gross proceeds of approximately \$18.2 million through the sale of 6,700,000 shares of common stock plus warrants for the purchase of 2,345,000 shares of common stock in a registered direct offering pursuant to

our shelf registration statement as filed with the Securities and Exchange Commission that became effective on August 20, 2009. In connection with this offering, we paid commissions and other offering-related costs of approximately \$1.5 million.

**Auction Rate Securities** 

At March 31, 2010, our short-term investments of \$11.4 million consisted of the fair value of principal invested in certain ARS and the fair value of the ARS Rights. The ARS held by us are private placement securities with long-term nominal maturities for which the interest rates are reset through a dutch auction on 28 or 35 day cycles. Although the monthly auctions had historically provided a liquid market for these securities, in early 2008, with the liquidity issues in the global credit and capital markets, auctions for these, and similar, securities began to fail and by March 2008, market activity had essentially ceased. Our investments in these securities represent interests in collateralized debt obligations supported by pools of structured credit instruments consisting of student loans. None of the collateral for the ARS held by us includes mortgage, credit card or insurance securitizations. As of March 31, 2010, our ARS holdings had a par value of \$11.4 million and all but approximately \$4.4 million were AAA/Aaa rated and insured by the Federal Family Education Loan Program (FFELP) and/or over-collateralized by more than 10%. Of the remaining \$4.4 million, all were collateralized at 100% and, consistent with our investment policy at the time of purchase, \$0.75 million carried an A rating, \$1.15 million carried an Aa3/AAA rating and the remainder carried AAA/Aaa ratings.

During the fourth quarter of 2008, we accepted the terms of the settlement agreement from UBS for ARS Rights (the ARS Rights ) for our illiquid ARS holdings purchased from and maintained at UBS as of February 13, 2008. The ARS Rights provide us with the ability to sell the ARS, along with the ARS Rights, to UBS at the par value of the ARS no earlier than June 30, 2010 and expire on July 2, 2012. UBS also agreed that an affiliate would provide us with a no net-cost line of credit for up to a portion of the market value (as determined by UBS) of our ARS holdings as of October 31, 2008. In March 2009, the line of credit was amended to provide us with a credit line of up to the full par value of our ARS holdings at UBS and, accordingly, we have fully drawn down the line of credit and have recorded a corresponding liability at March 31, 2010 of \$11.4 million. The loan and any alternative financing will not be payable by us prior to the time that we are able to exercise our UBS ARS Rights in accordance with our agreement with UBS. We expect to repay the line of credit with the proceeds from the exercise of those ARS Rights. Proceeds of any sales of our UBS ARS will first be applied to repayment of the line of credit with the balance, if any, deposited into our account. Per the terms of the ARS Rights that allow us to redeem our ARS holdings at UBS on June 30, 2010, at the earliest, we have classified the fair value of our ARS holdings at UBS and the fair value of the associated ARS Rights as short-term assets at March 31, 2010. Accordingly, we have also classified the liability recorded for the line of credit as a short term liability at March 31, 2010.

Based on our estimate of fair value, utilizing a discounted cash flow model that approximates the values determined by UBS under their independent methodology, no additional trading loss for the three months ended March 31, 2010 was deemed necessary. As of March 31, 2010, the fair value of our ARS holdings combined with the fair value of our ARS Rights total 100% of the par value of all ARS holdings at UBS.

We have incurred negative cash flows from operations since inception. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, our commercialization and marketing activities for droxidopa and our efforts to secure opportunities for strategic alliances. Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing or strategic alliances. Management believes that currently available capital resources will be sufficient to meet our operating needs into the first quarter of 2011. We continue to actively pursue additional sources of liquidity, including but not limited to, strategic relationships, out-licensing of our products, public or private sales of equity or debt and other sources. Such strategic relationships or out-licensing arrangements might require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves. Such additional funds might not become available on acceptable terms, or at all, and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs. From inception through March 31, 2010 we had losses of \$101.8 million. We had net losses of \$6.2 million and \$7.4 million for the three months ended March 31, 2010 and 2009, respectively, and we anticipate losses at least through 2011 unless we should successfully negotiate a strategic agreement earlier that might include out-licensing, co-development or co-promotion of our drug candidates. Actual losses will depend on a number of considerations including:

discussions with regulatory agencies concerning the design and results of our clinical trials;

the pace and success of development activities, including clinical programs for droxidopa, antifolates and other product candidates;

our ability to identify and recruit patients into our clinical trials at costs consistent with our current estimates;

seeking regulatory approval for our various product candidates;

the pace of commercialization and marketing efforts for droxidopa;

possible out-licensing of our product candidates;

the pace of development of new intellectual property for our existing product candidates;

in-licensing and development of additional product candidates;

implementing additional internal systems and infrastructure; and

hiring additional personnel.

Should we raise additional funds by selling shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be required to delay, reduce the scope of, or eliminate one or more of our development programs or curtail operations. As a result, our business, financial condition and results of operations would be materially harmed.

#### **Off-Balance Sheet Arrangements**

We do not have any unconsolidated entities, and accordingly, we have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

#### **Contractual Obligations**

As of March 31, 2010, we had contractual obligations and commitments of approximately \$22.6 million, primarily related to recently contracted research and development activities. To facilitate an understanding of our contractual obligations and commercial commitments, the following data is provided as of March 31, 2010:

	Payments due by period							
Category	Total	< 1 Year	1-3 Years	3-5 Years	More than 5 Years			
Operating lease obligations	\$ 913,099	\$ 248,927	\$ 519,808	\$ 144,365	\$			
Purchase obligations	21,685,705	18,870,283	2,815,422					
Total	\$ 22,598,805	\$ 19,119,210	\$ 3,335,230	\$ 144,365	\$			

In addition, we have entered into certain licensing and related agreements that, as of March 31, 2010, might require we make contingent milestone payments of up to approximately \$4.75 million over the life of the agreements upon the achievement of certain clinical or commercial milestones. Such future payments are subject to our right to terminate the agreements. In the event that the milestones are not achieved, we elect not to pursue further testing of the drug candidate or we terminate such agreements, we will have no further obligations under the agreements. The uncertainty relating to the timing and occurrence of the commitments described prevents us from including them in the table above.

#### Item 3. Quantitative and Qualitative Disclosures about Market Risk

We invest our cash in a variety of financial instruments in order to preserve principal and liquidity while maximizing returns and we do not invest in financial instruments or their derivatives for trading or speculative purposes. To minimize the exposure due to adverse shifts in interest rates, we maintain investments of shorter maturities. Our investment guidelines include security type, credit quality and maturity and are intended to limit market risk by restricting our investments to high quality debt instruments with relatively short maturities. At March 31, 2010, a portion of our cash was maintained in non-interest bearing accounts at federally insured financial institutions that, under the Temporary Liquidity Guarantee Program, are fully insured by the Federal Deposit Insurance Corporation. In addition, we maintained funds on deposit that were invested primarily in fully liquid interest-bearing money market accounts, certificates of deposit and Treasury funds with a maturity under 90 days. Our short-term investments consist of ARS with long-term nominal maturities for which the interest rates are reset through a dutch auction each month or, should those auctions fail, as determined by contractual obligation. All

deposits and investments to date have been made in U. S. dollars and, accordingly, we do not have any exposure to foreign currency rate fluctuations.

Our interest income is sensitive to changes in the general level of interest rates in the United States, particularly since our investments are and will be in short-term investments. To assess our interest rate risk, we performed a sensitivity analysis projecting potential future interest earnings on investments in which we estimated the impact of a 0.25% to 0.5%, or 25 to 50 basis points, increase or decrease in our average interest rate over a 12 month time horizon. This analysis resulted in an annual potential effect of between approximately \$54,000 and \$107,000 on the interest earned on investments.

At March 31, 2010, we had investments in ARS with par value of \$11.4 million and an estimated fair value of approximately \$9.2 million and ARS Rights with an estimated fair value of approximately \$2.2 million. Historically, ARS were priced at par, as per industry convention, based on observed or reported verifiable trades that provided a liquid market for these ARS investments. However, liquidity issues since February 2008 have virtually shut down most active market transactions for ARS. Our investments in ARS represent interests in collateralized debt obligations supported by pools of student loans, typically over-collateralized and/or insured by the FFELP. None of the ARS investments in our portfolio were backed by sub-prime mortgage loans or other collateral with exposure to certain current market conditions. However, liquidity issues experienced in early 2008 and afterward in global credit and capital markets have prevented us from liquidating our ARS investments as the amount of securities submitted for sale at ARS auctions has exceeded the market demand, though they continue to pay interest according to their stated terms. Although insufficient demand related to the ARS auctions is expected to continue, we have successfully completed settlements for all of our ARS holdings and have received funding equivalent to 100% of the par value of our investments in ARS.

#### Item 4. Controls and Procedures

Disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) are designed only to provide reasonable assurance that they will meet their objectives that information required to be disclosed in our Exchange Act reports 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 our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e)) pursuant to Exchange Act Rule 13a-15. Based upon that evaluation and subject to the foregoing, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of March 31, 2010.

#### Changes in internal control over financial reporting.

Management has determined that, as of March 31, 2010, no changes in our internal control over financial reporting occurred during our fiscal quarter then ended that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

# PART II OTHER INFORMATION

# Item 6. Exhibits

Exhibit		Registrant s			
Number 31.1	Description of Document Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Form	Dated	Exhibit Number	Filed Herewith
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X

#### **SIGNATURES**

In accordance with the requirements of the Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

# Chelsea Therapeutics International, Ltd.

Date: May 4, 2010 By: /s/ J. Nick Riehle J. Nick Riehle

J. Nick Riehle
Vice President, Administration and

Chief Financial Officer

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