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CHELSEA THERAPEUTICS INTERNATIONAL, LTD.

FORM 10-Q
(Quarterly Report)

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

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

FORM 10-Q

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

For the quarterly period ended September 30, 2011

or

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

For the transition period from to .

Commission file number: 000-51462

CHELSEA THERAPEUTICS INTERNATIONAL, LTD.
(Exact name of Registrant as specified in its charter)

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)

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 November 1, 2011 there were 61,847,700 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, 2011 (unaudited)	December 31, 2010 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 37,103,864	$ 47,593,055
Short-term investments	20,502,791	—
Prepaid contract research and manufacturing	368,035	316,363
Other prepaid expenses and other current assets	745,916	246,374
Total current assets	58,720,606	48,155,792
Property and equipment, net	266,527	180,021
Other assets	38,095	38,095
	$ 59,025,228	$ 48,373,908
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,704,577	$ 2,288,241
Accrued compensation and related expenses	1,182,779	1,167,082
Accrued contract research and manufacturing	6,722,227	8,950,469
Other accrued expenses	1,034,455	780,352
Total liabilities	13,644,038	13,186,144
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, 100,000,000 shares authorized, 61,847,700 and 49,790,975 shares issued and outstanding, respectively	6,186	4,979
Additional paid-in capital	216,242,171	168,056,121
Deficit accumulated during the development stage	(170,867,167)	(132,873,336)
Total stockholders' equity	45,381,190	35,187,764
	$ 59,025,228	$ 48,373,908

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, 2011
	2011	2010	2011	2010	
Operating expenses:					
Research and development	$ 7,417,477	$ 7,424,682	$ 29,557,451	$ 20,699,430	$ 138,047,736
Sales and marketing	2,203,898	424,453	4,639,245	1,343,421	13,596,113
General and administrative	1,278,085	954,540	3,928,255	3,018,299	23,875,782
Total operating expenses	10,899,460	8,803,675	38,124,951	25,061,150	175,519,631
Operating loss	(10,899,460)	(8,803,675)	(38,124,951)	(25,061,150)	(175,519,631)
Interest income	45,222	19,003	131,120	188,478	4,910,811
Interest expense	—	(2,055)	—	(70,389)	(258,348)
Net loss	$ (10,854,238)	$ (8,786,727)	$ (37,993,831)	$ (24,943,061)	$ (170,867,168)
Net loss per basic and diluted share of common stock	$ (0.18)	$ (0.22)	$ (0.64)	$ (0.65)	
Weighted average number of basic and diluted common shares outstanding	61,847,700	40,316,699	59,544,028	38,668,900	

See accompanying notes to condensed consolidated financial statements.

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

	Common stock		Additional paid-in capital	Deficit accumulated during the development stage	Total stock-holders' equity
	Shares	Amount			
Balance at January 1, 2011	49,790,975	$4,979	$168,056,121	$(132,873,336)	$ 35,187,764
Stock-based compensation	—	—	2,015,150	—	2,015,150
Sale and issuance of common stock in February 2011 at approximately $3.75 per share, net of issuance costs	10,062,500	1,006	37,725,532	—	37,726,538
Recovery of short-swing profits, net of expenses	—	—	73,103	—	73,103
Common stock issued in 2011 at $4.20 per share pursuant to cash exercises of common stock warrants	1,993,444	200	8,372,265	—	8,372,465
Common stock issued in 2011 at par, pursuant to net-share (cashless) exercises of common stock warrants	781	—	—	—	—
Net loss	—	—	—	(37,993,831)	(37,993,831)
Balance at September 30, 2011	61,847,700	$6,186	$216,242,171	$(170,867,167)	$ 45,381,190

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, 2011	For the nine months ended September 30, 2010	Period from April 3, 2002 (inception) to September 30, 2011
Operating activities:			
Net loss	$ (37,993,831)	$ (24,943,061)	$ (170,867,168)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash stock-based compensation	2,015,150	1,497,043	8,357,065
Depreciation and amortization	87,780	52,307	393,294
Stock issued for license agreement	—	—	575,023
Non-cash interest expense	—	—	34,020
Gain on disposition of assets	—	—	(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	(551,214)	91,822	(1,113,951)
Accounts payable, accrued contract research and manufacturing expenses and other accrued expenses	442,197	(311,185)	12,461,262
Accrued compensation and related expenses	15,697	(141,825)	1,182,779
Net cash used in operating activities	(35,984,221)	(23,754,899)	(148,546,134)
Investing activities:			
Acquisitions of property and equipment	(174,286)	(16,995)	(661,291)
Proceeds from sale of assets	—	—	3,677
Purchases of short-term investments	(65,608,361)	—	(115,146,697)
Redemptions and sales of short-term investments	45,105,570	11,450,000	94,643,906
Security deposits	—	38,855	(38,095)
Net cash (used in) provided by investing activities	(20,677,077)	11,471,860	(21,198,500)
Financing activities:			
Proceeds from borrowings from affiliate	—	—	1,745,000
Borrowings from (repayments of) line of credit	—	(11,466,012)	—
Proceeds from exercise of stock options	—	—	80,729
Proceeds from exercise of common stock warrants	8,372,465	29,631	8,946,876
Recapitalization of the Company	—	—	(400,000)
Proceeds from sales of equity securities, net of issuance costs	37,726,538	19,614,300	196,398,165
Receipt of recovery of short-swing profits	73,103	—	73,103
Receipt of cash for stock subscription receivable	—	—	4,625
Net cash provided by financing activities	46,172,107	8,177,919	206,848,499
Net (decrease) increase in cash and cash equivalents	(10,489,191)	(4,105,120)	37,103,864
Cash and cash equivalents, beginning of period	47,593,055	22,294,649	—
Cash and cash equivalents, end of period	$ 37,103,864	$ 18,189,529	$ 37,103,864
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ —	$ 70,389	$ 224,328

See accompanying notes to condensed consolidated financial statements.

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

Supplemental disclosure of non-cash investing and financing activities:

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

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

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

In conjunction with the merger and recapitalization of the Company on 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, 2011
(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 development stage pharmaceutical company focused on the acquisition, development and commercialization of innovative pharmaceutical products. Specifically, the Company is developing Northera ™ (droxidopa), a novel therapeutic agent for the treatment of symptomatic neurogenic orthostatic hypotension, or NOH, in patients with primary autonomic failure, dopamine ß-hydroxylase, or DBH, deficiency, non-diabetic autonomic neuropathy, and the reduction of falls in patients with NOH associated with Parkinson's disease, or PD, as well as other potentially norepinephrine related conditions and diseases including intradialytic hypotension, fibromyalgia and adult attention deficit hyperactivity disorder. The Company is also developing pharmaceuticals for multiple autoimmune disorders, including rheumatoid arthritis, psoriasis, inflammatory bowel disease and cancer. 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 Chelsea Ltd.'s 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, 2011 are not necessarily indicative of the results for the year ending December 31, 2011 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/A filed on April 7, 2011 and available on the website (www.sec.gov) of the United States Securities and Exchange Commission, or SEC. The accompanying condensed consolidated balance sheet as of December 31, 2010 has been derived from the audited balance sheet as of that date included in the Form 10-K/A.

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

The Company has sustained operating losses since its inception and expects that such losses could continue at least through the launch of Northera in 2012. The Company's continued operation depends on its ability to raise funds through various potential sources, such as equity and debt financing, the exercise of warrants or strategic alliances. Such strategic relationships or out-licensing arrangements might require the Company to relinquish rights to certain of its technologies, product candidates or products that the Company would otherwise seek to develop or commercialize itself. If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its development programs or curtail operations.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
AS OF SEPTEMBER 30, 2011
(Unaudited)

Management believes that capital resources available at September 30, 2011 will be sufficient to meet the operating needs of the Company, including planned activities associated with the anticipated commercial launch of Northera in the United States, at least into the second quarter of 2012.

Basis of Consolidation

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

Use of Estimates

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

NOTE 2 SHORT-TERM INVESTMENTS

On September 30, 2011, the Company held short-term investments of $20.5 million consisting of investments in certificates of deposit, or CD's, with maturities of 26-weeks as of the dates of purchase, that were purchased through the Certificate of Deposit Account Registry Service, or CDARS ®. Investments are made through a single CDARS Network member and when a large deposit is made, that institution uses the CDARS service to place funds into CDs issued by other members of the CDARS Network. Investments occur in increments below the standard Federal Deposit Insurance Corporation, or FDIC, insurance maximum ($250,000) so that both principal and interest are eligible for FDIC insurance. The Company also held an additional $12.0 million of CDARS investments at September 30, 2011 that are classified as cash equivalents based on their 13-week maturities.

During the quarter ended September 30, 2011, all of the Company's short-term investments in commercial paper and corporate bonds matured and were fully redeemed.

During 2010, the Company liquidated its remaining investments in auction rate securities, or ARS, by exercising the ARS Rights received under a settlement agreement, finalized in the fourth quarter of 2008, with UBS Financial Services, Inc., or UBS. At January 1, 2010, the Company held total investments in ARS with a par value of approximately $11.45 million that were classified as trading securities and held at UBS. These ARS investments represented interests in collateralized debt obligations supported by pools of student loans and none were collateralized by mortgage, credit card or insurance securitizations. The ARS Rights provided 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 were to expire on July 2, 2012. The ARS Rights were not transferable, not tradable, were not quoted or listed on any securities exchange or any other trading network, were recorded at fair value and were classified as short-term investments. Additionally, 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 equivalent to 100% of the par value of the Company's ARS investments, providing the Company with full liquidity for all its investments in ARS held with UBS. Upon exercise of the ARS Rights on June 30, 2010 and, after applying the proceeds of the redemptions of those ARS Rights, the Company had no remaining liability under the line of credit. During 2010, based upon analysis of fair value, the Company recorded no additional trading loss related to its trading securities or any corresponding adjustment to the fair value of its ARS or ARS Rights, prior to redemption on June 30, 2010.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
AS OF SEPTEMBER 30, 2011
(Unaudited)

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. At September 30, 2011, assets measured at fair value on a recurring basis consisted of cash and cash equivalents of approximately $37.1 million and short-term investments (see Note 2) of $20.5 million. Based on the short-term liquid nature of these assets, the fair value, determined using level 1 inputs, is equivalent to the recorded book value.

NOTE 4 STOCK-BASED COMPENSATION

The Company has a stock incentive plan, as amended (the “Plan”), under which stock options for 7,400,000 shares of the Company’s common stock may be granted. Grants under the Plan may be made to employees (including officers), directors, consultants, advisors or other independent contractors who provide services to the Company or its subsidiary.

During the three months ended September 30, 2011, the Company granted stock options to newly-hired employees for the purchase of 82,500 shares of its common stock with a weighted-average exercise price of $4.39 per share, a weighted-average grant date fair value of $3.03 per share and exercise prices greater than the market value at September 30, 2011, resulting in no intrinsic value as of that date. During the three months ended September 30, 2010, the Company granted no stock options.

During the nine months ended September 30, 2011, the Company granted stock options to employees and non-employee directors for the purchase of 1,100,500 shares of its common stock with a weighted-average exercise price of $7.09 per share, a weighted-average grant date fair value of $4.71 per share and each with an exercise price greater than the market value at September 30, 2011, resulting in no intrinsic value as of that date. During the nine months ended September 30, 2010, the Company granted stock options to employees and non-employee directors for the purchase of 801,000 shares of its common stock, of which options for 798,000 shares remain outstanding with a weighted-average exercise price of $2.95 per share, a weighted-average grant date fair value of $2.14 per share and an intrinsic value as of September 30, 2011 of approximately $0.6 million.

Each option granted to employees and non-employee directors during the three and nine months ended September 30, 2011 and 2010 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 fair value of each option award made to employees and directors was estimated on the date of grant using the Black-Scholes-Merton closed-form option valuation model utilizing the assumptions noted in the following table. Effective January 1, 2011, the Company began relying exclusively on the trading and price history of the Company’s stock in order to determine the expected volatility given that, as of that date, there existed sufficient trading history to be able to determine historical volatility. The Company plans to continue to analyze the expected stock price volatility, as well as other assumptions utilized in the calculations, at each grant date as more historical data becomes available. As of January 1, 2011, taking into consideration hiring completed and planned by the Company and the potential impact of forfeitures given the roles of these newly filled positions, the Company estimates a forfeiture rate of 3%. Prior to 2011, the Company estimated that it would experience no forfeitures or that the rate of forfeiture would be immaterial to the recognition of compensation expense given the Company’s low historical rate of attrition and the senior nature of a significant portion of the Company’s employees granted options during that time. Due to the limited amount of historical data available to the Company, particularly with respect to stock-price volatility, employee exercise patterns and forfeitures, actual results could differ from the Company’s assumptions. The table below summarizes the assumptions utilized in estimating the fair value of the stock options granted during the three and nine months ended September 30, 2011 and 2010.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
AS OF SEPTEMBER 30, 2011
(Unaudited)

	For the three months ended September 30,		For the nine months ended September 30,	
	2011	2010	2011	2010
Weighted average risk-free interest rate	1.08%	n/a	1.91%	2.46%
Weighted average expected life of options	5 years	n/a	5 years	5 years
Weighted average expected dividend yield	0%	n/a	0%	0%
Weighted average expected volatility	89.06%	n/a	87.72%	94.43%
Anticipated forfeiture rate	3%	n/a	3%	n/a

The Company recorded compensation expense for the three and nine months ended September 30, 2011 of $668,147 and $2,015,150, respectively, in conjunction with option grants made to employees and non-employee directors. Compensation expense recorded in conjunction with option grants for the three and nine months ended September 30, 2010 were $487,589 and $1,497,043, respectively. As of September 30, 2011, the Company had total unrecognized compensation expense related to options granted to employees and non-employee directors of approximately $6.2 million, which it expects to recognize over a remaining average period of 2.25 years.

As of September 30, 2011, there were 5,737,430 options outstanding under the Plan with a weighted average remaining contractual life of 6.63 years and a weighted average exercise price of approximately $4.32 per share. Of these, options for 3,314,410 shares had vested and were exercisable at September 30, 2011 with a weighted average remaining contractual life of 5.29 years and a weighted average exercise price of approximately $3.86 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, 2011 for those awards that have an exercise price below the quoted closing price. As of September 30, 2011, there were options outstanding to purchase an aggregate of 2,910,234 shares with an exercise price below the quoted closing price of the common stock of the Company, resulting in an aggregate intrinsic value of approximately $3.4 million. Of those, options for 1,857,714 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 $2.2 million.

During the three and nine months ended September 30, 2011 and 2010, no options were exercised. During the three months ended September 30, 2011, options for 25,000 shares were forfeited by an employee that resigned during that period. During the nine months ended September 30, 2010, options for 12,000 shares were forfeited by an employee who resigned during that period.

NOTE 5 LOSS PER SHARE

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. For the periods presented, basic and 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, 2011 and 2010 upon exercise or conversion that were not included in the computation of net loss per share totaled 8,978,980 and 10,974,254 shares, respectively.

NOTE 6 EXERCISE OF COMMON STOCK WARRANTS

During January and February 2011, various warrant holders exercised their rights to purchase an aggregate of 1,993,444 shares of the common stock of the Company, with an exercise price of $4.20 per share, pursuant to cash exercises whereby the Company received proceeds of approximately $8.4 million.

In June 2011, a warrant holder exercised the right to purchase 1,994 shares of the common stock of the Company, with an exercise price of $2.89 per share, pursuant to a cashless exercise whereby the Company, in a net share settlement, issued 781 shares of its common stock to the warrant holder based on the excess of the market price over the exercise price on the date of exercise.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
AS OF SEPTEMBER 30, 2011
(Unaudited)

In September 2010, a warrant holder exercised the right to purchase 26,379 shares of the common stock of the Company, with an exercise price of $2.62 per share, pursuant to a cashless exercise whereby the Company, in a net share settlement, issued 14,298 shares of its common stock to the warrant holder based on the excess of the market price over the exercise price on the date of exercise.

In September 2010, various warrant holders exercised their rights to purchase an aggregate of 7,055 shares of the common stock of the Company at an exercise price of $4.20 per share pursuant to cash exercises whereby the Company recorded proceeds of approximately $30,000.

NOTE 7 COMMON EQUITY SALES PROGRAM

On July 26, 2011 the Company renewed its agreement for an at-the-market common equity sales program, initially dated July 2010. Under the renewed agreement, the Company may sell a maximum of $19.75 million of its common stock at a minimum price of $6.00 per share, pursuant to the Company's 2011 shelf registration statement filed with the SEC that became effective as of January 19, 2011. To date, the Company has made no sales under the program.

NOTE 8 REGISTERED DIRECT SALE OF COMMON STOCK

On February 24, 2011, the Company raised gross proceeds of approximately $40.25 million through the sale of 10,062,500 shares of its common stock in a publicly-marketed offering. These shares were offered pursuant to the Company's 2011 shelf registration statement filed with the SEC 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 January 19, 2011. In connection with this offering, the Company paid commissions and other offering-related costs of approximately $2.5 million, resulting in net proceeds to the Company of approximately $37.7 million.

NOTE 9 FACILITY LEASE

On October 21, 2010, the Company entered into an amendment to its lease agreement, dated March 7, 2008, to increase the office space in Charlotte, North Carolina that serves as its corporate headquarters. The Company accepted the additional space on March 14, 2011. Occupancy for the originally leased space occurred on or about May 15, 2008. Upon taking delivery of the newly added space and upon expiration, on September 14, 2011, of a free rental period of six months from the date of delivery, the monthly payments have increased by approximately $8,000 per month to a total of approximately $29,000. The lease, as amended, expires on or about March 14, 2016 and calls for annual rent increases of 3%. A security deposit of approximately $38,000 is being held by the lessor in conjunction with the lease.

NOTE 10 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 the Company as CH-1504 and related compounds. The license provides the Company exclusive, worldwide (excluding India) rights for CH-1504 and related compounds. 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 II 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. In September 2010, the Company made a milestone payment of $100,000 related to patient dosing in a Phase II study as required by the agreement. The Company is 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. There are no minimum royalties required under the agreement. The Company is also obligated to make future potential milestone payments based on the achievement of specific development and regulatory approval milestones. Based on the Company's current development plans for compounds licensed under this agreement, approximately $1.5 million of payments may become due if specific milestones are achieved, subject to the Company's right to terminate the license agreement. In addition, should the Company enter into an out-licensing agreement, such payments could be offset by revenue received from the sub-licensee.

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 DSP Agreement of $500,000 related to patient dosing in a Phase III study and has remaining potential future milestone payments, subject to the Company's right to terminate the DSP 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 at September 30, 2011, the Company had recorded expense of approximately $3.5 million and had a remaining liability of $0.4 million.

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 was conditioned on an event that occurred in January 2007 and, accordingly, the Company recorded a charge for the fair value of the warrants at January 2007 of $433,750. The Company utilized the Black-Scholes-Merton valuation model for estimating the fair value of the warrants at the date the condition lapsed, based on a risk-free interest rate of 4.79%, an expected life of three years, an expected dividend yield of 0%, an expected volatility of 66.01% and no estimated forfeitures. As additional consideration, the Company agreed to (1) make future milestone payments to Paramount, upon achievement of milestones as defined in the Finder's Agreement, (2) pay royalties on sales should any licensed compound become available for commercial sale, and (3) compensate a stated third-party consultant for services rendered in the evaluation of the transaction with DSP. The Company has remaining potential future milestone payments under the Finder's Agreement of $150,000.

NOTE 11 INCOME TAXES

The Company had accumulated tax losses, generating federal net operating loss carryforwards, or NOLs, of $122.5 million as of December 31, 2010. These losses will expire for federal tax purposes, if unused, in the years 2024 through 2030. The Company's deferred tax assets include NOL carryforwards with a tax effected value of $48.2 million as of December 31, 2010 for which the Company has established a valuation allowance equal to the total corresponding deferred tax asset given that the Company's ability to realize its deferred tax assets is not considered more likely than not. The increase in the valuation allowance during 2010 was primarily related to the increase in net operating losses.

Under limitations imposed by Internal Revenue Code Section 382, or IRC§382, certain potential changes in ownership of the Company, which may be outside the Company's knowledge or control, may restrict future utilization of these NOL carryforwards. During the quarter ended March 31, 2011, the Company undertook, with the assistance of its tax advisors, a detailed study in order to determine any potential IRC§382 limitations on its ability to utilize, in future periods, its federal NOL carryforwards available at December 31, 2010. This detailed study resulted in a determination that there had been two ownership changes previously, as defined by IRC§382, limiting the Company's NOLs available for federal tax purposes to approximately $52.2 million at December 31, 2010. However, all NOLs would be available for use prior to their expiration,

resulting in no adjustment to the tax provision and disclosure at December 31, 2010. In future years, the use of the remainder of the Company's NOLs at December 31, 2010 would be limited to approximately $8.9 million annually for years from 2011 to 2013, approximately $7.6 million for 2014, approximately $4.1 million annually for the years from 2015 to 2022 with the remainder in 2023. Any portion of an NOL limited by IRC§382 not used in a given year can be carried forward to subsequent years. Any NOLs generated during periods since the date of the most recent ownership change and those that might be generated in any future periods can be used without restriction unless a future ownership change occurs.

The Company has provided a valuation allowance equal to its deferred tax asset for NOLs as the realization of that deferred tax asset is dependent upon future generation of taxable income and it cannot be determined that it is more likely than not that the deferred tax asset will be realized. Until such realization can be reasonably determined based on established sources of earnings sufficient to utilize the NOL carryforwards, the Company will continue to provide an allowance for the entire deferred tax asset. Given the Company's establishment of a valuation allowance equal to the total deferred tax assets, the annual limitations resulting from restrictions on the Company's ability to utilize NOL carryforwards are immaterial to the Company's financial condition or results of operations.

Although a detailed study has not been completed, similar limitations might be expected under Internal Revenue Code Section 383, or IRC§383, on the utilization of research and development tax credits that may be available to the Company. The Company is currently unable to fully estimate the impact of any such available research and development tax credits and any related IRC§383 limitations nor has it undertaken the steps necessary to fully estimate the potential benefits that may be available to it from the utilization of research and development tax credits in future periods.

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/A for the year ended December 31, 2010 and "Item 1A. Risk Factors" in our Quarterly Report on Form 10-Q for the period ended March 31, 2011.

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 alternatives to current methods of treatment. Specifically, we are developing a novel therapeutic agent for the treatment of symptomatic neurogenic orthostatic hypotension, or NOH, in patients with primary autonomic failure, dopamine ß-hydroxylase, or DBH, deficiency and non-diabetic autonomic neuropathy and the reduction of falls in patients with NOH associated with Parkinson's disease, or PD, as well as other potentially norepinephrine related conditions and diseases including intradialytic hypotension, or IDH, fibromyalgia and adult attention deficit hyperactivity disorder. We are also developing pharmaceutical products for multiple autoimmune disorders, including rheumatoid arthritis, psoriasis, inflammatory bowel disease and cancer.

Northera™ (droxidopa), our most advanced investigational product candidate, is an orally-active synthetic precursor of norepinephrine being developed for the treatment of symptomatic NOH. In Japan, Northera has been approved since 1989 and is marketed by Dainippon Sumitomo Pharma Co., Ltd., or DSP, for the treatment of frozen gait and dizziness on standing in PD, orthostatic hypotension, syncope and dizziness on standing in multiple systems atrophy (Shy-Drager Syndrome) and familial amyloid polyneuropathy and symptoms of orthostatic hypotension in hemodialytic patients. During 2007, the FDA granted orphan drug status to Northera for the treatment of symptomatic NOH and the European Medicines Agency, or EMA, granted orphan medicinal product designation for the treatment of patients with Pure Autonomic Failure, or PAF, and patients with multiple system atrophy, or MSA.

In September 2011, we submitted a New Drug Application, or NDA, to the U. S. Food and Drug Administration, or FDA, seeking approval to market Northera in patients with primary autonomic failure, DBH deficiency and non-diabetic autonomic neuropathy. In our application, we requested priority review of the NDA, which, if granted, could mean the FDA's goal, under the Prescription Drug User Fee Act, or PDUFA, would be to review and act on the NDA by the end of the first quarter of 2012.

The clinical portion of the NDA includes combined safety and efficacy data from our two completed Phase III studies in NOH, Study 301 and Study 302, two long-term open-label extension studies, Study 303 and Study 304, a dedicated thorough QTc study and a 24-hour ambulatory blood pressure monitoring study, Study 305. During our pre-NDA meeting with the FDA in December 2010 and in subsequent communication with the agency, the FDA agreed that the proposed NDA for Northera could be submitted based on combined data from these studies without the need for any further efficacy studies. Also during the pre-NDA meeting, the FDA requested a thorough QTc study of Northera be completed and indicated that results could be submitted at the time of the 90-day safety update. During the second quarter of 2011, we announced the successful completion of this dedicated QTc study of Northera to formally evaluate and confirm the cardiac safety of Northera. As such, we included top-line data in the NDA and will include the full study report at the time of the 90-day safety update. The results of this ECG trial showed that Northera, at either therapeutic or supra-therapeutic doses, did not increase heart rate or prolong AV conduction or cardiac polarization times as measured by the PR interval, QT interval and duration of the QRS complex. The FDA has also requested that we conduct a post-marketing study to evaluate the clinical pharmacology of Northera in renally-impaired patients.

Upon review of anecdotal evidence in the adverse events reported in Study 301 and Study 302 suggesting that Northera treatment was associated with fewer falls, we decided to prospectively assess this benefit as a secondary efficacy parameter in Study 306, a Phase III trial initiated in 2010 prior to the completion of Study 301. Since Study 306 was originally intended to support our registration of Northera for the treatment of NOH, the primary endpoint for Study 306 was the relative mean change in the OHQ composite between treatment and placebo arms. In February 2011, we announced our plans to modify Study 306 following a determination of futility at the planned interim analysis of the study's primary

endpoint. Our subsequent unblinded review of multiple, secondary outcome measures showed an approximate 60% reduction in the rate of patient reported falls and supportive signs of therapeutic activity associated with Northera in the first 51 patients to complete Study 306.

We have modified and separated Study 306 such that the first 51 patients evaluated in the unblinded interim analysis are considered Part A (Study 306A) while the remaining 62 patients already enrolled in the study at the time of the interim analysis but not unblinded as part of that analysis would form the basis for Part B (Study 306B). Based on the analysis of the unblinded interim data from Study 306A, we modified the primary endpoint of Study 306B and plan to add an additional 100 patients to demonstrate an approximate 45% reduction in the rate of falls per patient, per week in patients with NOH associated with PD. Based on preliminary estimates, we anticipate data from Study 306B will likely be available during the second quarter of 2012. In keeping with the FDA's recommendations, we did not seek a falls claim in the initial labeling at the time we filed for approval of Northera for the treatment of symptomatic NOH, but we intend to continue an ongoing clinical evaluation of the effects of Northera in reducing the number of falls in patients with NOH associated with PD, including additional clinical trials as necessary, with the intent of pursuing future label expansion opportunities for Northera post-approval.

In August 2011, we successfully reached our target enrollment of 120 patients in our Phase II trial of droxidopa, alone and in combination with carbidopa, for the treatment of fibromyalgia. This trial began in early 2009 under approval from the United Kingdom's Medicines and Healthcare Products Regulatory Agency. On July 1, 2010, we announced the completion and favorable outcome of an independent Data Monitoring Committee review of the safety and efficacy data from approximately half the patients expected to participate in the trial. We currently anticipate top-line results from this study will be available during the fourth quarter of 2011. Also, in September 2011, we announced that we had been issued U.S. Patent No. 8,008,285 entitled "Droxidopa and pharmaceutical composition thereof for the treatment of fibromyalgia." The claims of the patent are related to methods of reducing pain associated with fibromyalgia by administering droxidopa alone, or in combination with other specified medications.

In July 2011, we announced that an investigator-led Phase II study of droxidopa, in combination with carbidopa, for the treatment of adult attention deficit hyperactivity disorder, or ADHD, initiated in February 2010, had been completed. Preliminary results from this study suggest that droxidopa rapidly improved ADHD symptoms during open-label treatment and was well tolerated with no serious adverse events.

In October 2011, an investigator-led, Phase II study began to evaluate droxidopa for the treatment of orthostatic hypotension resulting from spinal cord injury.

In October 2011, we notified the principal investigator of an investigator-led, open label Phase II study of droxidopa for the treatment of chronic fatigue syndrome, or CFS, of our intent to terminate support of the trial as a result of a slow pace of patient recruitment and our assessment that the trial was unlikely to be concluded within a reasonable time period.

In addition to droxidopa, we are currently developing a portfolio of molecules for the treatment of various autoimmune/inflammatory diseases. The most advanced platform is a portfolio of metabolically-inert antifolate molecules engineered to have potent anti-inflammatory and anti-tumor activity to treat a range of immunological disorders, including two clinical stage product candidates designated as CH-1504 and CH-4051. In March 2009, we announced positive results from the completed Phase II head-to-head clinical trial of CH-1504 for the treatment of rheumatoid arthritis, designed to compare the efficacy and tolerability of CH-1504 against methotrexate, currently the leading antifolate treatment and standard of care for a broad range of abnormal cell proliferation diseases. The preliminary analysis showed comparable American College of Rheumatology efficacy criteria, or ACR20/50/70 response rates, to patients treated with daily 0.25mg, 0.50mg and 1.0mg of CH-1504 against patients treated with a standard weekly 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.

Based on these findings, in September 2010 we initiated a multinational, 12-week, double-blind Phase II trial designed to compare the efficacy and tolerability of CH-4051 against methotrexate in 250 patients with rheumatoid arthritis who experience an inadequate response to methotrexate treatment. The primary efficacy analysis will be conducted using the ACR hybrid score, an endpoint that combines a continuous scale of percentage improvement with the well-known ACR20/50/70. The trial was initiated with a staggered start wherein the first patients were randomized to receive either 0.3mg or 1.0mg of CH-4051 daily or 20mg methotrexate weekly in combination with a folate supplement. Enrollment in the high dose arms of the study was deferred until May 2011, when we announced that an independent Data Safety Monitoring Board had met to review patient safety data from this study and, finding no signals that precluded proceeding, recommended that each on-going arm of the study continue as planned and that enrollment be initiated in the 3.0mg dose groups of the trial. In October 2011, we conducted a planned unblinded, interim efficacy analysis for a subset of study participants including patients from the lower dose groups. In this unblinded efficacy analysis, the 1.0 mg daily dose of CH-4051 demonstrated comparable efficacy and improved safety compared to a 20 mg weekly dose of methotrexate in patients. Also in October 2011, we successfully reached our target enrollment of 250 patients for this study. We currently anticipate full study results to become available in the second quarter of 2012.

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

Since inception we have focused primarily on organizing and staffing our company, negotiating in-licensing agreements with our partners, acquiring, developing and securing our proprietary technology, participating in regulatory discussions with the FDA, the EMA and other regulatory agencies, undertaking preclinical and clinical trials of our product candidates and, more recently, preparing for the planned commercial launch in the United States of one of its product candidates in anticipation of regulatory approval. We are a development stage company and have generated no revenue since inception. We do not anticipate generating any product revenue until and unless we successfully obtain approval from the FDA or equivalent foreign regulatory bodies to begin selling our pharmaceutical candidates although we could potentially generate revenue by entering into strategic agreements including out-licensing, co-development or co-promotion of our drug candidates. Developing pharmaceutical products is a lengthy and expensive process. Even if we do not encounter unforeseen safety issues or timing or other delays during the course of developing our currently licensed product candidates, we would not anticipate receiving regulatory approval to market any such products until, at the earliest, 2012. Assuming FDA approval of Northera for marketing in the United States under a priority review, we currently anticipate launching the product and having initial sales or royalty revenue from it in the second quarter of 2012. Currently, development expenses are being funded with proceeds from equity financings and, to a much lesser extent, through the issuance of our common stock pursuant to option or warrant exercises. We completed equity financings in December 2004, February 2006, March 2007, November 2007, July 2009, March 2010, October 2010 and February 2011. In addition, we received additional proceeds under a controlled equity offering for sales made during September 2010. To the extent we move our products into additional clinical trials and expand our commercialization and marketing efforts for droxidopa, our need to finance operating costs will continue. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development and/or commercialization of the products (see “Liquidity and Capital Resources”).

Critical Accounting Policies

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

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

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

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

These contracts generally include pass-through fees. Pass-through fees include, but are not limited to, regulatory expenses, investigator fees, travel costs, and other miscellaneous costs including shipping and printing fees. Because these

fees are incurred at various times during the contract term and they are used throughout the contract term, we record a monthly expense allocation to recognize the fees during the contract period. Fees incurred to set up the clinical trial are expensed during the setup period.

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

Accounting for Stock-Based Compensation. We account for our stock options and warrants utilizing a fair value based method of accounting. In determining the fair value of the equity instrument, we consider, among other factors, (i) the risk-free interest rate, (ii) the expected life of the options granted, (iii) the anticipated dividend yield, (iv) the estimated future volatility of the underlying shares and (v) anticipated future forfeitures. To determine the risk-free interest rate, we utilize the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected life of our awards. We estimate the expected life of the options granted based on anticipated exercises in future periods assuming the success of our business model as currently forecasted. The expected dividends reflect our current and expected future policy for dividends on our common stock. To determine the expected stock price volatility for our stock options, we analyze the historical volatility of our stock price 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. Given our low historical rate of attrition and the senior nature of the roles for a significant portion of our employees, beginning in 2011 we estimate that our rate of anticipated future forfeitures will be 3% or less. In prior periods our rate of forfeiture was immaterial to the recognition of compensation expense for options. Our results of operations include non-cash compensation expense as a result of the issuance of stock option grants that are valued using 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 employee exercise patterns and forfeitures, actual results could differ from our assumptions.

Results of Operations

Three Months Ended September 30, 2011 and 2010

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 three months ended September 30, 2011	For the three months ended September 30, 2010	$ Increase	% Change
Research and development expense	$ 7,417	$ 7,425	$ (8)	0%
Sales and marketing expense	2,204	424	1,780	420%
General and administrative expense	1,278	955	323	34%
Interest income	45	19	26	137%
Interest expense	—	(2)	2	-100%

Research and development expenses remained flat in the third quarter of 2011 when compared to the same period of 2010. In 2010, we completed our second pivotal Phase III trial in NOH, Study 301 and initiated Study 306. In 2011, we continue to incur costs for NOH306 and our open-label extension study, Study 304. We also incurred expenses for a Phase II trial of our antifolate, CH-4051, in rheumatoid arthritis for which enrollment was initiated in September 2010. Finally, during 2011, we had costs for the preparation and filing of our NDA for Northera. Specifically, third quarter 2011 expenses included approximately $0.7 million related to the preparation and filing of our NDA, $0.7 million related to our ongoing Phase II trial of CH-4051, $1.7 million related to NOH306 and $0.9 million for NOH extension studies. Additionally, we incurred costs during the period related to medical affairs activities, including hiring, on a contract basis, a team of Medical Science Liaison employees, generating period costs of $1.1 million. We also continued to incur expenses for our ongoing Phase II trial of droxidopa in fibromyalgia and the costs of manufacturing, packaging, labeling and distributing clinical trial material. During the quarter ended September 30, 2010, primary expenditures were associated with our Phase III NOH study, NOH extension studies, our Phase II trial of droxidopa in fibromyalgia and initial costs related to our Phase II trial of our antifolates in rheumatoid arthritis. Also contributing to our expenses in both periods were compensation and related costs. As a percentage of operating expenses, research and development costs were 68% for the three months ended September 30, 2011 and 84% for the same period of 2010.

From inception through September 30, 2011, cumulative research and development expenses related to our major research and development projects were approximately $138.1 million and are detailed as follows:

(in thousands)	For the three months ended September 30, 2011	For the three months ended September 30, 2010	Through September 30, 2011
Antifolates	$ 1,300	$ 700	$ 37,600
Droxidopa	6,100	6,800	98,000
I-3D	—	—	2,500
	$ 7,400	$ 7,500	$138,100

Droxidopa. From inception through September 30, 2011, we had spent approximately $98 million in research and development expenses on droxidopa. Based on our earlier discussions with the FDA, the pre-clinical and clinical programs required to complete and file our NDA seeking marketing approval of Northera (droxidopa) for the treatment of symptomatic NOH are essentially complete. Our access and safety program, Study 304, remains ongoing. However, we will continue to incur research and development costs for droxidopa, primarily related to completing our preparations for the commercialization of Northera in the United States. For the six-month period from September 30, 2011 through our anticipated PDUFA date at the end of March, 2012, we expect these costs to total approximately $13.5 million. Included in this total are license fees on acceptance and approval of our NDA, should those actions occur; regulatory activity, primarily related to support of our NDA filing and a possible advisory committee meeting; commercial supply purchases and related drug manufacture, which are expensed prior to NDA approval; launch preparations related to medical information, medical affairs and commercial operations, including quality, compliance, distribution and related activities. Additional droxidopa-related clinical research and development costs during this period are estimated at $6.1 million and include our ongoing Phase III study 306, continuation of access and safety programs for NOH patients and our Phase II study of droxidopa in fibromyalgia.

Antifolates. From inception through September 30, 2011, we had spent approximately $37.6 million in research and development expenses on our portfolio of antifolates. We currently intend to seek a partner to assist us in the development of our antifolates after the completion of our ongoing Phase II proof-of-concept study for CH-4051 in rheumatoid arthritis, that is expected to be completed in 2012. We estimate that we will spend approximately $1.6 million in 2011 and approximately $3.2 million in the first half of 2012 to complete this study. Assuming an approval for marketing, we currently estimate launch of this product and initial royalty revenue from it no sooner than 2014.

I-3D Portfolio. From inception through September 30, 2011, 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 sufficient additional financing.

Sales and marketing expenses . Although we had no formalized selling activities, during the third quarter of 2011 expenses increased significantly when compared to the same period of 2010. A significant component of this increase is related to increased compensation and related costs as we added personnel with the appropriate expertise in this area to support our planned commercialization of Northera. In addition, we continue to see the expected ramp up in the costs of developing and implementing our sales and marketing initiatives for Northera. Such costs include market research, sales force strategy and planning, planning for advertising and promotional campaigns, website development, sales operations planning, employee training programs and public relations. In addition, we had increases in travel costs and legal expenses related to our intellectual property. During the third quarter of 2010, expenses were primarily related to compensation and related costs and legal expenses related to our intellectual property. We anticipate our sales and marketing spending to continue to increase through 2011 and into 2012 as we prepare for the commercialization of Northera in the United States. We currently expect the various launch preparation activities for marketing to require spending of between $3.9 million and $4.7 million over the remainder of 2011 with an additional $3.0 million to $4.0 million in the first quarter of 2012. Activities related to building and hiring our sales force will be approximately $1.1 million over the remainder of 2011 and are estimated at $2.4 million during the first quarter of 2012.

General and administrative expenses. During the quarter ended September 30, 2011, we incurred increases in compensation and related costs, communications expense, supplies and office expense, commercial insurance, financial printing, depreciation, taxes/government fees and transfer agent fees. In addition, facilities costs increased primarily related to the acceptance of expansion space at our headquarters location in the first quarter of 2011 under a lease amendment entered into during the fourth quarter of 2010. Individually, each of these increases, most related to our overall increase in headcount, is immaterial. However, in the aggregate, generate the increase in general and administrative expenses.

Interest income and interest expense . At September 30, 2011, we had cash and cash equivalents of $37.1 million and short-term investments of $20.5 million. The increase in interest income reflects an increase of approximately $39.4 million in funds available for investment in the third quarter of 2011 when compared to the third quarter of 2010, primarily related to our equity offering and the cash exercise of warrants during the first quarter of 2011. Interest expense decreased as the line of credit associated with our investments in ARS held at UBS was fully paid on June 30, 2010 upon redemption of those investments.

Nine Months Ended September 30, 2011 and 2010

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 September 30, 2011	For the nine months ended September 30, 2010	$ Increase	% Change
Research and development expense	$ 29,557	$ 20,699	$8,858	43%
Sales and marketing expense	4,639	1,343	3,296	245%
General and administrative expense	3,928	3,018	910	30%
Interest income	131	188	(57)	-30%
Interest expense	—	(70)	70	-100%

Research and development expenses increased significantly during the nine months ended September 30, 2011 to $29.6 million compared to $20.7 million during the same period of 2010. This increase primarily reflects increases in costs associated with our planned registration and anticipated launch of Northera. Specifically, 2011 expenses included approximately $3.9 million related to the manufacturing of and process validation for commercial drug product, approximately $2.6 million related to the Northera QTc study and approximately $1.9 million on the preparation and filing of our NDA for Northera. Additionally, we incurred an increase of $2.5 million in costs during 2011, when compared to 2010, related to our ongoing Phase II trial of CH-4051 in rheumatoid arthritis. Lastly, costs during the period related to ongoing medical affairs planning, including entering into an agreement and launching our Medical Science Liaison team, generated period costs of $2.1 million. Although we continue to incur expenses related to our ongoing Northera NOH trials, including Study 306B and extension study 304, aggregate expenses associated with these clinical programs decreased by approximately $0.5 million when compared to 2010. We also incurred increased expenses associated with our ongoing Phase II trial of droxidopa in fibromyalgia offset by a decrease in the costs of manufacturing, packaging and labeling clinical trial material for our clinical trials. During the nine months ended September 30, 2010, primary expenditures were associated with our NOH program including implementing changes to Study 301 and the initiation of Study 306, along with costs of our Phase II trial of droxidopa in fibromyalgia and initial costs related to our Phase II trial of our antifolates in rheumatoid arthritis. Also contributing to our expenses in both periods were compensation and related costs. As a percentage of operating expenses, research and development costs were 78% for the nine months ended September 30, 2011 and 83% for the same period of 2010.

Sales and marketing expenses . Although we had no formalized selling activities, during the nine months ended September 30, 2011 sales and marketing expenses increased significantly when compared to the same period of 2010. A significant component of this increase is related to increased compensation and related costs as we added personnel with the appropriate expertise in this area to support our planned commercialization of Northera. In addition, we also have begun to see the expected ramp up in the costs of developing and implementing our sales and marketing initiatives for Northera. Such costs include market research, sales force strategy and planning, planning for advertising and promotional campaigns, website development, sales operations planning, employee training programs and public relations. In addition, we also had increases in travel costs, promotional costs that include conference sponsorships and legal expenses related to our intellectual property. During the nine months ended September 30, 2010, primary expenditures were related to compensation and related expenses and legal expenses related to our intellectual property.

General and administrative expenses. During the nine months ended September 30, 2011, general and administrative expenses increased by approximately $0.9 million when compared to the same period of 2010. Contributing to this increase were increases in compensation and related costs, primarily for stock-based compensation, professional fees, including audit,

tax and legal fees, rent expense, related to the expansion of our headquarters office space, financial printing, depreciation, taxes/government fees and transfer agent fees.

Interest income and interest expense . At September 30, 2011, we had cash and cash equivalents of $37.1 million and short-term investments of $20.5 million. The decrease in interest income is primarily related to the loss of interest income on auction rate securities investments that were fully liquidated by June 30, 2010 but that paid premium interest rates during the first six months of 2010. Interest expense decreased as the line of credit associated with our investments in ARS held at UBS was fully paid on June 30, 2010.

Liquidity and Capital Resources

From inception to September 30, 2011, we have incurred an aggregate net loss of approximately $170.9 million as a result of expenses similar in nature to those described above.

As of September 30, 2011, we had working capital of approximately $45.1 million including cash and cash equivalents of approximately $37.1 million, short-term investments of $20.5 million and liabilities of $13.6 million. We have financed our operations primarily through sales of our common stock and, to a lesser extent, through the issuance of our common stock pursuant to option or warrant exercises. Cash on hand results primarily from previous financing activities offset by funds utilized for operating and investing activities.

In February 2011, we raised gross proceeds of approximately $40.25 million through the sale of 10,062,500 shares of our common stock in a publicly-marketed offering. These shares were offered pursuant to our shelf registration statement as filed with the Securities and Exchange Commissions, or SEC, under which we may offer shares of 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. The registration statement became effective as of January 19, 2011. In connection with this offering, we paid commissions and other offering-related costs of approximately $2.5 million, resulting in net proceeds of approximately $37.7 million.

In July 2011, we renewed our agreement for an at-the-market common equity sales program, initially dated July 2010. Under the renewed agreement, we may sell a maximum of $19.75 million of our common stock at a minimum price of $6.00 per share, pursuant to our 2011 shelf registration statement filed with the SEC that became effective as of January 19, 2011. To date, we have made no sales under the program.

We invest our cash in a variety of financial instruments in order to preserve principal and liquidity while seeking reasonable returns. To limit market risk, investments are restricted to high quality instruments with relatively short maturities including, but not limited to, fully liquid interest-bearing money market accounts, commercial paper, certificates of deposit and Treasury funds typically with a maturity of six months or less.

During 2010, we successfully redeemed, at full par value, all of our holdings in ARS. At January 1, 2010, we held short-term investments of $11.45 million, consisting of principal invested in certain ARS and the fair value of the ARS Rights. Our investments in these securities represented 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 included mortgage, credit card or insurance securitizations. During 2010, approximately $5.3 million of our investments in ARS were redeemed at full par value and on June 30, 2010, we exercised our right, as outlined under the settlement agreement with UBS, to sell the remaining ARS investments of approximately $6.2 million, along with our ARS rights, to UBS at par value. In addition, we repaid the related line of credit provided by UBS in conjunction with the settlement agreement with the proceeds from redemptions.

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 Northera and our efforts to secure opportunities for strategic alliances.

We believe that capital resources available at September 30, 2011 will be sufficient to meet our operating needs at least into the second quarter of 2012, including the anticipated commercial launch of Northera in the United States.

Our continued operations depend on our ability to raise funds through various potential sources, such as equity and debt financing, the exercise of warrants or strategic alliances. 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, 2011 we had losses of $170.9 million. We had net losses of $38.0 million and $24.9 million for the nine months ended September 30, 2011 and 2010, respectively, and we anticipate losses at least through 2011 unless we should successfully negotiate a strategic agreement earlier that might include out-licensing, co-development or co-promotion of one or more of our drug candidates. Actual losses will depend on a number of considerations including:

- seeking regulatory approval for our various product candidates;
- the pace of commercialization and marketing efforts for Northera;
- discussions with regulatory agencies concerning the design and results of our clinical trials;
- the pace and success of development activities, including clinical programs for droxidopa, antifolates and other product candidates;
- our ability to identify and recruit patients into our clinical trials at costs consistent with our current estimates;
- possible out-licensing of our product candidates;
- the pace of development of new intellectual property for our existing product candidates;
- in-licensing and development of additional product candidates;
- implementing additional internal systems and infrastructure; and
- hiring additional personnel.

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

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

As of September 30, 2011, we have known contractual obligations and commitments of approximately $24.7 million, primarily related to contracted activities for research and development, medical affairs, marketing and sales in anticipation of the planned commercialization of Northera in the United States in 2012. To facilitate an understanding of our contractual obligations and commercial commitments, the following data is provided as of September 30, 2011:

	Payments due by period				
Category	Total	< 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations	$ 1,675,010	$ 368,329	$ 754,884	$551,796	$ —
Purchase obligations	23,061,350	22,109,035	853,269	99,046	—
Total	$24,736,360	$22,477,364	$1,608,154	$650,842	$ —

We have also entered into certain other agreements that, based on our development and commercialization plans as of September 30, 2011, might require us to make contingent milestone payments of up to approximately $4.75 million over the life of the agreements upon the achievement of certain clinical or commercial milestones. Included in this total are license milestone payments of $750,000 and $1.5 million, payable upon acceptance and approval of our NDA for Northera, respectively, if and when those events should occur. All such future payments are subject to our right to terminate the agreements. In the event that the milestones are not achieved, we elect not to pursue further testing of the drug candidate or we terminate such agreements, we will have no further obligations under the agreements. The uncertainty relating to the timing and occurrence of the commitments described prevents us from including them in the table above.

In addition, in October 2011, we committed to the purchase of active pharmaceutical ingredient from DSP to be used in the production of commercial inventory in preparation for the market launch of Northera in the United States. The value of this obligation is approximately $7.2 million. A small initial shipment of this material is scheduled for delivery in the fourth quarter of 2011. Although the remainder of this material could be shipped at any time within a two-year period following the completion of its manufacture, it is not anticipated to be shipped prior to the commercial launch of Northera in the United States.

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. A portion of our cash is maintained in non-interest bearing accounts at federally insured financial institutions that, under the Transaction Account Guarantee Program of the Federal Deposit Insurance Corporation, or FDIC, are fully insured until December 31, 2012. In addition, we maintained and continue to maintain funds on deposit in commercial accounts that include non-interest bearing commercial checking accounts, fully liquid interest-bearing money market accounts, certificates of deposit, or CDs, money market funds and Treasury funds typically with maturities of six months or less. Investments in CDs are made through the Certificate of Deposit Account Registry Service, or CDARS ®, through a single CDARS Network member. When a large deposit is made, the CDARS network member uses the CDARS service to place funds into CDs issued by other members of the CDARS Network. Investments occur in increments at or below the standard FDIC insurance maximum ($250,000) at each participating member institution so that both principal and interest are eligible for FDIC insurance. All deposits and investments to date have been made in U. S. dollars and, accordingly, have no exposure to foreign currency rate fluctuations on these investments.

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. Currently, the returns on such liquid, short-term investments are at historic lows. Accordingly, we estimate that any sensitivity experienced due to fluctuations of interest rates in the United States for such investments would have no material impact on our consolidated financial position or results of operations.

Item 4. Controls and Procedures

Disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) are designed only to provide reasonable assurance that they will meet their objectives that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e)) pursuant to Exchange Act Rule 13a-15. Based upon that evaluation and subject to the foregoing, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of September 30, 2011.

Changes in Internal Control over Financial Reporting.

Management has determined that, as of September 30, 2011, 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/A for the year ended December 31, 2010 and in our Quarterly Report on Form 10-Q for the period ended March 31, 2011 except as set forth below.

The U.S. Food And Drug Administration, or FDA, may not accept or approve our recently filed New Drug Application, or NDA, for Northera ™.

In September 2011, we filed with the FDA our NDA seeking approval to market Northera for the treatment of symptomatic neurogenic orthostatic hypotension, or NOH, in patients with primary autonomic failure, dopamine-ß-hydroxylase deficiency and non-diabetic autonomic neuropathy. The FDA had previously agreed, in a pre-NDA meeting held in December 2010, that our NDA could be submitted based on combined data from our two completed Phase III studies of Northera in NOH, Study 301 and Study 302. The FDA also had previously agreed to changes in the protocol for Study 301, including a change in the primary endpoint. The FDA further agreed that results from Study 306, an ongoing Phase III study, would not be required as part of the integrated summary of efficacy for the indication claimed in the filing.

While we believe that the design, performance and results of Study 302 and Study 301 are adequate to meet the FDA's expectations, we continue to face risks associated with our NDA filing, including:

- upon filing the NDA, the FDA has 60 days to conduct a preliminary review which will assess whether the NDA is "sufficiently complete to permit a substantive review". If the NDA is found to be insufficiently complete for any reason, the FDA can reject the application. Although we believe our filing to be sufficiently complete, we cannot, with any certainty, be assured that the FDA will accept our filing;
- the FDA may decide to utilize an advisory committee to provide an independent review and expert advice related to our NDA filing. Should the FDA choose to call for an advisory committee review of our filing, we cannot be assured that the advisory committee would make a favorable recommendation to the FDA based upon their review of data contained in our NDA;
- Study 301 was conducted under a Special Protocol Assessment, or SPA, granted by the FDA in February 2008, providing an agreement that the study design, including trial size, clinical endpoints and/or data analyses are acceptable to support regulatory approval. The FDA has significant latitude and discretion in interpreting the terms of an SPA and the data and results from any study that is the conducted under an SPA. We cannot, with any certainty, determine that Study 301 data will be adequate to support the approval of our NDA, even given the 2008 SPA determination;
- The FDA or the advisory committee, should one be utilized, may fail to accept as an appropriate primary endpoint of Study 301 the relative improvement in the Orthostatic Hypotension Questionnaire, or OHQ, composite score between Northera and placebo;
- the FDA or the advisory committee, should one be utilized, may find that the safety database information contained in the NDA is inadequate to effectively establish the clinical safety of Northera;
- the FDA or the advisory committee, should one be utilized, may find that the clinical data submitted in the NDA is not sufficient to establish the clinical efficacy of Northera; and
- while the FDA agreed, during a December 2010 pre-NDA assessment meeting, that our NDA for Northera could be submitted based on combined data from Study 301 and Study 302 and that results from Study 306 would not be required as part of the integrated summary of efficacy for the indication claimed in the filing, there can be no assurance that the FDA or the advisory committee, should one be utilized, will not require additional clinical efficacy to support approval of our NDA.

Item 6. Exhibits

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
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
101	Financials submitted in XBRL format.				X

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SIGNATURES

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

Chelsea Therapeutics International, Ltd.

Date: November 2, 2011

By: /s/ J. NICK RIEHLE

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

EXHIBIT 31.1

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, 2011

By: /s/ Simon Pedder
Simon Pedder
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, J. Nick Riehle, 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, 2011

By: /s/ J. Nick Riehle
J. Nick Riehle
Vice President, Administration and
Chief Financial Officer

EXHIBIT 32.1

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, 2011 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/ Simon Pedder
Simon Pedder
President and Chief Executive Officer

November 2, 2011

EXHIBIT 32.2

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, 2011 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. Nick Riehle
J. Nick Riehle
Vice President, Administration and
Chief Financial Officer

November 2, 2011