

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF NORTH CAROLINA  
CHARLOTTE DIVISION

MICHAEL KLEIN, Individually and on Behalf) No.  
of All Others Similarly Situated, )  
 ) CLASS ACTION  
Plaintiff, )  
 ) COMPLAINT FOR VIOLATION OF THE  
vs. ) FEDERAL SECURITIES LAWS  
 )  
CHELSEA THERAPEUTICS )  
INTERNATIONAL, LTD., L. ARTHUR )  
HEWITT and SIMON PEDDER, )  
 )  
Defendants. )  
 ) DEMAND FOR JURY TRIAL  
\_\_\_\_\_ )

1. This is a securities class action on behalf of all persons who purchased or acquired the common stock of Chelsea Therapeutics International, Ltd. (“Chelsea” or the “Company”) between November 3, 2008 and March 28, 2012, inclusive (the “Class Period”). The claims asserted arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”), and Rule 10b-5 promulgated thereunder. Chelsea is a biopharmaceutical company whose stock trades on the NASDAQ under the ticker symbol “CHTP.” Defendants are Chelsea, Simon Pedder (“Pedder”), Chelsea’s Chief Executive Officer (“CEO”), President and a director, and L. Arthur Hewitt (“Hewitt”), Chelsea’s Chief Scientific Officer.

### **SUMMARY OF THE ACTION**

2. Chelsea has been developing the drug Northera (trade name Droxidopa) (“Droxidopa”) for use in treating neurogenic orthostatic hypotension (“NOH”) (a form of hypotension in which a person’s blood pressure suddenly falls when standing up or stretching) in patients with primary autonomic failure, including Parkinson’s disease. Northera has been approved since 1989 in Japan for the same indication, but is marketed at lower doses. In November 2008, defendants started touting clinical evidence supporting the efficacy of Droxidopa in the treatment of NOH. On September 28, 2011, defendants issued a press release announcing the submission of a New Drug Application (“NDA”) for Droxidopa in patients with NOH to the FDA, touting the safety and efficacy of the drug. The NDA was accepted by the FDA in November 2011. Defendants subsequently announced that Droxidopa was scheduled for review by the FDA Advisory Committee at a February 23, 2012 meeting, and that the FDA had promised to issue its determination by March 28, 2012.

3. During the Class Period, defendants issued materially false and misleading statements regarding the safety and efficacy of Droxidopa for patients with NOH and the likelihood that it would be approved by the FDA. As a result of defendants’ false statements, Chelsea’s stock traded

at artificially inflated prices during the Class Period, reaching a high of \$8.15 per share on January 10, 2011.

4. On February 13, 2012, defendants announced that the FDA had provided Chelsea with the briefing document that the FDA staff had prepared for the February 23, 2012 Advisory Committee meeting, which raised questions concerning Droxidopa's risk-benefit analysis.

5. On February 21, 2012, the FDA publicly released the briefing document prepared by the staff of the FDA that had been provided to Chelsea on February 13, 2012. The FDA staff, in the briefing document for the FDA Advisory Committee, recommended that Droxidopa for patients with NOH not be approved for use in the United States. The FDA staff stated in the briefing document that Droxidopa had not demonstrated durable effectiveness in clinical trials and showed "worrisome" safety signals in test results and in post-marketing cases in Japan, where it has been in use in lower doses. The FDA physician Melanie Blank stated in the briefing document that "[o]n the basis of the safety concerns compounded by absence of evidence of durability of effect, my regulatory recommendation is that we should not grant approval for droxidopa at this time." "[T]he specter of serious safety issues related to Droxidopa has been raised and should not be ignored." On these two announcements, the price of Chelsea's common stock dropped significantly.

6. Then, on March 28, 2012, Chelsea received a response letter from the FDA to its NDA for Droxidopa. The FDA was requesting that Chelsea submit data from an additional positive study to support the efficacy of Droxidopa and further indicated that additional bioequivalence work would be needed to support the approval of the drug.

7. On this news, Chelsea stock dropped \$1.05 per share, to close at \$2.62 per share on March 29, 2012, a one-day decline of 29% on volume of 9.4 million shares.

8. This action involves alleged material misstatements and omissions by defendants during the Class Period concerning the safety and efficacy of Droxidopa for patients with NOH, the results of the Phase III testing of Droxidopa for patients with NOH, the post-marketing events in Japan, and the likelihood of FDA approval of Droxidopa for patients with NOH in light of the known adverse material facts concerning Droxidopa for patients with NOH. Plaintiff alleges that defendants' material misstatements and omissions violated the federal securities laws and artificially inflated the market price of Chelsea common stock throughout the Class Period. It is further alleged that when the true facts concerning the safety and efficacy of Droxidopa for patients with NOH were revealed to the market, the artificial inflation of Chelsea's common stock was removed and Chelsea's common stock price declined dramatically. Plaintiff and members of the Class allege that they were injured by defendants' wrongful conduct.

9. As a result of defendants' false statements, Chelsea stock traded at artificially inflated levels during the Class Period. However, after the above revelations seeped into the market, the Company's shares were hammered by massive sales, sending them down 68% from their Class Period high.

### **JURISDICTION AND VENUE**

10. This Court has jurisdiction over the subject matter of this action pursuant to §27 of the Exchange Act, 15 U.S.C. §78aa, and 28 U.S.C. §§1331 and 1367.

11. Venue is proper in this District pursuant to §27 of the Exchange Act, 15 U.S.C. §78aa, and 28 U.S.C. §1391(b)-(c). Chelsea maintains its executive offices in this District at 3530 Torington Way, Charlotte, North Carolina 28277. In addition, many of the acts and transactions giving rise to the violations of law alleged herein, including the preparation and dissemination to the public of materially false and misleading information, occurred in this District.

12. In connection with the wrongs complained of herein, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including the United States mails and interstate telephone communications, and the facilities of the NASDAQ, a national securities exchange.

### **THE PARTIES**

13. Plaintiff Michael Klein purchased Chelsea common stock at artificially inflated prices during the Class Period, as set forth in the certification filed herewith.

14. Chelsea is a biopharmaceutical company. Its lead investigational drug in development, and the drug upon which Chelsea's financial and operational success and future hinges, is Droxidopa for patients with NOH. Chelsea has no revenues and is rapidly burning through its cash as it works toward achieving FDA approval for Droxidopa in patients with NOH as quickly as possible. Droxidopa had been granted Orphan Drug Designation and received Fast Track designation from the FDA. During the Class Period, Chelsea was registered with the Securities and Exchange Commission ("SEC") and filed annual, quarterly and other reports with the SEC. The material facts concerning the safety and efficacy of Droxidopa for patients with NOH were critical to the market's assessment of the Company.

15. Defendant Pedder is, and has been since before the commencement of the Class Period, Chelsea's CEO and President and a member of the Company's Board of Directors. Because of his positions with the Company, Pedder had access to the adverse, undisclosed information concerning the safety and efficacy of Droxidopa for patients with NOH, the results of the Phase III trial, the post-marketing events in Japan, the NDA submitted to the FDA, the prospects for FDA approval, the safety and efficacy of Droxidopa for patients with NOH and all material facts concerning the development of Droxidopa for patients with NOH. Pedder directly participated in and controlled the management of the Company, including, without limitation, day-to-day decisions

concerning the development of Droxidopa for patients with NOH, submission of the NDA to the FDA, publication of statements made to the market, the SEC and the FDA concerning the safety and efficacy of Droxidopa for patients with NOH, monitoring of post-marketing events in Japan and publication of statements by and on behalf of Chelsea concerning Droxidopa in patients with NOH in Chelsea's press releases, SEC filings and other public statements.

16. Defendant Hewitt is, and was during all relevant times, the Chief Scientific Officer of Chelsea. Hewitt had knowledge of and/or access to all aspects of the development of Droxidopa for patients with NOH, the results of the clinical trials of Droxidopa and the post-marketing events in Japan. Hewitt made false and misleading statements in Chelsea's press releases concerning the clinical trial results of Droxidopa in patients with NOH, as alleged herein.

17. Pedder, as the senior officer of Chelsea and a director of Chelsea, and Hewitt, as Chelsea's Chief Scientific Officer, each had a duty to disseminate promptly accurate, complete and truthful information with respect to the Company's development of Droxidopa, the safety and efficacy of the drug and the Phase III trial results, and to correct any previously issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly traded common stock would be based upon truthful, complete and accurate information. Pedder and Hewitt each, during the Class Period, violated these specific requirements and obligations by making the false and misleading statements alleged herein in violation of the federal securities laws.

18. Pedder and Hewitt are each primarily liable for the misrepresentations and misleading statements alleged and Pedder is also liable as a controlling person of Chelsea. Pedder and Hewitt are each liable as participants in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Chelsea common stock by disseminating materially false and misleading statements and/or concealing material adverse facts, as alleged herein. The scheme deceived the

investing public regarding Chelsea's financial and operational condition and the prospects for obtaining FDA approval for Droxidopa in patients with NOH and caused plaintiff and other members of the class to purchase Chelsea common stock at artificially inflated prices during the Class Period.

**DEFENDANTS' MATERIALLY FALSE AND MISLEADING  
STATEMENTS MADE DURING THE CLASS PERIOD**

19. On November 3, 2008, Chelsea issued a press release announcing that data from the Phase III trial of Droxidopa demonstrated patients treated with the drug showed a significant reduction in the severity of symptoms associated with NOH. The release stated in part:

“Given the extensive body of existing clinical evidence supporting the efficacy of Droxidopa in the treatment of neurogenic orthostatic hypotension, it is not surprising to see the robust efficacy signal reflected in these data,” commented Dr. Kaufmann. “However, the unique enrichment design of this trial has provided us with the first evidence of an individualized response between 100mg TID through 600 mg TID along with evidence that while Droxidopa has a significant impact on standing systolic blood pressure, patients have only a minimal increase in supine systolic blood pressure. Based on the findings to date, the titration to effect paradigm appears to be a rational and effective method for optimizing treatment in this diverse patient population. I look forward to continuing this clinical evaluation and confirming these preliminary findings in the full study results.”

20. On November 5, 2008, Chelsea issued a press release announcing its third quarter 2008 financial results. The press release stated in part:

“The third quarter was a highly productive one for Chelsea, as we continued to make steady progress in our Droxidopa pivotal program for neurogenic orthostatic hypotension, increasing the number of centers activated in the study, initiating the second trial in this program and securing Fast Track designation from the FDA,” commented Dr. Simon Pedder, President and CEO of Chelsea. “The substantial efforts and achievements in this program were complemented by significant advances in the remainder of our clinical programs. We have now completed enrollment in our CH-1504 Phase II trial in rheumatoid arthritis, are nearing completion of enrollment in our Droxidopa Phase II trial in intradialytic hypotension and are in the process of initiating our Droxidopa Phase II trial in fibromyalgia. Looking ahead, the next few quarters promise not only to be busy, but potentially rewarding as we eagerly anticipate the read out of data from several key trials.”

21. On February 17, 2009, the Company issued a press release announcing findings from the open-label titration portion of its Phase III study. The Company stated the following, in relevant part:

Chelsea Therapeutics International, Ltd. announced that the Company has completed a second analysis of data from the open-label titration portion of its Phase III Study 302 which demonstrated patients treated with Droxidopa, a synthetic precursor to norepinephrine, showed a similarly robust reduction in the severity of symptoms associated with neurogenic orthostatic hypotension (NOH) and a improvement standing systolic blood pressure as reported in November 2008.

Patients identified as responders during the open-label titration phase of the study, and therefore eligible for inclusion in the double-blind, randomized trial, demonstrated a mean improvement of 4.2 units on Item 1 (dizziness or light-headedness) of the Orthostatic Hypotension System Assessment Scale (OHSA) during titration and a mean improvement in standing systolic blood pressure (SBP) of 25 mmHg. The average baseline OHSA score for responders prior to treatment was 6.3 and the average score at the end of the titration was 2.1. The OHSA scale is a validated scale designed to rate symptoms occurring specifically as a result of low blood pressure and uses an 11-point scale (zero to 10), with more severe symptoms scoring higher. The same measure will be used as the primary endpoint in the blinded study to determine the relative difference in symptomatic benefit between Droxidopa and placebo 14 days post-randomization.

22. On March 4, 2009, Chelsea issued a press release announcing its fourth quarter and full year 2008 financial results. The release stated in part:

“2008 marked a year of unprecedented development activity and clinical accomplishment for Chelsea,” commented Dr. Simon Pedder, President and CEO of Chelsea. “Over the course of the past year, we not only successfully initiated five clinical trials, but completed enrollment in two of them by year end. As a direct result of the traction made in each of our programs last year, we have already begun delivering the first in a series of much anticipated reporting events beginning with the positive efficacy data reported from our Phase II IDH study earlier this week, followed by our CH-1504 proof-of-concept data before the end of this quarter and culminating in data from two pivotal trials in our lead Droxidopa indication of neurogenic orthostatic hypotension.”

23. On May 6, 2009, Chelsea issued a press release announcing its first quarter 2009 financial results. The release stated in part:

“During the first quarter, we successfully advanced each of our drug candidates, delivering an impressive succession of data that validated the

development rationale of each of our clinical programs,” commented Dr. Simon Pedder, President and CEO of Chelsea. “Strengthening our balance sheet by regaining full liquidity on our auction rate securities leaves us well positioned to achieve our most significant milestone in 2009, the completion of our pivotal Phase III program in neurogenic orthostatic hypotension, and drive significant value creation for our shareholders.”

24. On June 30, 2009, Chelsea issued a press release announcing it had successfully reached its target enrollment of patients for the first of two pivotal Phase III clinical trials in the Droxidopa program. The release stated in part:

“We are delighted to have reached our target enrollment in Study 302 as this milestone moves us closer to our goal of initiating a U.S. marketing application by year-end and bringing Droxidopa to market for patients suffering from neurogenic orthostatic hypotension,” commented Dr. Simon Pedder, Chelsea’s President and CEO. “As the only therapeutic agent treating the underlying cause of neurogenic orthostatic hypotension, Droxidopa has the potential to become the first line treatment for a significant number of patients in this country. We sincerely appreciate the participation of all the clinicians and patients in this trial who share Chelsea’s commitment to address the needs of this underserved population. With them, we eagerly look forward to seeing the top-line results from this trial and completing enrollment in our second on-going Phase III trial in the third quarter.”

25. On August 5, 2009, Chelsea issued a press release announcing its second quarter 2009 financial results. The release stated in part:

“The robust activity and strong clinical results achieved during the first six months of 2009 provided the opportunity to clearly demonstrate the considerable breadth and value of Chelsea’s pipeline. We clearly established proof-of-concept for our portfolio of metabolically inert antifolates, generated compelling safety and efficacy data on our second compound from this portfolio, and demonstrated the significant symptomatic benefit of Droxidopa for the treatment of intradialytic hypotension in a Phase II trial,” commented Dr. Simon Pedder, President and CEO of Chelsea. “Having completed enrollment in our first pivotal study in June and recently strengthened our balance sheet, we are focusing our attention on several significant value drivers in the second half of the year including data from both pivotal studies in neurogenic orthostatic hypotension, initiation of our first NDA filing, and the launch of our commercialization strategy for Droxidopa in this indication.”

26. On September 9, 2009, Chelsea issued a press release announcing it had achieved its target enrollment in the second of two pivotal Phase III clinical trials for its Droxidopa program.

The release stated in part:

“With top-line data from Study 302 expected within weeks, reaching our target enrollment in Study 301 marks a significant turning point in our Droxidopa development program as we conclude our clinical efficacy evaluations and move ahead with our regulatory submission and commercialization efforts,” commented Dr. Simon Pedder, Chelsea’s President and CEO. “Top-line data from Study 301 is expected late next quarter and we anticipate initiating a rolling NDA submission in the same quarter.”

27. On September 24, 2009, Chelsea issued a press release announcing its preliminary data from the first of two Phase III trials of Droxidopa, which stated in part:

“While the outcome on Item 1 of the OHSA scale did not meet the company’s expectations, our preliminary look at each of the secondary symptomatic outcome measures was encouraging and supportive of the therapeutic benefit of Droxidopa in neurogenic orthostatic hypotension,” commented Dr. Simon Pedder, Chelsea’s President and CEO. “Further, we anticipate a more comprehensive review of the data will help determine the relative impact of a higher than anticipated placebo response and what, if any, additional factors may have contributed to these unexpected results. Key features to the design of this study included an initial 7-day open-label drug treatment period following dose titration and prior to a 14-day randomized withdrawal treatment period. While we intended to stabilize patients immediately prior to withdrawal, the observed decline in BP during this period appears to have had a negative effect on the study’s ability to discern treatment effect. In addition, the benefits of Droxidopa, as measured by both BP and item 1 of the OHSA scale, appeared to persist to some extent despite absence of therapy, raising potential questions regarding the suitability of this type of trial design for an NOH study. We remain hopeful that the results of Study 301, which is a standard induction design study in which patients are washed out between titration and the blinded study, may provide a better opportunity to clearly demonstrate the efficacy of Droxidopa in this indication.”

28. On November 2, 2009, Chelsea issued a press release announcing its third quarter 2009 financial results. The release stated in part:

“Our operational focus during the third quarter was primarily on the completion of our two Phase III trials of Droxidopa in neurogenic orthostatic hypotension and these efforts resulted in the reporting of our first study and reaching our target enrollment in the second,” commented Dr. Simon Pedder, President and CEO of Chelsea. “While we did not achieve statistical significance on our primary

endpoint in Study 302, data from the study clearly demonstrate activity, support the symptomatic and functional benefits, and validate safety and tolerability of Droxidopa in neurogenic orthostatic hypotension. We are currently scheduled to meet with the FDA later this month to solicit feedback on the results of Study 302, discuss what, if any, changes could be made to strengthen then [sic] outcome of Study 301, and determine the best course of action to secure approval of Droxidopa for the treatment of symptomatic NOH in the US.”

29. On December 15, 2009, Chelsea issued a press release announcing approval from the FDA to allow the Company to “modify the primary endpoint and enroll an additional 24 patients in Study 301, a pivotal Phase III study of Droxidopa for the treatment of symptomatic neurogenic orthostatic hypotension.”

30. On March 10, 2010, Chelsea issued a press release announcing its fourth quarter and full year 2009 financial results. The release stated in part:

“During 2009, Chelsea’s development programs generated an unprecedented amount of clinical data all clearly supporting the efficacy of our drug candidates in their target indications,” commented Dr. Simon Pedder, President and CEO of Chelsea. “The combined results of these trials are of great value as we incorporate our findings from the past year, continue to advance our core pipeline of drug candidates and work toward the commercialization of Droxidopa for the treatment of symptomatic neurogenic orthostatic hypotension.”

31. On April 29, 2010, Chelsea issued a press release announcing its first quarter 2010 financial results. The release stated in part:

“During the first quarter, we made substantial progress in advancing our Northera registration program in neurogenic orthostatic hypotension and are on track to have pivotal Phase III data from Study 301 in the third quarter,” commented Dr. Simon Pedder, President and CEO of Chelsea. “As we prepare to complete enrollment in Study 301 in June, we also look forward to beginning patient enrollment this quarter in both our Northera Study 306 and CH-4051 Phase II trial in rheumatoid arthritis. Combined with ongoing studies in fibromyalgia and adult attention deficit hyperactivity disorder, Chelsea is well-positioned to benefit from multiple, value-creating clinical milestones over the next several quarters.”

32. On July 29, 2010, Chelsea issued a press release announcing its second quarter 2010 financial results. The release stated in part:

“The significant progress made since January, both in enrolling more than 40 additional patients into Study 301 and getting a robust start to our enrollment into Study 306, reflect not only the successful efforts of our clinical team but also the growing interest in Northera and support of clinicians seeking a safe and effective treatment option for symptomatic neurogenic orthostatic hypotension,” commented Dr. Simon Pedder, President and CEO of Chelsea. “Having increased the total number of patients and implemented a new endpoint that previously demonstrated a statistically significant symptomatic improvement in this patient population, we eagerly look forward to the results of Study 301 in September.”

33. On November 1, 2010, Chelsea issued a press release announcing its third quarter 2010 financial results. The release stated in part:

“The last few months have been momentous for Chelsea as we reported highly favorable findings from Study 301 demonstrating that Northera provided significant symptomatic relief of neurogenic orthostatic hypotension, continued to enroll patients into Study 306 at a better than expected pace, and substantively strengthened our balance sheet,” commented Dr. Simon Pedder, President and CEO of Chelsea. “While collectively these accomplishments should put us in a strong position to complete our first NDA filing in 2011, we believe they are only just the beginning of a transformative period for Chelsea. Over the next several quarters, we eagerly anticipate reporting data from five on-going clinical trials including: our Phase III trial of Northera in NOH associated with Parkinson’s disease; our Phase II trial of CH-4051 in rheumatoid arthritis; our Phase II trial of droxidopa/carbidopa combination therapy in fibromyalgia; as well as from the investigator-led Phase II trials of droxidopa/carbidopa combination therapy in adult attention deficit hyperactivity disorder and droxidopa monotherapy in chronic fatigue syndrome.”

34. On December 20, 2010, Chelsea issued a press release announcing completion of pre-NDA assessment with the FDA for Droxidopa, which stated in part:

“The successful outcome of our pre-NDA meeting with the FDA reflects the strength of the data already generated by our pivotal program and marks a significant step forward for Chelsea,” commented Dr. Simon Pedder, president and CEO of Chelsea Therapeutics. “We believe that the Phase III trials we have already completed, combined with the extensive Japanese and European data available to us, clearly demonstrate Northera’s meaningful clinical benefit to patients whose day to day lives are severely impacted by the signs and symptoms of neurogenic orthostatic hypotension. Furthermore, based on feedback received during the meeting and subsequent correspondence, we believe the safety profile of Northera is unlikely to result in a black box warning for supine hypertension in its label. We appreciate the guidance that the FDA has given the company as it prepares this new NDA, and look forward to working with the FDA as we seek marketing approval for Northera in the US in 2011.”

35. On January 10, 2011, Chelsea reached its Class Period high of \$8.15 per share. Chelsea's stock was artificially inflated as Chelsea misrepresented the safety and efficacy of Droxidopa for patients with NOH and failed to disclose adverse facts as described below.

36. On March 2, 2011, Chelsea issued a press release announcing its fourth quarter and full year 2010 financial results. The release stated in part:

“Following the robust data generated by our Phase III clinical program and the success of our recent financing, we believe Chelsea is well positioned to seek approval to market Northera in the U.S. for the treatment of symptomatic neurogenic orthostatic hypotension and well funded for a U.S. launch early next year,” commented Dr. Simon Pedder, President and CEO of Chelsea. “In the coming months, I look forward to having the opportunity to report data from multiple Phase II trials of droxidopa in new indications, get our first look at the efficacy of CH-4051 in RA patients and file our first new drug application for Northera.”

37. On April 18, 2011, Chelsea issued a press release announcing confirmation of the NDA filing with the FDA for Droxidopa, which stated in part:

“We believe the remarkable safety and tolerability of Northera coupled with the robust clinical benefit demonstrated throughout our Phase III program provide a strong basis for the approval of Northera as a novel treatment for symptomatic neurogenic orthostatic hypotension,” commented Dr. Simon Pedder, president and CEO of Chelsea Therapeutics. “We continue to be appreciative of the guidance that the FDA has provided to Chelsea as we prepare to file this new NDA in the third quarter of 2011. Following the approval of Northera, we look forward to building on the clinical work currently underway in Study 306B and completing the necessary studies to allow for a post-marketing expansion of the label including a claim that Northera reduces falls in neurogenic orthostatic hypotension from Parkinson's Disease.”

38. On May 9, 2011, Chelsea issued a press release announcing its first quarter 2011 financial results. The release stated in part:

“While we began to ramp up our pre-launch initiatives during the first quarter in anticipation of Northera approval early next year, we continued to seek to strengthen our pipeline through several ongoing trials,” commented Dr. Simon Pedder, President and CEO of Chelsea. “In the coming months, we expect to report what we believe will be compelling data from our Phase II trial of CH-4051 in rheumatoid arthritis, establish proof of concept for droxidopa in multiple norepinephrine related disorders and potentially expand the claims for Northera to include the reduction of falls.”

39. On June 9, 2011, Chelsea issued a press release announcing new data from the Phase III trial of Droxidopa for patients with NOH. The press release highlighted and touted the data from the Phase III clinical trial and summarized two poster presentations of the results at a symposium. The full posters and presentations were available on Chelsea's website. The press release stated that "[Droxidopa] Treatment Provides Durable Beneficial Effects on both Systolic Blood Pressure and the Symptoms of NOH in Patients with Multiple System Atrophy." In the press release, defendant Hewitt is quoted as follows:

"The results from our clinical trials in neurogenic hypotension have consistently highlighted the broad symptomatic benefits of [Droxidopa] in patients with autonomic failure and we are delighted to have had these findings showcased at the Movement Disorder Society's annual meeting . . . . These most recent data from Study 306A, though preliminary, suggests that in addition to chronic symptoms such as dizziness, weakness and fatigue, patients with NOH associated with Parkinson's disease are at a high risk for falls and associated injuries. If our on-going trial, Study 306B, replicates these early findings, it could not only have significant implications for the future treatment of neurogenic orthostatic hypotension but could also have important implications for subsequent studies of Parkinson's disease and other movement disorders associated with norepinephrine depletion."

40. Chelsea issued its financial results for the second quarter of 2011, the three months ended June 30, 2011, in a press release on July 26, 2011 and filed its Form 10-Q with the SEC on July 27, 2011. The press release stated: "[Droxidopa] New Drug Application for the Treatment of [NOH] on Track for Submission in Third Quarter 2011." Defendants further touted the presentation of the Droxidopa data discussed above. Defendant Pedder is quoted in the press release as follows: "During the second quarter of 2011, we made significant advancements toward our near-term objectives of completing our new drug application for [Droxidopa] . . . ." The Form 10-Q, in the Management's Discussion and Analysis ("MD&A") section, misrepresented and failed to disclose material facts, alleged below, concerning the safety and efficacy of the data from the two Phase III clinical trials of Droxidopa for patients with NOH and the post-marketing events in Japan. Pedder signed the Form 10-Q Certification stating that there were no misrepresentations or omissions of

material fact in the Form 10-Q. Both the press release and the Form 10-Q clearly revealed the critical importance of obtaining FDA approval for Droxidopa in patients with NOH as quickly as possible. Chelsea had no revenues and \$13.3 million in operating expenses in the second quarter, up from \$9.9 million in operating expenses in the second quarter of 2010. With only \$68 million in cash on its balance sheet at June 30, 2011, Chelsea was fast running out of cash. Without bringing Droxidopa for patients with NOH to market quickly, Chelsea's future was bleak.

41. On July 26, 2011, Chelsea held a conference call to discuss its second quarter results. Defendants Pedder and Hewitt were present on the call. In discussing the results for the filing of the NDA, defendant Pedder stated,

I have to say it's been incredibly gratifying working along side [the]entire Chelsea team, to see how well this document is coming together as we work on detailing the efficacy of Northera, spend time with the individual study reports, or get into the detailed work of crafting a potential label for Northera. It is difficult not to be struck by the strength of the data and start getting excited about the approval and our next steps . . . .

42. In discussing why Chelsea was confident in receiving FDA approval, Dr. Bill Schwieterman, Chelsea's Chief Medical Officer, stated:

There's lots reasons why we're confident about that, not the least of which is because we have already been designated fast track as part of our overall clinical development program. And programs that are on fast track generally get priority reviews just as part of that alone. But even irrespective of that, we have a drug that addresses serious and unmet medical need. There are no proven established therapies out there that give a patient symptomatic benefits for this condition and we've shown multiple symptomatic benefits, as you know, through our OHQ and through other endpoints throughout the study. So, the long and short of it is that the FDA has really granted us fast track. We've had discussions about priority review. They've given every indication that we're going to get that. And it's obvious that we have a therapy that's going to meet a serious and unmet medical need and in a big way. So we're quite confident.

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Yes, we've had nothing but a good relationship with the FDA, and they've looked favorably on our data all throughout the program, and that continues. And we're

very excited about the prospects, and, as we have discussed, [I] think that this is going to get a quick review at the agency.

43. On September 28, 2011, Chelsea issued a press release announcing the submission of the NDA for Droxidopa and the request to the FDA for Priority Review of the NDA, “which if granted could lead to a decision for marketing approval from the FDA for [Droxidopa] in the first quarter of 2012.” Defendant Pedder touted the results of the clinical trials, stating:

“The NDA submission for [Droxidopa] marks a significant milestone for Chelsea. . . . We believe the robust clinical data generated by our Phase III program clearly demonstrates that [Droxidopa] is safe and effective for treatment of symptomatic NOH. If approved, [Droxidopa] would be the first treatment that specifically improves symptoms of NOH and reduces their impact on a patient’s ability to perform daily activities that require standing or walking. We look forward to working closely with the FDA on this application while progressing other clinical studies currently underway for [Droxidopa] . . . .”

The press release further stated that the “clinical portion of the NDA includes combined safety and efficacy data from Chelsea’s two completed Phase III efficacy studies in NOH. . . , two long-term open-label extension studies, a dedicated thorough QTc study, and a 24-hour ambulatory blood pressure monitoring safety study.”

44. On November 2, 2011, Chelsea filed its Form 10-Q for the quarter ended September 30, 2011, reporting a net loss for the quarter of \$10.9 million. Defendant Pedder signed the Certification stating that there were no misrepresentations or omissions of material fact in the Form 10-Q. The MD&A section of the Form 10-Q misrepresented the safety and efficacy data from the clinical trials of Droxidopa for patients with NOH and failed to disclose the material facts alleged below.

45. Also on November 2, 2011, Chelsea held a conference call to discuss its third quarter results. Defendant Pedder participated in this call. In discussing the Company’s relations with the FDA, Pedder emphasized that “we have had a very good relationship with the FDA. We have had a very transparent discussion, and we expect those to continue during the review cycle.” In

responding to a question about further discussions with the FDA, Dr. Schweiterman noted, “we have had a good discussion with the FDA on a number of fronts and we continue to have a discussion in the normal course of events. So, yes, we’ve been in touch with the FDA and the usual sorts of questions are coming forward. It’s sort of business as usual moving ahead.”

46. On November 17, 2011, Chelsea issued a press release stating that the FDA had accepted the NDA for Droxidopa in patients with NOH and granted it Priority Review, promising to issue its determination on the NDA by March 28, 2012. On January 3, 2012, Chelsea issued another press release announcing that the date for the Advisory Committee meeting to review the NDA and make its recommendation to the FDA was set for February 23, 2012.

47. On January 6, 2012, reflecting a desperate need to raise cash before the truth about the safety and efficacy of Droxidopa in patients with NOH was revealed to the public by the upcoming FDA review process, Chelsea announced a common stock offering of 4.33 million shares. This was a change in plans from the Board’s prior authorization to renew Chelsea’s agreement for an at-the-market-with-equity sales program that would allow Chelsea to periodically sell up to a maximum of \$19.7 million in common stock at the prevailing market prices, provided the stock was trading above \$6 per share. On January 6, 2012, Chelsea’s stock price was trading in the \$5 per share range. Chelsea knew that the FDA staff briefing document would be made public on February 21, 2012, two days before the Advisory Committee meeting, at which time the truth would be in the public domain. Chelsea filed a Prospectus Supplement on January 6, 2012 with the SEC in connection with the common stock offering. On January 11, 2012, Chelsea announced that it had completed its previously announced underwritten public offering of 4,989,275 shares of common stock, including 650,775 shares issued pursuant to the underwriters’ exercise in full of their over-allotment option, at a public offering price of \$4.75 per share, with net proceeds to the Company of

approximately \$19.2 million to \$22.1 million. Additionally, less than one month later, defendants caused Chelsea to file a Form S-3 registration statement with the SEC for the sale of \$100 million worth of common stock, preferred stock, warrants, debt securities, and/or units, which prospectus became effective February 9, 2012. These SEC filings misrepresented and failed to disclose the material facts concerning the safety and efficacy of Droxidopa for patients with NOH alleged below.

48. On February 13, 2012, Chelsea issued a press release stating that it had received the briefing document from the FDA in advance of the Advisory Committee meeting on February 23, 2012. Defendants stated that the FDA had raised questions concerning the risk-benefit analysis of Droxidopa in patients with NOH and several deaths among patients who had taken Droxipoda. Defendant Pedder stated:

“A number of these questions relate to previously discussed issues identified for our development program, namely the short duration of our clinical studies, the limited size of our study population given the orphan indication and the challenges in quantifying symptomatic and clinical benefit. FDA has, however, placed increased emphasis on safety data from our long-term extension program and the post-marketing surveillance program in Japan.”

49. Although defendants sought to downplay the significance of the questions raised by the FDA in the briefing document, the market sensed that there were serious issues with the safety and efficacy of Droxipoda in patients with NOH that defendants had not disclosed to the market. As a result, the market price of Chelsea common stock dropped significantly, declining from \$4.99 per share to close at \$3.11 per share on February 13, 2012.

50. On February 21, 2012, the FDA staff released the briefing document to the market and the truth about the safety and efficacy of Droxipoda for patients with NOH became public. With that news, the market price plunged again from \$3.35 as of the close on February 17, 2012 to a February 21, 2012 closing of \$2.64 per share.

51. Then, on March 28, 2012, Chelsea received a response letter from the FDA to its NDA for Droxidopa. The FDA was requesting that Chelsea submit data from an additional positive study to support the efficacy of Droxidopa and further indicated that additional bioequivalence work would be needed to support the approval of the drug. The release stated in part:

Chelsea Therapeutics International, Ltd. announced today that the U.S. Food and Drug Administration (FDA) has issued a complete response letter regarding the new drug application (NDA) for Northera™ (droxidopa) Capsules. The application, which was filed on September 28, 2011, seeks approval for the treatment of symptomatic neurogenic orthostatic hypotension (known as Neurogenic OH or NOH) in patients with primary autonomic failure (Parkinson's disease, multiple system atrophy and pure autonomic failure), dopamine beta hydroxylase deficiency and non-diabetic autonomic neuropathy and was supported by the highly statistically significant (p=0.003) outcome of Study 301.

The complete response letter includes the request by the FDA that Chelsea submit data from an additional positive study to support efficacy demonstrated in Study 301 along with the recommendation that such a study be designed to demonstrate durability of effect over a 2- to 3-month period. While the FDA did not make reference to the Company's ongoing Study 306, a 10-week double-blind, placebo-controlled trial evaluating Northera in patients with symptomatic neurogenic OH associated with Parkinson's disease, Chelsea believes that data from this trial could potentially meet the criteria for clinical efficacy and durability of effect data identified in the Complete Response Letter. Notably, the complete response letter did not identify any outstanding concerns.

In addition to the clinical requests, the FDA indicated that additional bioequivalence work would be needed to support the approval of a 300mg capsule that Chelsea was considering making commercially available to complement availability of the 100mg and 200mg capsules utilized in Chelsea's clinical program, but would not required this for approval of the NDA.

While Chelsea was not able to engage in active labeling discussions with the FDA and certain sections will be subject to the completion and review of additional data submitted, the Agency did provide draft recommendations to several sections of the labeling submitted for Northera. Most notable was the narrowing of symptomatic benefits claim to emphasize dizziness, lightheadedness, feeling faint or "feeling like you might black out" as the clinical benefit associated with Northera treatment. Further, the FDA has, at this time, made a preliminary recommendation to include a black box warning related to supine hypertension. However, the letter indicates that such a boxed warning could be reconsidered if suitable data demonstrating a lack of severe hypertension in a fully prone position versus the 30-degree head-up tilt, the standard of care and criteria used in the Chelsea clinical program, were provided.

Chelsea plans to request a meeting with the FDA to review the Agency's comments, clinical trial recommendations and to help determine appropriate next steps toward securing approval of Northera.

"Chelsea is dedicated to improving the lives of patients with symptomatic Neurogenic OH," commented Dr. Simon Pedder, president and CEO of Chelsea Therapeutics. "We believe there continues to be an important unmet medical need in addressing the symptoms associated with Neurogenic OH and remain committed to working with the FDA to determine the appropriate next steps required to bring a much needed new therapy to the market as quickly as possible."

52. On this news, Chelsea stock dropped \$1.05 per share, to close at \$2.62 per share on March 29, 2012, a one-day decline of 29% on volume of 9.4 million shares.

#### **ADDITIONAL SCIENTER ALLEGATIONS**

53. As alleged herein, defendants acted with scienter in that they knew or recklessly disregarded that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of information reflecting the true facts regarding the safety and efficacy of Droxidopa for patients with NOH from the clinical trials of Droxidopa for patients with NOH, from the post-marketing events in Japan in patients with NOH who were taking Droxidopa, and from their analysis of the information used in the preparation of the NDA, the prospectus for the common stock offering in January 2012 and the Company's prior statements to the market concerning Droxidopa in patients with NOH, participated in the fraudulent scheme alleged herein.

**DEFENDANTS' KNOWLEDGE OF FACTS RENDERING  
THEIR CLASS PERIOD STATEMENTS FALSE AND MISLEADING**

54. Throughout the Class Period, defendants were involved in the all-important activity at Chelsea of obtaining FDA approval for Droxidopa for patients with NOH. In active and all-consuming pursuit of that goal, defendants knew of the safety and efficacy profile of Droxidopa for patients with NOH. In preparing the NDA, defendants knew of all of the results of the clinical trials of Droxipoda, as well as the post-marketing cases in Japan. In addition, defendants filed a registration statement with the SEC and disseminated a prospectus for Chelsea's common stock offering in January 2012 that required defendants to do their due diligence concerning the material facts regarding the safety and efficacy of Droxidopa for patients with NOH before issuing those documents.

**DEFENDANTS FAILED TO DISCLOSE  
MATERIAL ADVERSE INFORMATION**

55. The statements made by defendants, as alleged above, were false and misleading when made, as defendants knew when they made the statements, because defendants failed to disclose and misrepresented the following material facts when making the statements they made:

(a) The safety database was small in light of disconcerting safety signals which arose during the open-label phases of the trials, including 18 deaths from sepsis, heart attack, pneumonia, respiratory failure and other conditions, strokes, myocardial infarctions, progression of underlying disease and hypertensive crisis;

(b) There were nine cases of life-threatening neuroleptic malignant syndrome over a 10-year period in Japan in patients with NOH who were taking Droxidopa; and

(c) There were no durable effects from the drug lasting more than four weeks, a time frame that did not warrant approval in light of the issues concerning the safety profile of the drug.

56. Defendants' statements and omissions, as alleged herein, failed to disclose the material adverse facts alleged herein that raised serious questions as to the safety and efficacy of Droxidopa for patients with NOH, in light of current and applicable FDA standards for approval of new drugs. As detailed herein, during the Class Period, defendants knew or were reckless in not disclosing the material negative facts concerning the safety and efficacy of Droxidopa for patients with NOH as alleged herein.

57. The facts which defendants failed to disclose and misrepresented were material because they severely impacted the likelihood of FDA approval of Chelsea's NDA for Droxidopa for patients with NOH. Because Droxidopa for patients with NOH is Chelsea's most advanced investigational drug, all facts bearing on the safety and efficacy of the drug and consequent FDA approval of the drug are material.

#### **LOSS CAUSATION/ECONOMIC LOSS**

58. During the Class Period, as detailed herein, defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Chelsea common stock and operated as a fraud or deceit on Class Period purchasers of Chelsea common stock by failing to disclose the adverse data concerning the safety and efficacy of Droxidopa for patients with NOH resulting from the clinical trials of the drug and the post-marketing of the drug in Japan. When defendants' prior misrepresentations, omissions and fraudulent conduct were disclosed and became apparent to the market, the price of Chelsea common stock fell. As a result of their purchases of Chelsea common stock during the Class Period, plaintiff and the other class members suffered economic loss, *i.e.*, damages, under the federal securities laws.

59. By failing to disclose the adverse facts and misrepresenting the clinical trial results concerning the safety and efficacy of Droxidopa for patients with NOH, defendants presented a misleading picture of Chelsea's business and prospects, including the likelihood of FDA approval of

Chelsea's NDA for Droxidopa for patients with NOH. Defendants' false and misleading statements had the intended effect of causing and did in fact cause Chelsea common stock to trade at artificially inflated levels throughout the Class Period and enabled Chelsea to sell 4.33 million shares of common stock of Chelsea to unsuspecting class members in an effort to secure critical cash.

60. As a direct and proximate result of the disclosures on February 13, 2012 and February 21, 2012, alleged above, the price of Chelsea common stock fell precipitously, declining an aggregate 47%, to close at \$2.64 per share on February 21, 2012.

61. Then, as a direct and proximate result of the disclosure on March, 28, 2012, Chelsea stock dropped \$1.05 per share, to close at \$2.62 per share on March 29, 2012, a one-day decline of 29% on volume of 9.4 million shares.

62. These declines removed the artificial inflation from the price of Chelsea common stock, causing real economic loss to investors who purchased Chelsea common stock during the Class Period.

63. The 68% decline in the price of Chelsea common stock after these misrepresentations and omissions came to light was a direct result of defendants' fraud finally being revealed to investors and the market. Moreover, the timing and magnitude of the price decline in Chelsea common stock negates any inference that the loss suffered by plaintiff and the other class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to defendants' fraudulent conduct. The economic loss, *i.e.*, damages, suffered by plaintiff and the other class members was a direct result of defendants' fraudulent scheme to artificially inflate the price of Chelsea common stock and of the subsequent decline in the value of Chelsea common stock when defendants' prior misrepresentations and other fraudulent conduct were revealed.

**APPLICABILITY OF PRESUMPTION OF RELIANCE:  
FRAUD-ON-THE-MARKET DOCTRINE**

64. At all relevant times, the market for Chelsea common stock was an efficient market for the following reasons, among others:

(a) Chelsea common stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Chelsea filed periodic public reports with the SEC;

(c) Chelsea regularly communicated with public investors via established market communication mechanisms, including regular dissemination of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services; and

(d) Chelsea was followed by securities analysts employed by major brokerage firms, banks and investment houses.

65. As a result, the market for Chelsea common stock promptly digested current information regarding Chelsea from all publicly available sources and reflected such information in Chelsea's common stock price. Under these circumstances, all purchasers of Chelsea common stock during the Class Period are entitled to a presumption of reliance. Further, plaintiff is entitled to, and will rely on, the presumption of reliance doctrine based on the material omissions alleged herein.

66. The market for Chelsea common stock was open, well-developed and efficient at all relevant times. As a result of the materially false and misleading statements and failures to disclose alleged herein, Chelsea common stock traded at artificially inflated prices during the Class Period. Plaintiff and other members of the class purchased or otherwise acquired Chelsea common stock relying upon the integrity of the market price of Chelsea common stock and market information relating to Chelsea, and have been damaged thereby.

67. During the Class Period, defendants materially misled the investing public, thereby inflating the price of Chelsea common stock, by publicly issuing false and misleading statements and omitting to disclose material facts necessary to make defendants' statements, as alleged herein, not false and misleading. Said statements and omissions were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company, its business and operations, as alleged herein.

68. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly and proximately caused, or were a substantial contributing cause of, the damages sustained by plaintiff and other members of the class. During the Class Period, defendants made or caused to be made a series of materially false or misleading statements and omitted material facts. These material misstatements and omissions had the effect of creating in the market an unrealistically positive assessment of Droxidopa for patients with NOH and Chelsea's business, prospects and operations, causing the Company's common stock to be overvalued and artificially inflated at all relevant times. Defendants' materially false and misleading statements during the Class Period resulted in plaintiff and other members of the class purchasing the Company's common stock at artificially inflated prices, thus causing the damages complained of herein.

#### **APPLICABILITY OF SAFE HARBOR**

69. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to the false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, defendants are liable for those false

forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Chelsea who knew that those statements were false when made.

### **PLAINTIFF'S CLASS ACTION ALLEGATIONS**

70. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons who purchased or acquired the common stock of Chelsea during the Class Period and who were damaged thereby (the "Class"). Excluded from the Class are defendants and their families, the officers and directors of the Company and its subsidiaries and affiliates, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest and the underwriters of Chelsea's January 2012 common stock offering.

71. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes that there are thousands of members in the proposed Class. As of January 20, 2012, Chelsea had more than 67 million shares of common stock outstanding and 2,740 shareholders of record. Record owners and other members of the Class may be identified from records maintained by Chelsea or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

72. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

73. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

74. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) Whether the federal securities laws were violated by defendants' acts as alleged herein;

(b) Whether statements made by defendants to the investing public during the Class Period misrepresented and/or omitted material facts about Droxidopa for patients with NOH; and

(c) The extent to which members of the Class have sustained damages and the proper measure of damages.

75. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

## COUNT I

### **For Violation of §10(b) of the Exchange Act and Rule 10b-5 Against All Defendants**

76. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

77. During the Class Period, defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (a) deceive the investing public,

including plaintiff and other Class members, as alleged herein; (b) artificially inflate and maintain the market price of Chelsea common stock; (c) enable Chelsea to sell 4.33 million shares of common stock at artificially inflated prices; and (d) cause plaintiff and other members of the Class to purchase Chelsea common stock at inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants took the actions set forth herein.

78. Defendants: (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading; and (c) engaged in acts, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's common stock in an effort to maintain artificially high market prices for such stock in violation of §10(b) of the Exchange Act and Rule 10b-5. In addition to the duties of full disclosure imposed on defendants as a result of their making of affirmative statements and reports, or their participation in the making of affirmative statements and reports to the investing public, defendants had a duty to promptly disseminate truthful information that would be material to investors as required by the integrated disclosure provisions of the SEC, including accurate and truthful information with respect to the Company's operations so that the market price of the Company's common stock would be based on truthful, complete and accurate information.

79. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business and future prospects of Chelsea as alleged herein. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices and a course of conduct as alleged herein in an effort to assure investors of Chelsea's value and performance and

continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Chelsea and its business operations and future prospects, in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon purchasers of Chelsea common stock during the Class Period.

80. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions by defendants were done knowingly or recklessly and for the purpose and effect of concealing the truth concerning the safety and efficacy of Droxidopa for patients with NOH, the likelihood of FDA approval of the NDA and to enable Chelsea to sell its common stock in a public offering before the truth concerning Droxidopa's safety and efficacy were made known by the FDA in February 2012. As demonstrated by defendants' misstatements alleged herein, defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking the steps necessary to discover whether those statements were false or misleading.

81. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Chelsea common stock was artificially inflated during the Class Period. In ignorance of the fact that the market price of Chelsea common stock was artificially inflated, and relying directly or indirectly on the false and misleading statements made by defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or

recklessly disregarded by defendants but not disclosed in public statements by defendants during the Class Period, plaintiff and the other members of the Class acquired Chelsea common stock during the Class Period at artificially high prices and were damaged thereby.

82. At the time of said misrepresentations, plaintiff and other members of the Class were ignorant of their falsity and believed them to be true. Had plaintiff, other members of the Class and the marketplace known of the true facts as alleged herein, which were not disclosed or were misrepresented by defendants, plaintiff and other members of the Class would not have purchased or otherwise acquired their Chelsea common stock during the Class Period, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

83. By virtue of the foregoing, defendants violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

84. As a direct and proximate result of defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of the Company's common stock during the Class Period.

## **COUNT II**

### **For Violation of §20(a) of the Exchange Act Against All Defendants**

85. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

86. Defendants Pedder and Hewitt acted as controlling persons of Chelsea within the meaning of §20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and awareness of the true facts alleged herein, defendants Pedder and Hewitt had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the

Company, including the content and dissemination of the various statements which plaintiff alleges are false and misleading. The Company controlled Pedder and Hewitt and all of its other employees.

87. As alleged above, defendants violated §10(b) and Rule 10b-5 by the acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons of Chelsea, defendants are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of defendants' wrongful conduct, plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's common stock during the Class Period.

### **PRAYER FOR RELIEF**

WHEREFORE, plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action and certifying plaintiff as Lead Plaintiff and as class representative under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Granting such other and further relief as the Court may deem just and proper.

### **JURY DEMAND**

Plaintiff hereby demands a trial by jury.

DATED: April \_\_\_\_, 2012

ESSEX RICHARDS, PA  
NORRIS A. ADAMS, II  
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