

# CHELSEA THERAPEUTICS INTERNATIONAL, LTD.

## FORM 10-Q (Quarterly Report)

Filed 11/02/09 for the Period Ending 09/30/09

Address	3530 TORINGDON WAY SUITE 200 CHARLOTTE, NC 28277
Telephone	704-341-1516
CIK	0001333763
Symbol	CHTP
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Fiscal Year	12/31

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

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2009

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

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**CHELSEA THERAPEUTICS INTERNATIONAL, LTD.**

(Exact name of Registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**20-3174202**  
(I.R.S. Employer  
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)

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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  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   
Non-accelerated Filer  (Do not check if smaller reporting company) Smaller Reporting Company

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of October 30, 2009 there were 33,500,406 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**

	September 30, 2009 (unaudited)	December 31, 2008 (Note 1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 30,050,390	\$ 21,532,553
Short-term investments	11,475,000	10,305,745
Prepaid contract research and manufacturing	310,222	625,377
Other prepaid expenses and other current assets	225,344	101,861
Total current assets	42,060,956	32,565,536
Property and equipment, net	115,575	159,189
Long-term investments	—	11,328,768
Other assets	76,950	76,950
	<u>\$ 42,253,481</u>	<u>\$ 44,130,443</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,377,895	\$ 4,304,283
Accrued compensation and related expenses	605,222	579,875
Accrued contract research and manufacturing	7,671,215	7,029,838
Other accrued expenses	709,170	391,082
Line of credit payable	11,475,000	—
Total current liabilities	23,838,502	12,305,078
Line of credit payable	—	7,277,468
Total liabilities	<u>23,838,502</u>	<u>19,582,546</u>
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 and 45,000,000 shares authorized, respectively and 33,500,406 and 30,111,479 shares issued and outstanding, respectively	3,350	3,011
Additional paid-in capital	107,988,473	94,316,239
Deficit accumulated during the development stage	(89,576,844)	(69,771,353)
Total stockholders' equity	<u>18,414,979</u>	<u>24,547,897</u>
	<u>\$ 42,253,481</u>	<u>\$ 44,130,443</u>

See accompanying notes to condensed consolidated financial statements.

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**CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY**  
**(A Development Stage Company)**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**

	For the three months ended September 30,		For the nine months ended September 30,		Period from April 3, 2002 (inception) to September 30, 2009
	2009	2008	2009	2008	
Operating expenses:					
Research and development	\$ 5,357,373	\$ 7,041,343	\$ 19,960,065	\$ 19,915,204	\$ 73,594,107
Sales and marketing	714,064	294,686	1,352,486	1,176,898	5,543,408
General and administrative	1,014,299	940,652	3,039,234	2,797,908	14,756,154
Total operating expenses	<u>7,085,736</u>	<u>8,276,681</u>	<u>24,351,785</u>	<u>23,890,010</u>	<u>93,893,669</u>
Operating loss	(7,085,736)	(8,276,681)	(24,351,785)	(23,890,010)	(93,893,669)
Interest income	32,427	306,214	263,925	1,493,260	4,463,883
Interest expense	(40,544)	—	(108,118)	—	(147,058)
Other income (expense)	—	(2,109,927)	4,390,487	(3,676,173)	—
Net loss	<u>\$ (7,093,853)</u>	<u>\$ (10,080,394)</u>	<u>\$ (19,805,491)</u>	<u>\$ (26,072,923)</u>	<u>\$ (89,576,844)</u>
Net loss per basic and diluted share of common stock	<u>\$ (0.22)</u>	<u>\$ (0.34)</u>	<u>\$ (0.64)</u>	<u>\$ (0.87)</u>	
Weighted average number of basic and diluted common shares outstanding	<u>32,428,692</u>	<u>30,048,839</u>	<u>30,892,371</u>	<u>29,998,676</u>	

See accompanying notes to condensed consolidated financial statements.

**CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY**  
**(A Development Stage Company)**  
**CONDENSED CONSOLIDATED STATEMENT OF**  
**STOCKHOLDERS' EQUITY**  
**(Unaudited)**

	<u>Common stock</u>		<u>Additional paid-in capital</u>	<u>Deficit accumulated during the Development stage</u>	<u>Total stock- holders' equity</u>
	<u>Shares</u>	<u>Amount</u>			
Balance at January 1, 2009	30,111,479	\$3,011	\$ 94,316,239	\$(69,771,353)	\$ 24,547,897
Common stock issued in 2009 at par, pursuant to net-share (cashless) exercises of common stock warrants	63,927	6	(6)	—	—
Sale and issuance of common stock in July 2009 at approximately \$3.74 per share, net of issuance costs	3,325,000	333	12,429,667	—	12,430,000
Stock-based compensation	—	—	1,242,573	—	1,242,573
Net loss	—	—	—	(19,805,491)	(19,805,491)
Balance at September 30, 2009	<u>33,500,406</u>	<u>\$3,350</u>	<u>\$107,988,473</u>	<u>\$(89,576,844)</u>	<u>\$ 18,414,979</u>

See accompanying notes to condensed consolidated financial statements.

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**CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY**  
**(A Development Stage Company)**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(Unaudited)**

	For the nine months ended September 30,		Period from April 3, 2002 (inception) to September 30, 2009
	2009	2008	
<b>Operating activities:</b>			
Net loss	\$(19,805,491)	\$(26,072,923)	\$ (89,576,844)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash stock-based compensation	1,242,573	1,028,533	3,924,568
Depreciation and amortization	52,338	38,272	212,811
Stock issued for license agreement	—	150,000	575,023
Non-cash interest expense	—	—	34,020
(Gain on recovery) other-than-temporary impairment of short-term and long-term investments	(4,390,487)	3,676,173	—
Gain on disposition of assets	—	(2,208)	(2,208)
Fair value of warrants for finder's agreement	—	—	433,750
Changes in operating assets and liabilities:			
Prepaid contract research and manufacturing expenses, other prepaid expenses and other assets	191,672	(42,049)	(535,566)
Accounts payable, accrued contract research and manufacturing expenses and other accrued expenses	33,077	4,371,721	11,758,281
Accrued compensation and related expenses	25,347	(43,026)	605,222
Net cash used in operating activities	<u>(22,650,971)</u>	<u>(16,895,507)</u>	<u>(72,570,943)</u>
<b>Investing activities:</b>			
Acquisitions of property and equipment	(8,724)	(171,513)	(329,856)
Proceeds from sale of assets	—	3,677	3,677
Purchases of investments	—	—	(49,538,336)
Redemptions and sales of investments	14,550,000	2,563,336	38,063,336
Security deposits	—	—	(76,950)
Net cash provided by (used in) investing activities	<u>14,541,276</u>	<u>2,395,500</u>	<u>(11,878,129)</u>
<b>Financing activities:</b>			
Proceeds from borrowings from affiliate	—	—	1,745,000
Net proceeds from borrowings from line of credit	4,197,532	—	11,475,000
Proceeds from exercise of stock options	—	58,944	80,729
Proceeds from exercise of common stock warrants	—	47,040	299,080
Recapitalization of the Company	—	—	(400,000)
Proceeds from sales of equity securities, net of issuance costs	12,430,000	5,733	101,295,028
Receipt of cash for stock subscription receivable	—	—	4,625
Net cash provided by financing activities	<u>16,627,532</u>	<u>111,717</u>	<u>114,499,462</u>
Net increase (decrease) in cash and cash equivalents	8,517,837	(14,388,290)	30,050,390
Cash and cash equivalents, beginning of period	21,532,553	34,076,217	—
Cash and cash equivalents, end of period	<u>\$ 30,050,390</u>	<u>\$ 19,687,927</u>	<u>\$ 30,050,390</u>
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for interest	<u>\$ 108,118</u>	<u>\$ —</u>	<u>\$ 113,038</u>

See accompanying notes to condensed consolidated financial statements.

**CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY**  
**(A Development Stage Company)**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS—(Continued)**  
**(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.

See accompanying notes to condensed consolidated financial statements.

**CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY  
(A Development Stage Company)  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
AS OF SEPTEMBER 30, 2009  
(Unaudited)**

**NOTE 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND NATURE OF OPERATIONS**

***The Company***

Chelsea Therapeutics International, Ltd. (“Chelsea Ltd.” or the “Company”) is a specialty pharmaceutical company focused on the acquisition, development and commercialization of innovative pharmaceutical products. The Company’s currently licensed compounds target a variety of prevalent medical conditions, particularly rheumatoid arthritis, psoriasis, cancer, other immunological disorders, neurogenic orthostatic hypotension and other 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 and nine months ended September 30, 2009 are not necessarily indicative of the results for the year ending December 31, 2009 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 4, 2009 and available on the website of the United States Securities and Exchange Commission ([www.sec.gov](http://www.sec.gov)). The accompanying condensed consolidated balance sheet as of December 31, 2008 has been derived from the audited 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 (“FDA”), the European Medicines Agency (“EMA”) 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 accompanying financial statements have been prepared assuming the Company will continue operations into next year, contemplating the realization of assets and the settlement of liabilities and commitments in the normal course of business. The condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities. The Company has sustained operating losses since its inception and expects that such losses could continue over the next several years. Although differing scenarios might arise based on our planned discussions with the FDA and the results of our second pivotal Phase III study of droxidopa in NOH, management believes that currently available capital resources, under any of the anticipated spending scenarios that might result from such discussions, will be sufficient to meet our operating needs into the

**CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY**  
**(A Development Stage Company)**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**AS OF SEPTEMBER 30, 2009**  
**(Unaudited)**

third quarter of 2010. The Company 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.

***Basis of Consolidation***

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 September 30, 2009 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 April 2009, the Financial Accounting Standards Board (FASB) issued guidance on how to report recognized and unrecognized subsequent events, providing guidelines on the timing of evaluations for disclosure of subsequent events and requiring additional disclosures around the Company's evaluation of subsequent events. Such guidance was effective for interim or annual financial periods ending after June 15, 2009 and became effective for the Company on June 30, 2009. Its adoption did not have a material impact on the Company's consolidated financial position or results of operations.

In June 2009, the FASB established a hierarchy of generally accepted accounting principles making the FASB Accounting Standards Codification the single source of authoritative United States accounting and reporting standards for all nongovernmental entities. It was effective for interim and annual financial periods ending after September 15, 2009 and

**CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY**  
**(A Development Stage Company)**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**AS OF SEPTEMBER 30, 2009**  
**(Unaudited)**

became effective for the Company on September 30, 2009. Its adoption did not have a material impact on the Company's consolidated financial position or results of operations.

**NOTE 2 AUCTION RATE SECURITIES**

At September 30, 2009, the Company held investments in student-loan backed ARS with an aggregate par value of \$11.475 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 September 30, 2009.

At March 31, 2009, the Company held investments in student-loan backed ARS, classified as available-for-sale securities and short-term investments, with an aggregate par value of approximately \$11.6 million. These ARS were redeemed at full par value during the quarter ended June 30, 2009.

The Company's ARS investments at September 30, 2009 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 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 and nine month periods ended September 30, 2009, 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 September 30, 2009.

On December 31, 2008, the Company held total investments in ARS with a par value of approximately \$26 million. Of these holdings, approximately \$14.5 million were classified as available-for-sale. During the nine months ended September 30, 2009, the Company had received proceeds of \$14.5 million fully redeeming these available-for-sale securities, including \$0.4 million from partial redemptions at par, \$11.6 million from full redemptions at par under a settlement agreement, \$2.1 million for the sale of its \$2.5 million par value position in Mississippi Higher Ed Assistance Corp. in a secondary market transaction and \$0.4 million as reimbursement of the loss on that secondary market transaction under a settlement agreement. The Company recorded a gain of approximately \$4.1 million from the recovery of the other-than-temporary impairment that the Company had recorded against these investments during 2008. During the three and nine months ended September 30, 2008, the Company recorded other-than-temporary impairment losses related to its available-for-sale investments of approximately \$1.7 million and \$2.5 million, respectively.

The par value of the Company's remaining ARS investments, classified as trading securities and held at UBS Financial Services, Inc. (UBS), as of September 30, 2009 was \$11.475 million and as of December 31, 2008 was \$11.575 million. During the fourth quarter of 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 recorded a liability at September 30, 2009 of \$11.475 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

**CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY**  
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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
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**(Unaudited)**

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 it is 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 September 30, 2009. 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 September 30, 2009. 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-term investments on the consolidated condensed balance sheet as of September 30, 2009. 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 September 30, 2009.

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 September 30, 2009, 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 \$9.3 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 September 30, 2009. In addition, the Company recorded a gain of approximately \$0.2 million during the nine months ended September 30, 2009 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. For the three and nine months ended September 30, 2008, the Company had recorded other-than-temporary impairment losses related to its trading securities, that were then classified as available-for-sale securities, of approximately \$0.4 million and \$1.2 million, respectively.

**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 September 30, 2009, 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

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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:

(in thousands)	Assets Measured at Fair Value on a Recurring Basis			Total
	Quoted prices in active markets for identical assets (Level 1)	other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
As of September 30, 2009				
Cash and Treasury funds	\$ 30,050	\$ —	\$ —	\$30,050
Auction rate securities <sup>(1)</sup>	—	—	9,272	9,272
ARS Rights (Note 2)	—	—	2,203	2,203
	\$ 30,050	\$ —	\$ 11,475	\$41,525

(1) 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 September 30, 2009 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 nine months ended September 30, 2009 (in thousands):

Balance as of December 31, 2008	\$ 21,634
Redemptions	(12,384)
Sales on secondary market	(2,075)
Increase in fair value of ARS Rights	247
Realized gains on redemption	4,053
Transfers in and/or out of Level 3	—
Balance as of September 30, 2009	\$ 11,475

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**

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.

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During the three months ended September 30, 2009, the Company granted stock options to an employee and a non-employee director for the purchase of 55,000 shares of its common stock with a weighted-average exercise price of \$4.94 per share, a weighted average grant date fair value of \$3.42 per share and with each grant having an exercise price greater than the market value at September 30, 2009, resulting in no intrinsic value as of that date. During the three months ended September 30, 2008, the Company granted stock options to employees for the purchase of 32,500 shares of its common stock with a weighted average exercise price of approximately \$4.81 per share and a weighted average grant date fair value of approximately \$2.77 per share with each grant having an exercise price greater than the market value at September 30, 2009, resulting in no intrinsic value as of that date.

During the nine months ended September 30, 2009 and 2008, the Company granted stock options to employees and non-employee directors for the purchase of 863,290 and 837,500 shares of its common stock, respectively. The grants made during the nine months ended September 30, 2009 had a weighted average exercise price of approximately \$1.92 per share, a weighted average grant date fair value of approximately \$1.27 per share and an aggregate intrinsic value at September 30, 2009 of approximately \$0.6 million. The grants made during the nine months ended September 30, 2008 had a weighted average exercise price of approximately \$6.11 per share and a weighted average grant date fair value of approximately \$3.41 per share with each grant having an exercise price greater than the market value at September 30, 2009, resulting in no intrinsic value as of that date.

Each option granted to employees and non-employee directors during the three and nine months ended September 30, 2009 and 2008 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 and nine months ended September 30, 2009 and 2008:

	<u>For the three months ended September 30,</u>		<u>For the nine months ended September 30,</u>	
	<u>2009</u>	<u>2008</u>	<u>2009</u>	<u>2008</u>
Risk-free interest rate	2.51% to 2.6%	2.52% to 3.41%	1.61% to 2.6%	2.52% to 3.73%
Expected life of options	5 years	5 years	5 years	5 years
Expected dividend yield	0%	0%	0%	0%
Expected volatility	87.51%	65.93%	80.96% to 87.51%	63.55% to 65.93%
Estimated forfeitures	0%	0%	0%	0%

The Company recorded compensation expense for the three and nine months ended September 30, 2009 of approximately \$0.4 million and approximately \$1.2 million, respectively and compensation expense for the three and nine months ended September 30, 2008 of approximately \$0.4 million and approximately \$1.0 million, respectively, in conjunction with option grants made to employees and non-employee directors. As of September 30, 2009, the Company had total unrecognized compensation expense related to options granted to employees and non-employee directors of approximately \$3.4 million, which it expects to recognize over a remaining average period of two years.

As of September 30, 2009, there were 3,737,930 options outstanding under the Plan with a weighted average remaining contractual life of 7.7 years and a weighted average exercise price of approximately \$3.81 per share. Of these, options for

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1,807,369 shares had vested and were exercisable at September 30, 2009 with a weighted average remaining contractual life of 6.5 years and a weighted average exercise price of approximately \$3.63 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 September 30, 2009 for those awards that have an exercise price below the quoted closing price. As of September 30, 2009, there were options outstanding to purchase an aggregate of 922,998 shares with an exercise price below the quoted closing price of the common stock of the Company, resulting in an aggregate intrinsic value of \$0.9 million. Of those, options for 114,708 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 \$0.3 million.

During the three and nine months ended September 30, 2009, no options were exercised. During the three and nine months ended September 30, 2008, options for 94,230 shares were exercised with a weighted average exercise price of approximately \$0.63 per share and an aggregate intrinsic value as of the dates of exercise of approximately \$354,000.

**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 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 September 30, 2009 and 2008 upon exercise or conversion that were not included in the computation of net loss per share totaled 7,798,688 and 7,094,516 shares, respectively.

**NOTE 6 EXERCISE OF COMMON STOCK WARRANTS**

During the three and nine months ended September 30, 2009, various warrant holders exercised rights to purchase 119,691 shares of the common stock of the Company, with an average exercise price of approximately \$3.27 per share, pursuant to cashless exercises whereby the Company, in net share settlements, issued 63,927 shares of its common stock to the warrant holders based on the excess of the market price over the exercise price on the respective dates of exercise.

During the nine months ended September 30, 2008, various warrant holders exercised rights to purchase 100,487 shares of the common stock of the Company, with an average exercise price of approximately \$2.91 per share, pursuant to cashless exercises whereby the Company, in net share settlements, issued 57,983 shares of its common stock to the warrant holders based on the excess of the market price over the exercise price on the respective dates of exercise.

In August 2008, a warrant holder exercised the right to purchase 10,000 shares of the common stock of the Company at an exercise price of \$4.20 per share pursuant to a cash exercise whereby the Company recorded proceeds of \$42,000.

In January 2008, a warrant holder exercised the right to purchase 1,200 shares of the common stock of the Company at an exercise price of \$4.20 per share pursuant to a cash exercise whereby the Company recorded proceeds of \$5,040.

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

On July 28, 2009, the Company raised gross proceeds of approximately \$13.3 million through the sale of 3,325,000 shares of its common stock. These shares were offered pursuant to the Company's shelf registration statement, as amended effective July 22, 2009 pursuant to Rule 462(b) to increase the dollar amount of securities available for sale, as filed with the Securities and Exchange Commission under which the Company could 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 \$62,218,060. There are no more securities available under this shelf

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registration. In connection with the July 2009 offering, the Company received net proceeds, after deducting placement fees and offering expenses, of approximately \$12.4 million.

On August 10, 2009, the Company filed a shelf registration statement with the Securities and Exchange Commission under which the Company 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 \$60,000,000. Such registration statement became effective as of August 20, 2009.

**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 that had been accrued at March 31, 2009. 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 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 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 September 30, 2009, the Company had recorded expense of approximately \$3.4 million and had a remaining liability of \$2.2 million at September 30, 2009.

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

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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.

**NOTE 9 SUBSEQUENT EVENTS**

For the period ended September 30, 2009, the Company evaluated events that occurred after September 30, 2009, the balance sheet date, through November 2, 2009, the date that financial statements were issued.

On October 29, 2009, the Company granted options for the purchase of 75,000 shares of its common stock to a newly-hired employee. The options were issued with an exercise price of \$2.82 per share (the closing market value of the Company's stock on the date of grant).

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### 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, 2008.*

#### 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 neurogenic orthostatic hypotension ("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 symptomatic neurogenic hypotension and other potential indications; 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. It is being developed for the treatment of 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 ("IDH"). During 2007, the U.S. Food and Drug Administration, or FDA, granted orphan drug status to droxidopa 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. Our clinical Phase III development program for the registration of droxidopa in the United States for the treatment of symptomatic NOH includes two double-blind, placebo-controlled studies. Both are designed to compare droxidopa to placebo for the treatment of NOH and to demonstrate a mean improvement over placebo of 1.6 units on the 11-point Orthostatic Hypotension Symptom Assessment (OHSA) scale.

In September 2009, we announced preliminary data from Study 302, the first of these two pivotal double-blind Phase III trials. While strong symptomatic benefit was demonstrated during the open-label dose titration and run-in phase of the trial, results of the trial did not demonstrate a statistically significant improvement relative to placebo, as measured by the mean score of Item 1 (dizziness or light-headedness) of the OHSA scale during the double-blind phase of the trial, the study's primary endpoint. While the study did not meet its primary endpoint, additional analysis confirmed statistically significant symptomatic benefit across five clinically relevant assessment criteria that reflect symptomatic improvements and corroborate other supportive symptom data. Data from the trial also supported the safety and tolerability of droxidopa. We intend to meet with the FDA in November 2009 to obtain greater clarity about our options for completing the planned clinical and registration program for droxidopa. We also reached our targeted enrollment of 118 patients in Study 301, the second double-blind pivotal Phase III trial, in September 2009. The results from this study are not expected to be unblinded until after we meet with the FDA to review our planned registration program. The timing of a new drug application to the FDA for droxidopa will depend upon the outcome of our discussions with the FDA and resulting changes, if any, in our clinical program that might potentially include recruitment of additional patients for study 301, supplementary studies and/or additional clinical trials. Please see Item 1A -Risk Factors of this Form 10-Q for a discussion of risks we face related to the recently announced results of our study 302 clinical trial for droxidopa.

In March 2009, we announced positive results from a preliminary analysis of the completed double-blind, placebo controlled Phase II trial of Droxidopa for the treatment of IDH. Droxidopa demonstrated benefit and indication of dose response in multiple measures of IDH, particularly in alleviating serious adverse events and complications, such as dialysis disruption. In addition, an ongoing Phase II trial of droxidopa, alone and in combination with carbidopa, for the treatment of fibromyalgia began in early 2009, under approval from the United Kingdom's Medicines and Healthcare Products Regulatory Agency .

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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 a preliminary analysis of the recently completed Phase II head-to-head clinical trial of CH-1504 for the treatment of rheumatoid arthritis. This trial was 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 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. 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.

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, 2011. Currently, development expenses are being funded with proceeds from equity financings completed in December 2004, February 2006, March 2007, November 2007 and July 2009. 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.

### 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

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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 as prescribed in ASC 718-10 that defines a fair value based method of accounting for stock options or similar equity instruments. 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 September 30, 2009 and 2008*

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.

	For the three months ended	For the three months ended		
	September 30,	September 30,	\$	%
(in thousands, except percentages)	2009	2008	Increase	Change
Research and development expense	\$ 5,357	\$ 7,041	\$(1,684)	-24%
Sales and marketing expense	714	295	419	142%
General and administrative expense	1,014	941	73	8%
Interest income	32	306	(274)	-90%
Interest expense	(41)	—	(41)	100%
Other income (expense)	—	(2,110)	2,110	100%

*Research and development expenses* decreased in the third quarter of 2009 when compared to the same period of 2008 as our pivotal Phase III NOH programs reached or neared completion during the period. The expenses associated with these programs, along with costs related to our ongoing Phase II trial of droxidopa in fibromyalgia and final costs related to our Phase I and Phase II trials of our antifolates accounted for the majority of the costs during the period. The primary expenditures in 2008 related to our then ongoing Phase II trial in rheumatoid arthritis for CH-1504 and significant costs associated with the start of our pivotal Phase III trials in NOH for droxidopa. Also contributing to our expenses were

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compensation and related costs, in both periods, and initial regulatory expenses in the third quarter of 2009 associated with our planned registration program for droxidopa. As a percentage of operating expenses, research and development costs were 76% for the three months ended September 30, 2009 and 85% for the three months ended September 30, 2008.

From inception through September 30, 2009, cumulative research and development expenses related to our major research and development projects were approximately \$73.6 million and are detailed as follows:

(in thousands)	Nine months ended September 30,		Inception through September 30,
	2009	2008	2009
Antifolates	\$ 1,900	\$ 7,000	\$ 25,700
Droxidopa	18,100	12,900	45,400
I-3D	—	—	2,500
	<u>\$20,000</u>	<u>\$19,900</u>	<u>\$ 73,600</u>

*Droxidopa.* From inception through September 30, 2009, we had spent approximately \$45.4 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 \$8.8 million more to complete our Phase III clinical trials and other development work through to approval of a New Drug Application, or NDA, from the FDA, excluding costs associated with regulatory applications, milestone payments and initial commercial inventory. Assuming regulatory approval for marketing, we currently estimate launch of this product and initial sales or royalty revenue from it no sooner than 2011. In addition to the spending requirements above, we plan spending approximately \$4.6 million from the fourth quarter of 2009 through the end of 2010 for clinical proof of concept studies in other indications, our once-daily formulation and other droxidopa related programs.

*Antifolates.* From inception through September 30, 2009, we had spent approximately \$25.7 million in research and development expenses on our portfolio of antifolates. We continue to explore opportunities to engage a partner to assist us in the development of our antifolates after the completion in March 2009 of a Phase II proof-of-concept study for CH-1504 in rheumatoid arthritis and our Phase 1 dosing evaluation in CH-4051, completed in April 2009. However, we may choose to conduct additional Phase II studies starting in 2010 if we believe it will significantly enhance the value of this portfolio and if funding is available. We estimate that we will spend less than \$0.2 million more for the development of our antifolate compounds in 2009. Assuming regulatory approval for marketing, we currently estimate launch of this product and initial royalty revenue from it no sooner than 2013.

*I-3D Portfolio.* From inception through September 30, 2009, 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 third quarter of 2009 when compared to the same period of 2008 primarily related to the initiation of market research and planned commercialization activities for droxidopa. Other expenses for both periods included compensation and related costs and legal expenses related to our intellectual property.

*General and administrative expenses.* General and administrative expenses increased due to minor increases in compensation and related expenses, office rent related to our headquarter facility and printing costs and travel expenses, offset by a minor reduction in franchise tax expense. Franchise tax expense decreased during 2009 due to our operating losses incurred in 2008 and the related decrease in our stockholders' equity.

*Interest income.* At September 30, 2009, we had cash and cash equivalents of \$30.1 million and short-term investments of \$11.475 million. Although the funding received from our July 2009 financing, proceeds from the sale and redemption of ARS and additional funding under the UBS line of credit allowed us to maintain a higher than expected average cash and investments level over the period, the average cash and investment level during 2009 was significantly lower than the level for the same period of 2008. When those lower average levels are combined with a general reduction in interest rates, a loss

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of interest income related to our ARS investments and a shift of our holdings, other than ARS, into non-interest bearing accounts, Treasury funds and similar investments, interest earned decreased by \$0.3 million.

*Other income and expense.* During the quarter ended September 30, 2009, we recorded no adjustment to our previously recorded impairment losses on ARS. For the same period of 2008, we recorded an other-than-temporary impairment charge related to our investment in ARS of approximately \$2.1 million.

### Nine Months Ended September 30, 2009 and 2008

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)	For the nine months ended	For the nine months ended	\$ Increase	% Change
	September 30, 2009	September 30, 2008		
Research and development expense	\$ 19,960	\$ 19,915	\$ 45	0%
Sales and marketing expense	1,352	1,177	175	15%
General and administrative expense	3,039	2,798	241	9%
Interest income	264	1,493	(1,229)	-82%
Interest expense	(108)	—	(108)	100%
Other income (expense)	4,390	(3,676)	8,066	-219%

*Research and development expenses.* We continue to incur significant expenses in 2009, primarily related to our extensive clinical testing programs, particularly, clinical activities for droxidopa, including our pivotal Phase III trials in NOH and Phase II trial in fibromyalgia. In addition, we incurred costs associated with our Phase II study of CH-1504 in rheumatoid arthritis, completed in March 2009, and our Phase I dosing study of CH-4051, completed in April 2009. Other activities contributing to expenses in 2009 include manufacture, formulation, labeling and packaging and regulatory costs. As a percentage of operating expenses, research and development costs were 82% for the nine months ended September 30, 2009, relatively flat when compared with 83% for the same period of 2008. Also contributing to our expenses were compensation and related costs, in both periods. A significant component of our costs in 2008 was related to the ongoing Phase II clinical trial for CH-1504 in rheumatoid arthritis and investigational activities for follow-on molecules in our portfolio of antifolates. We also incurred significant costs during 2008 for clinical activities for droxidopa including the start of our Phase III programs in NOH and our Phase II study in IDH. Other activities for droxidopa included manufacturing and formulation costs in support of the clinical programs and license milestone payments for dosing in a Phase III trial.

*Sales and marketing expenses.* Although we had no formalized selling activities, contributing to the increase in sales and marketing expenses in 2009 were the costs of initiating market research and commercialization activities for droxidopa during the third quarter. Other expenses included compensation and related costs, legal expenses and related costs for our intellectual property and travel costs for our business development efforts. During 2008, we incurred expenses of a similar nature but rather than preliminary marketing activities related to the planned commercialization of droxidopa, our efforts were focused on the printing of educational materials and a pricing study for droxidopa.

*General and administrative expenses.* The \$0.2 million increase in general and administrative expenses primarily consists of an increase in compensation and related expenses. The remainder of the increase is related to moderate increases in other categories of spending during the period including office rent related to our new headquarters and professional fees for accounting services offset by a decrease in franchise tax expense due to the impact of 2008 operating losses on the taxable equity base.

*Interest income.* At September 30, 2009, we had cash and cash equivalents of \$30.1 million and short-term investments of \$11.475 million. Although the funding received from our July 2009 financing, proceeds from the sale and redemption of ARS and additional funding under the UBS line of credit allowed us to maintain a higher than expected average cash and investments level over the period, the average cash and investment level during 2009 was significantly lower than the level for the same period of 2008. When those lower average levels are combined with the loss of interest income on ARS earned in 2008, the deterioration of overall market interest rates and a shift of our holdings, other than ARS, into non-interest bearing accounts, Treasury funds and similar investments, interest earned decreased by \$1.3 million.

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*Other expense.* During the nine months ended September 30, 2009, we recorded a gain of \$4.4 million on the recovery of previously recorded impairment losses for ARS that were redeemed at par and an increase in the fair value of our ARS Rights. During the nine months ended September 30, 2008, we had recorded the subsequently recovered other-than-temporary impairment loss related to our investments in ARS of approximately \$3.7 million.

### Liquidity and Capital Resources

From inception to September 30, 2009, we have incurred an aggregate net loss of approximately \$89.6 million as a result of expenses similar in nature to those described above.

As of September 30, 2009, we had working capital of approximately \$18.2 million, cash and cash equivalents of approximately \$30.1 million and short-term investments of \$11.475 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 July 28, 2009, we raised gross proceeds of approximately \$13.3 million through the sale of 3,325,000 shares of our common stock at \$4.00 per share in a registered direct offering pursuant to our shelf registration statement, as amended effective July 22, 2009 pursuant to Rule 462(b) to increase the dollar amount of securities available for sale, as filed with the Securities and Exchange Commission. There are no more securities available under this shelf registration. In connection with this offering, we received net proceeds, after deducting placement fees and offering expenses, of approximately \$12.4 million.

On August 10, 2009, we filed a shelf registration statement with the Securities and Exchange Commission under which we may offer shares of our 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 \$60,000,000. Such registration statement became effective as of August 20, 2009.

#### *Auction Rate Securities*

At September 30, 2009, our short-term investments of \$11.475 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 September 30, 2009, our ARS holdings had a par value of \$11.475 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.

Beginning in early February 2008 we have experienced difficulty in liquidating our ARS as the amount of securities submitted for auction has exceeded the market demand and auctions began to fail. When the auctions for these securities fail, the investments are not readily convertible into cash until a future auction is successful, secondary markets emerge, the securities are redeemed by the issuer or they mature.

Per the terms of a settlement agreement executed in May 2009, all of our ARS holdings that were then classified as available-for-sale and had been purchased from BA were redeemed at 100% of par value, or \$11.6 million, in June 2009. In addition, BA also refunded to us the \$0.4 million realized loss we incurred in January 2009 upon the sale of our \$2.5 million par value ARS holding in Mississippi Higher Ed Assistance Corp. As such, we recorded a gain of approximately \$4.1 million related to the recovery of the previously recorded other-than-temporary impairment for these ARS holdings.

During the fourth quarter of 2008, we finalized the details of our settlement agreement with UBS under the published terms accepting 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

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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 September 30, 2009 of \$11.475 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 we can exercise our 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 our pledged UBS ARS at par. As a result, 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 September 30, 2009. Accordingly, we have also classified the liability recorded for the line of credit as a short term liability at September 30, 2009.

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 nine months ended September 30, 2009 was deemed necessary. In addition, we recorded other income and a corresponding increase in the asset of \$0.2 million for the increase in the fair value of the ARS Rights recognized upon the full funding of par value under our line of credit. As of September 30, 2009, 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.

The valuation of our ARS investment portfolio is sensitive to market conditions and is based on our best estimate given the facts available at the balance sheet date. The assumptions we utilized in the estimate of fair value have been difficult to predict and the resulting fair value estimate has been subject to fluctuation. However, with our recent success in gaining full liquidity on our remaining ARS holdings at UBS, the future risk of such fluctuations is effectively offset by corresponding changes in the fair value of the ARS Rights.

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. Although differing scenarios might arise based on our planned discussions with the FDA and the results of our second pivotal Phase III study of droxidopa in NOH, management believes that currently available capital resources, under any of the anticipated spending scenarios that might result from those discussions, will be sufficient to meet our operating needs into the third quarter of 2010. 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 September 30, 2009 we had losses of \$89.6 million. We had net losses of \$19.8 million and \$26.1 million for the nine months ended September 30, 2009 and 2008, respectively, and we anticipate losses at least through 2010 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;
- specifically, discussions with the FDA concerning the potential for additional Phase III trials or additional Phase III patients for droxidopa in NOH based on the results of Study 302;
- 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;

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- 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 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.

### 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 September 30, 2009, 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 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 \$40,000 and \$75,000 on the interest earned on investments.

At September 30, 2009, we had investments in ARS with par value of \$11.475 million and an estimated fair value of approximately \$9.3 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 and 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

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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 September 30, 2009.

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

Management has determined that, as of September 30, 2009, 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 1A. Risk Factors**

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2008 except the following:

**We face risks related to the recently announced results of our study 302 clinical trial for droxidopa for the treatment of symptomatic neurogenic orthostatic hypotension (NOH).**

In September 2009, we announced that preliminary data from Study 302, the first of two pivotal Phase III trials of droxidopa for the treatment of NOH, did not demonstrate a statistically significant improvement relative to placebo as measured by the study's primary endpoint. While the study did not meet its primary endpoint, additional analysis confirmed statistically significant symptomatic benefit across five clinically relevant assessment criteria that reflect symptomatic improvements and corroborate other supportive symptom data. Data from the trial also supported the safety and tolerability of droxidopa. This clinical outcome may have significant impact on our operations. We intend to meet with the FDA in November 2009 to obtain greater clarity about our options for completing the planned clinical and registration program for droxidopa. There are, however, significant risks as we attempt to formulate a revised clinical plan for droxidopa. Specifically:

- Although we will seek approval to change the primary endpoint of our 301 study, the FDA may not agree to this approach and we may therefore fail to achieve significance on the existing 301 study endpoint, which is the same endpoint used in the 302 study.
- Even if we change the primary endpoint in our 301 study, significance in that end point may still not be achieved, thus requiring at least one additional study and possibly more.
- We may determine that it is in our best interest to reactivate the 301 study in order to recruit additional patients into the trial, thus delaying the results of the 301 study and the eventual filing, if at all, of an NDA with the FDA and other regulatory agencies.
- Although we will discuss the use of the 302 study and certain other studies as being supportive for an NDA filing based on the 301 study, the FDA may insist on full significance in two separate studies similar to the 301 and 302 studies that we have been conducting over the past two years.
- Any of these risks would delay, probably for several quarters but perhaps longer, or prevent us from filing for approval with the FDA and other regulatory agencies.
- Any of these risks are likely to require additional financing for the droxidopa clinical program, and if such financing is an equity financing it would cause dilution for our stockholders, which could be significant depending on the price and the amount of stock sold.
- If we require additional capital for the development of droxidopa, we may not be able to raise capital on favorable terms or at all.
- Given the regulatory and financing uncertainties, we may determine that it is in our best interest to out-license droxidopa, which might significantly limit future earnings opportunities for us. Moreover, we may not be able to complete an out-licensing agreement on terms beneficial to us or at all.

**Item 5. Other Information**

Effective October 29, 2009, we hired William D. Schwieterman, M.D. as our Chief Medical Officer. Dr. Schwieterman is a rheumatologist and a board-certified internist who was formerly Chief of the Medicine Branch and Chief of the Immunology and Infectious Disease Branch in the Division of Clinical Trials at the FDA. In these capacities and others, Dr. Schwieterman spent 10 years at the FDA in the Center for Biologics overseeing a wide range of clinical development plans for a large number of different types of molecules. Dr. Schwieterman helped author the FDA's "Good Review Practices" for investigational products, and was instrumental in developing several guidance documents for the industry. More recently, he has served as an independent consultant to biotechnology and pharmaceutical companies, focusing on clinical drug development and regulatory matters. Dr. Schwieterman holds a B.S. and M.D. from the University of Cincinnati.

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As a condition to his employment with us, Dr. Schwieterman resigned as a member of our Board of Directors effective October 28, 2009. His resignation was not related to any disagreement with us on any matter relating to our operations, policies or practices.

### Item 6. Exhibits

<u>Exhibit Number</u>	<u>Description of Document</u>	<u>Registrant's Form</u>	<u>Dated</u>	<u>Exhibit Number</u>	<u>Filed Herewith</u>
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
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



## CERTIFICATION

I, Simon Pedder, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Chelsea Therapeutics International, Ltd.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2009

By: \_\_\_\_\_ / s / SIMON PEDDER  
Simon Pedder  
President and Chief Executive Officer



**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT  
TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Chelsea Therapeutics International, Ltd. (the "Company") for the period ended September 30, 2009 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Simon Pedder, President and Chief Executive Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

/ s / S IMON P EDDER

**Simon Pedder**  
President and Chief Executive Officer

November 2, 2009

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT  
TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Chelsea Therapeutics International, Ltd. (the "Company") for the period ended September 30, 2009 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, J. Nick Riehle, Vice President, Administration and Chief Financial Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

/ s / J. N ICK R IEHLE

**J. Nick Riehle**  
Vice President, Administration and Chief Financial Officer

November 2, 2009