

**IN THE MATTER OF THE SECURITIES ACT,  
R.S.O. 1990, c. S.5, as amended**

**-and-**

**IN THE MATTER OF BIOVAIL CORPORATION, EUGENE N. MELNYK,  
BRIAN H. CROMBIE, JOHN R. MISZUK and KENNETH G. HOWLING**

**SETTLEMENT AGREEMENT BETWEEN  
STAFF OF THE ONTARIO SECURITIES COMMISSION AND  
BIOVAIL CORPORATION**

**I. INTRODUCTION**

1. By Notice of Hearing and related Statement of Allegations dated March 24, 2008 (the “Notice of Hearing”), the Ontario Securities Commission (the “Commission”) announced that it proposed to hold a hearing to consider whether, pursuant to s. 127 and s. 127.1(1) and (2) of the *Securities Act*, R.S.O. 1990, c. S.5, as amended (the “Act”), it is in the public interest to make certain orders against Biovail Corporation (“Biovail”), Eugene N. Melnyk (“Melnyk”), Brian H. Crombie (“Crombie”), John R. Miszuk (“Miszuk”) and Kenneth G. Howling (“Howling”) as described in the Notice of Hearing.

**II. JOINT SETTLEMENT RECOMMENDATION**

2. Staff of the Commission (“Staff”) agree to recommend settlement of the proceeding initiated in respect of Biovail by the Notice of Hearing in accordance with the terms and conditions set out below. Biovail agrees to the settlement on the basis of the facts agreed to in Part IV and consents to the making of an Order in the form attached as Schedule “A”.

**III. ACKNOWLEDGEMENT**

3. Biovail admits the facts set out in Part IV of this Settlement Agreement solely for the purposes of this Settlement Agreement. This Settlement Agreement and the

facts and admissions set out herein are without prejudice to Biovail in any other proceeding including, without limitation, any civil, administrative, quasi-criminal or criminal actions or proceedings that may be brought by any person or agency, whether or not this Settlement Agreement is approved by the Commission. On March 24, 2008 Biovail announced that it had resolved a proceeding issued on that day by the United States Securities and Exchange Commission involving similar issues to those raised in this proceeding.

4. Without limiting the generality of the foregoing, Staff and Biovail expressly agree that this Settlement Agreement and the facts and admissions contained in it are made without prejudice to any other respondent to this proceeding and are not intended to, and do not, bind any other respondent to this proceeding, whether in this proceeding or in any other proceeding. In particular, Staff and Biovail acknowledge that Staff intends to pursue all of the allegations raised in the Notice of Hearing against all of the remaining respondents.

#### **IV. FACTS**

5. Biovail is a reporting issuer in the province of Ontario. The common shares of Biovail are listed and posted for trading on the Toronto Stock Exchange and the New York Stock Exchange.
6. Biovail is Canada's largest publicly traded pharmaceutical company. Since the mid-1990s, Biovail's strategy has been to apply advanced drug-delivery technologies to improve the clinical effectiveness of medicines. The Company's business strategy involves commercializing these products both directly (as is the case in Canada) and through strategic partners. Its main therapeutic areas of focus have historically been central nervous system disorders, pain management and cardiovascular disease.
7. Melnyk was the Chairman of the Board of Directors of Biovail until his resignation from the Board effective June 30, 2007. From December 2001 to October 2004 Melnyk was Chairman and Chief Executive Officer of Biovail. Melnyk resigned as

CEO of Biovail on October 8, 2004. Melnyk first became a Director of Biovail in March of 1994. Melnyk became Executive Chairman of the Board of Biovail in November of 2004 and relinquished that title on June 27, 2006. Melnyk is no longer employed by Biovail and is no longer a director of Biovail.

8. Crombie was the Chief Financial Officer of Biovail from May 2000 to August 2004. He became the Senior Vice-President, Strategic Development in August 2004. Crombie is no longer employed by Biovail.
9. Miszuk was the Vice-President, Controller and Assistant Secretary of Biovail until 2008. He had held the positions of Vice-President and Controller since November of 1997, and the position of Assistant Secretary since June of 2000. Miszuk is no longer employed by Biovail
10. Howling was a Senior Vice-President and held the position of Chief Financial Officer of Biovail in 2006 and 2007. Howling was Biovail's Vice-President, Finance and Corporate Affairs from October 2004 to 2006 and Vice-President, Finance from May 2000 to October 2004. During the Material Time (as defined below), Howling also served as Biovail's head of investor relations.

## **Overview**

11. The conduct at issue relates to Biovail's annual financial statements for the fiscal year ended December 31, 2001, interim financial statements for Q3 of 2001, Q1, Q2 and Q3 of 2002, and Q1, Q2 and Q3 of 2003, as well as conduct concerning Biovail's disclosure during that time. These time periods are referred to individually as the "Relevant Fiscal Periods" and collectively as the "Material Time".
12. As a reporting issuer in Ontario, Biovail has continuous disclosure obligations pursuant to Part XVIII of the Securities Act, R.S.O. 1990, c. S-5 as amended (the "Act"). Sections 77 and 78 of the Act and related provisions in the Regulations direct that all financial statements filed with the Commission must be prepared in accordance with generally accepted accounting principles ("GAAP") recommended

in the Handbook of the Canadian Institute of Chartered Accountants. Moreover, all financial statements and other material filed with the Commission must not be misleading or untrue or omit a fact which would render them misleading.

13. Biovail filed with the Commission during the Material Time financial statements that, while represented to be prepared in accordance with Canadian GAAP, were, to the extent described herein, not prepared in accordance with Canadian GAAP and therefore such filings were contrary to sections 77 and 78 of the Act. Further, Biovail's representations that the financial statements had been prepared in accordance with Canadian GAAP were, to the extent described below, materially inaccurate, contrary to Ontario securities law and the public interest.
14. The matters that are the subject of this Settlement Agreement fall into five general categories:
  - (a) Biovail's failure to disclose in the documents filed with the Commission which are listed in Schedule "B" hereto (Biovail's "Public Disclosure") the establishment of and its arrangements with Pharmaceutical Technologies Corporation ("PTC");
  - (b) Biovail's improper recognition in its interim financial statements for Q2 of 2003 of revenue relating to a sale of Wellbutrin XL tablets;
  - (c) Biovail's failure to correct and disclose, on a timely basis, a material error in its 2003 financial statements;
  - (d) Biovail's dissemination of incorrect statements in certain press releases in October 2003 and March 2004, in an analyst conference call held on October 3, 2003, and in investor meetings held in October 2003 relating to a truck accident; and
  - (e) Biovail's provision of materially inaccurate information to OSC Staff during a continuous disclosure review conducted in 2003 and 2004 (the "Continuous Disclosure Review").

**Biovail's Failure to Disclose the Establishment of and its Arrangements with PTC****(a) The Establishment and Activities of PTC**

15. In 2001, Biovail sponsored the creation of a research and development vehicle, eventually incorporated as PTC. PTC was created to engage in the application of Biovail's drug delivery technologies to the formulation and development of a portfolio of six products.
16. On June 28, 2001, an individual equity investor acquired 100 percent of the common shares of PTC for \$U.S. 1 million. The equity investor acted as a consultant to Biovail from November 1999 to November 2001.
17. On June 29, 2001, the equity investor entered into a Share Option Agreement pursuant to which the equity investor granted to Biovail an irrevocable option, exercisable at any time until December 31, 2006 and at Biovail's sole discretion, to purchase all, but not less than all, of the outstanding common shares of PTC, at a price that increased over time.
18. On June 29, 2001, PTC entered into a Product Development and Royalty Agreement ("PDRA") with Biovail. Under the PDRA, PTC contracted to develop six products owned by Biovail Laboratories Inc. ("BLI"), a Biovail subsidiary, in exchange for the receipt of royalties upon the commercialization and sale of these products. PTC was also granted a license to use certain technology owned by BLI to complete the development of the products.
19. During the period June 30, 2001 to December 31, 2002, PTC engaged Biovail and third party developers to carry out research and development activities for the products in question.
20. On December 31, 2002, Biovail acquired 100 percent of the outstanding shares of PTC for \$22,600,000, including costs of acquisition. Biovail represents that, through the acquisition of PTC, Biovail extinguished any future milestone or

**(b) Biovail's Failure to Disclose its Arrangements with PTC**

21. During the period from June 2001 to December 2002 an issuer's continuous disclosure obligations included the filing of an Annual Information Form ("AIF") and an annual and interim Management's Discussion & Analysis ("MD&A") accompanying its financial statements. OSC Rule 51-501- "AIF & MD&A" set out the filing and delivery requirements of AIF and MD&A, as well as the form and content of these documents. The AIF was to be prepared in accordance with Form 44-101F1 and the MD&A was to be prepared in accordance with Form 44-101F2.
22. Pursuant to these disclosure requirements, Biovail was required to disclose, among other things, any event occurring during the reporting period that was reasonably expected to have a material effect on Biovail's business, financial condition or results of operations. Biovail filed AIFs and annual and interim MD&As during the Material Time.
23. On November 5, 2001, Biovail filed a Short Form Base Shelf Prospectus with the Canadian provincial securities commissions in relation to the potential sale of up to U.S. \$1.5 billion in any combination of common shares, debt securities and warrants. Subsequently, on November 14, 2001 and March 26, 2002, Biovail filed two Prospectus Supplements for offerings of 12.5 million common shares for U.S. \$587.5 million and U.S. \$400 million of senior subordinated notes, respectively (the "Prospectus Supplements"). All of these filings are referred to collectively as the "Prospectuses". Biovail was required to provide full, true and plain disclosure of material facts in the Prospectuses.
24. The Prospectus Supplement filed on November 14, 2001 incorporated by reference, among other things, the Q3 interim financial statements for the 2001 fiscal year. The Prospectus Supplement filed on March 26, 2002 also incorporated by reference, among other things, its press release dated February 21, 2002 containing

condensed consolidated balance sheets and income statements as at December 31, 2001.

25. The transfer of the development of the products and the related development expenses from Biovail to PTC was an event that was reasonably expected to have a material effect on Biovail's business, financial condition or results of operations and was a material fact.
26. The acquisition of PTC by Biovail was disclosed in a Form 20-F filed on May 20, 2003, which contained the annual and Q4 interim financial statements for its 2002 fiscal year. This was several months after Biovail had purchased PTC.
27. Biovail failed to disclose in its Public Disclosure during the Material Time the existence of PTC and the nature and substance of Biovail's arrangements with PTC. In so doing, Biovail violated the requirements of Ontario securities law and acted in a manner contrary to the public interest.

#### **Misleading Information Provided to OSC Staff during Continuous Disclosure Review**

28. During the Continuous Disclosure Review, Staff requested information from Biovail in relation to several issues, including the arrangements between Biovail and PTC.
29. A letter to Staff from Biovail dated January 28, 2003 contained the following statement: “[n]one of Biovail, nor any of its affiliates, directors or officers were involved in the formation of [PTC]”. This statement was materially inaccurate. By making this statement, Biovail violated Ontario securities law and engaged in conduct contrary to the public interest.

#### **Improper Revenue Recognition in Q2 2003 Financial Statements – the Wellbutrin XL Bill and Hold Arrangement**

30. On July 29, 2003, Biovail released its financial results for the quarter ending June 30, 2003 (the “Q2 2003 Press Release”). These results were further disseminated in a conference call and webcast held on July 29, 2003 (the “Q2 2003 Analyst

Call”). Biovail subsequently filed financial statements for this quarter with the Commission on August 29, 2003 (the “Q2 2003 Financial Statements”).

31. The Q2 2003 Press Release, Q2 2003 Analyst Call and the Q2 2003 Financial Statements included in Biovail’s revenue for the quarter approximately U.S. \$8 million relating to a sale of Wellbutrin XL (“WXL”) tablets to GlaxoSmithKline PLC (“GSK”) that was purportedly carried out on a “bill-and-hold” basis. Inclusion of this amount in revenue for the quarter increased Biovail’s operating income by approximately U.S. \$4.4 million. The transaction did not meet all of the revenue recognition requirements under Canadian GAAP for a bill and hold arrangement. Accordingly, the inclusion of the revenue in Q2 2003 was improper.

**(a) The Wellbutrin XL Agreement**

32. On October 26, 2001, Biovail (through its subsidiary BLI) entered into a Development, License and Co-Promotion Agreement with GSK. This agreement was modified by a Memorandum of Understanding effective January 1, 2003 (together, these two documents form the “Agreement”). Under the Agreement, Biovail agreed to manufacture and supply all of GSK’s requirements for tablets of WXL.
33. Under the Agreement, Biovail was to supply GSK with WXL tablets at two price points: “trade” prices for tablets which were to be sold to the public, and “sample” prices for tablets which were to be distributed free through physicians in order to promote the tablets in the marketplace.
34. Under the Agreement, the prices were fixed for sample tablets. Prices for trade tablets were based upon a tiered percentage of GSK’s net sales of WXL, and were higher than the sample tablet prices. The Agreement contemplated that Biovail would package the trade tablets at its own expense.
35. At the time of entering into the Agreement, WXL had not been approved by the U.S. Food and Drug Administration, and thus could not be sold to the public.

36. The FDA approved WXL on August 28, 2003. This included approving the form of packaging and labelling for WXL.

**(b) GSK's Purchase Orders**

37. The Agreement did not impose an obligation on Biovail to manufacture WXL prior to FDA approval. The Agreement did not make specific provision, whether through milestone payments or otherwise, for the expenses of pre-launch manufacture of WXL. It also did not specifically contemplate a price at which pills manufactured prior to launch would be sold.
38. During 2002, Biovail and GSK representatives met to discuss the pre-launch manufacture of WXL.
39. In April 2003, GSK sent out an initial order for 30,400,000 WXL tablets, for which it proposed to pay the sample prices provided in the Agreement (the "April Purchase Order"). These tablets were requested for June delivery.
40. Throughout April, May and June 2003, GSK and Biovail representatives continued to discuss the pre-launch manufacture of WXL. The parties agreed that in addition to the April Purchase Order, GSK would place an order for WXL for which it would pay a fixed price.
41. On June 20, 2003, GSK sent Biovail a purchase order requesting 27,090,000 WXL tablets at a fixed price per tablet and a \$1.00 per bottle packaging fee (the "June Purchase Order"). The June Purchase Order replaced the April Purchase Order and therefore also contained an order for 30,400,000 WXL tablets at sample prices.

**(c) The Recognition of Revenue**

42. On June 30, 2003, Biovail invoiced GSK for a total of 18,020,244 WXL tablets at fixed trade prices for a total amount of \$8,073,051.24 (the "June Invoice"). Biovail recorded this latter figure as revenue for its fiscal quarter ending June 30, 2003. The inclusion of this revenue increased Biovail's operating income for the quarter by approximately \$4.4 million, which was a material amount.

**(d) The Purported Bill-And-Hold Arrangement**

43. The June Invoice identified by lot number the specific WXL tablets that it encompassed (the “Specified Tablets”). Biovail represents that, subsequent to June 30, 2003, it maintained the Specified Tablets in a segregated area of its warehouse in Steinbach, Manitoba, and in a designated “site” in its inventory system. Biovail did not, however, supply all of the Specified Tablets to GSK in accordance with the terms reflected on the June Purchase Order and the June Invoice.
44. On August 1, 2003 and August 22, 2003, Biovail shipped some of the Specified Tablets to GSK as sample product. By August 31, 2003 Biovail had replaced most of those Specified Tablets with new WXL tablets (the “Pill Switch”).
45. Biovail ultimately cancelled the June Invoice and re-issued a different invoice, with different lot numbers, reflecting the sale of the new WXL tablets at the fixed prices agreed in the June Purchase Order. Credit notes were issued to prevent double-billing.
46. In July 2003, during the review of Biovail’s Q2 2003 financial statements by Biovail’s auditors, Biovail was questioned about the sale of the Specified Tablets at fixed trade prices. Biovail did not, at that time, inform its auditors that the sale was conducted on a “bill and hold” basis or of the Pill Switch.
47. In early 2004, as part of their 2003 year-end audit, Biovail’s auditors questioned the WXL revenue recorded on June 30. In response, Biovail represented that the WXL arrangement had been conducted on a bill-and-hold basis. Biovail represented that it had reached an agreement with GSK prior to June 30, 2003 that the Specified Tablets would be initially segregated within its warehouse and later shipped to GSK after FDA approval was received. The auditors required Biovail to obtain confirmation of certain particulars of the bill and hold arrangement that had not been memorialized in any contemporaneous documentation. Biovail asked for and received confirmation from GSK in the form required by the auditor.

(e) **Premature Recognition of Revenue**

48. Canadian GAAP provides that in most cases, revenue is not recognized until the passing of possession of goods. In other words, in most cases, revenue should not be recognized until delivery has occurred. Delivery generally is not considered to have occurred unless the product has been delivered to the customer's place of business or to another site specified by the customer.
49. "Bill and hold" transactions, in which delivery of the goods does not immediately take place, provide an exception to general revenue recognition principles. Such transactions, however, must meet very specific accounting requirements.
50. Biovail represents that it recognized the revenue with respect to the sale of the Specified Tablets on June 30, 2003 on a "bill and hold" basis.
51. However, Biovail now acknowledges that the revenue recognition requirements, under Canadian GAAP, for a "bill and hold" arrangement were not met with respect to the Specified Tablets.
52. Accordingly Biovail should not have recognized revenue in its Q2 2003 Financial Statements from the sale of WXL pills pursuant to the purported "bill and hold" arrangement. Biovail therefore violated Ontario securities law and engaged in conduct contrary to the public interest.
53. In its Q2 2003 Press Release and Q2 2003 Analyst Call, Biovail disseminated the financial results which incorporated this improperly recognized revenue. Doing so violated Ontario securities law and was contrary to the public interest.

**Biovail's Failure to Correct and Disclose on a Timely Basis a Material Financial Statement Error – The Foreign Exchange Error**

54. On April 29, 2003 Biovail released its financial results for the quarter ending March 31, 2003 (the "Q1 2003 Press Release"). As set out above, Biovail released its financial results for Q2 2003 on July 29, 2003. On October 30, 2003 Biovail

released its financial results for the quarter ending September 30, 2003 (the “Q3 2003 Press Release”). Biovail subsequently filed financial statements for the first quarter on May 30, 2003 (the “Q1 2003 Financial Statements” ), for the second quarter on August 29, 2003 (as defined above, the “Q2 2003 Financial Statements”) and for the third quarter on November 28, 2003 (the “Q3 2003 Financial Statements”).

55. Biovail failed to account properly for an obligation denominated in Canadian dollars in its Q1 2003 Financial Statements, its Q2 2003 Financial Statements and its Q3 2003 Financial Statements. Although questions regarding the proper recording of the Canadian dollar obligation had been raised by Biovail accounting personnel in early July 2003, prior to the release of its Q2 2003 financial results and the filing of the Q2 2003 Financial Statements, Biovail did not disclose the error until it issued on March 3, 2004 its earnings release for the fourth quarter 2003 and the full fiscal year ended December 31, 2003 (the “March 3, 2004 Press Release”).
56. In December of 2002, Biovail, through its subsidiary BLI, acquired the rights to certain drugs. In so doing, Biovail assumed an obligation denominated in Canadian dollars. Since Biovail reported its results in U.S. dollars, it was required to account for this obligation in its financial statements in U.S. dollars. Biovail properly accounted for this obligation in December 2002 when it converted the obligation from Canadian dollars to U.S. dollars using the then current U.S.\$/CAN\$ exchange rate (“FX Rate”).
57. Canadian GAAP requires that any outstanding balance of a foreign currency denominated obligation that is a monetary item be revalued using the FX Rate current at each balance sheet date. At March 31, 2003, however, Biovail, continued to use the FX Rate from December 2002 (the “Error”). Biovail also continued to use the FX Rate from December 2002 on June 30, 2003 and September 30, 2003. The interim financial statements for Q1, Q2 and Q3 of 2003 therefore did not

accurately reflect any unrealized exchange losses or gains and the outstanding balance of the obligation.

58. In early July 2003, the Error was raised with Biovail by BLI. Biovail represents that no immediate steps were taken to analyse the issue and confirm whether the appropriate accounting treatment was being used. The interim financial statements issued for Q2 2003 and Q3 2003 continued to record the debt obligation based on the FX Rate as of December 2002.
59. In 2004, in consultation with its auditors, Biovail took steps to file restated interim financial statements for Q1, Q2 and Q3 2003. Biovail disclosed the Error in a Press Release on March 3, 2004 and filed its restated interim financial statements on May 14, 2004. As a result of the restatement, Biovail's net income decreased by U.S. \$5.4 million and \$3.9 million for the Q1 and Q2 2003 Financial Statements respectively, and increased by \$3.1 million for the Q3 2003 Financial Statements.
60. In relation to the Error, Biovail failed to promptly analyze and deal with an issue that had the potential to, and did in fact, have a material effect on their financial statements. This resulted in the material under-reporting of income in one quarter, and the material over-reporting of income in two quarters. Biovail's conduct in this regard was contrary to Ontario securities law and the public interest.

#### **Biovail's Statements in Press Releases – The Truck Accident**

61. Biovail made statements in press releases issued on October 3, 8 and 30, 2003 and March 3, 2004 that, in a material respect, inaccurately disclosed the implications, for Biovail, of a truck accident that occurred on October 1, 2003.
62. The press releases concerned Biovail's disclosure that its preliminary financial results for its third quarter of 2003 would be below previously issued guidance. Particulars of the statements are outlined below.

**(a) Biovail's Revenue and Earnings Expectations**

63. On February 7, 2003, Biovail publicly disclosed in a press release its revenue and earnings guidance for 2003. The revenue range projected for the third quarter of 2003 was U.S. \$260 million to U.S. \$300 million.
64. Biovail did not achieve its third quarter 2003 revenue and earnings expectations. Rather, in its October 30, 2003 press release, Biovail reported U.S. \$215.3 million in revenue for that quarter.

**(b) The October 3, 2003 Press Release**

65. In a press release issued on October 3, 2003 (the "October 3, 2003 Press Release"), Biovail stated that its preliminary results for its 2003 third quarter "will be below previously issued guidance...Contributing significantly to this unfavourable variance was the loss of revenue and income associated with a significant in-transit shipment loss of Wellbutrin XL as a result of a traffic accident ... Revenue associated with this shipment is in the range of [U.S.] \$10 to [U.S.] \$20 million".
66. A truck carrying WXL tablets, destined for GSK's facility in the United States, departed from Biovail's warehouse in Steinbach, Manitoba on September 30, 2003.
67. The contractual delivery term between Biovail and GSK meant that Biovail would be entitled to recognize the revenue associated with a WXL shipment only when that shipment reached GSK's facility.
68. The truck carrying the WXL shipment was scheduled to reach GSK's facility after September 30, 2003. Biovail, therefore, could recognize the revenue associated with the WXL shipment only in its fourth quarter which ended on December 31, 2003.
69. On October 1, 2003, the truck carrying the WXL shipment was involved in an accident. However, given the f.o.b. destination contractual term, the truck accident had no impact on Biovail's revenue for its 2003 third quarter.

70. The traffic accident referred to in the press release was therefore not a reason for Biovail's failure to meet its previously issued revenue guidance for the third quarter of 2003.
71. The October 3, 2003 Press Release also stated that "[r]evenue associated with the [WXL] shipment was in the range of [U.S.] \$10 million to [U.S.] \$20 million". This statement was incorrect. Regardless of the truck accident, Biovail would not have been able to recognize the associated revenue until its fourth quarter for the reasons outlined above. Further, Biovail's statement that the value of the WXL shipment was U.S. \$10 million to U.S. \$20 million was materially in error. Biovail later stated in a March 3, 2004 press release, discussed below, that the "actual revenue loss" from the shipment on the truck was U.S. \$5 million.

**(c) The October 8, 2003 Press Release**

72. On October 8, 2003, Biovail issued a further press release (the "October 8, 2003 Press Release") which stated that Biovail had recovered the WXL shipment involved in the accident and that 60 percent of the shipment was saleable and might be re-shipped within 30 days. The press release went on to state "Biovail re-confirms that the sales value of these goods is within previously stated guidance".

**(d) The October 30, 2003 Press Release**

73. In its earnings press release for the third quarter of 2003 issued on October 30, 2003 (the "October 30, 2003 Press Release"), Biovail stated that "[a] late third quarter 2003 shipment of Wellbutrin XL involved in an accident outside of Chicago was returned to Biovail's facility on October 8, 2003 for inspection. No revenue was recognized from this shipment in Q3 2003."

**(e) The March 3, 2004 Press Release**

74. The March 3, 2004 Press Release stated that "Biovail announced [on October 3, 2003] that its estimated revenue from Wellbutrin XL for third quarter 2003 would be less than [U.S.] \$10 million partially as a result of the truck accident and that the loss in revenue due to the accident would be in the range of [U.S.] \$10.0 million to

[U.S.] \$20.0 million”. The March 3, 2004 Press Release further stated that “the actual revenue loss from the accident was determined to be [U.S.] \$5.0 million”. In fact, Biovail knew that there was no revenue loss in Q3 2003 as a result of the truck accident.

75. The October 8 and October 30, 2003 Press Releases, and the March 3, 2004 Press Release continued to disseminate the prior information provided by Biovail in its October 3, 2003 Press Release and failed to correct the incorrect information previously provided to the investing public.

**(f) October 3, 2003 Analyst Call**

76. Biovail held a conference call with analysts and a webcast held on October 3, 2003 following the release of the October 3, 2003 Press Release (the “October 3, 2003 Analyst Call”). During the October 3, 2003 Analyst Call, Biovail stated that the accident would have a material negative financial impact on its third quarter revenues. Biovail further stated that the negative impact of the truck accident on revenue would be in the range of U.S. \$15 million to U.S. \$20 million.
77. During the October 3, 2003 Analyst Call, an analyst questioned whether the accident would have fourth quarter rather than third quarter implications. Biovail responded that it was purely a third quarter issue.
78. For the reasons previously described, the above statements were incorrect in a material respect.

**(g) October 2003 Investor Meetings**

79. In October 2003, Biovail held a series of meetings with investors to, among other things, deal with questions surrounding the truck accident and the related announcements that followed (the “Investor Meetings”). The Investor Meetings took place in various cities on October 10, 13, 14 and 15 of 2003. The presentation materials contained similar incorrect statements to those described above.

80. Specifically, the presentation materials included a slide with the heading “Revised third quarter guidance” which stated “Revenue and EPS effected (sic) by three items[:] 1. Wellbutrin XL shipment / traffic accident ...”. Another slide entitled “Wellbutrin XL – timing issue” stated “Impact to Q3 ... Revenue [U.S.] \$10 to [U.S.] \$20 million”.
81. In summary, in the October 3, 2003 Press Release, Biovail made the claim that a truck accident was one of the reasons for Biovail’s failure to meet previously issued revenue guidance for the quarter. Also, Biovail disseminated information in its statement that the revenue associated with the WXL shipment was in the range of U.S. \$10 million to U.S. \$20 million. Biovail repeated, or implicitly reinforced these claims during the October 3, 2003 Analyst Call, and in statements made in the October 8, 2003 Press Release, the October 30, 2003 Press Release, the March 3, 2004 Press Release and the Investor Meetings.
82. Biovail should have taken greater care, from the outset, to accurately assess the revenue associated with the product on the truck, and to accurately assess whether, but for the accident, it would have been able to recognize revenue from the sale of the product on the truck in Q3. Upon learning the true state of affairs, Biovail should have clearly disclosed, at the earliest opportunity, that the truck accident was a Q4 issue. Biovail should have clearly disclosed, at the earliest opportunity, the revenue associated with the product on the truck. Biovail should have clearly disclosed, at the earliest opportunity, that previous statements suggesting that the truck accident was one of the reasons for the Q3 earnings miss, and that the revenue associated with the product on the truck was between \$10 million and \$20 million, were incorrect. By failing to do so, Biovail violated Ontario securities law and engaged in conduct contrary to the public interest.

## **V. TERMS OF SETTLEMENT**

83. Biovail agrees to the terms of settlement listed below.

84. The Commission will make an order pursuant to section 127(1) and section 127.1 of the Act that:
- (a) The Settlement Agreement be approved;
  - (b) Biovail be reprimanded;
  - (c) Biovail pay an administrative penalty of CAN\$5 million, to be paid to or for the benefit of third parties designated by the Commission, pursuant to section 3.4(2) of the Act;
  - (d) Biovail pay CAN\$1.5 million in respect of a portion of the costs of the investigation and hearing in relation to his matter;
  - (e) Pursuant to a Consent Final Judgment entered in the United States District Court for the Southern District of New York in *Securities and Exchange Commissions v. Biovail Corporation, et al.*, dated March 18, 2008, Biovail has retained a consultant (the “Consultant”) to conduct a comprehensive examination and review of Biovail’s internal accounting controls, policies and procedures, training, ethics and compliance policies and procedures and other matters (the “Review”). The terms of reference for the Consultant are attached hereto as Schedule “C”. The Consultant is required to provide reports from time to time to Biovail’s board of directors, audit committee and the United States Securities and Exchange Commission. Biovail will provide Staff with copies of any such reports;
  - (f) Biovail shall retain a further consultant acceptable to Staff (the “Ontario Consultant”) to examine and report on Biovail’s training of its personnel concerning compliance with the financial and other reporting requirements of Ontario securities law (the “Ontario Review”). In conducting the Ontario Review, the Ontario Consultant shall consider the investigations carried out by, and the reports prepared by, the Consultant pursuant to the Review, and may conduct such further investigations as are reasonably necessary. The

terms of reference for the Ontario Review are attached hereto as Schedule “D”; and

- (g) Biovail shall use its best efforts to ensure that individuals who are current or former Biovail employees, and whom Staff wishes to interview, or call to testify at the hearing in this proceeding, are made available as Staff may reasonably require. Biovail shall use its best efforts to provide such additional documentation as Staff may reasonably require for the purposes of this proceeding.

## **VI. STAFF COMMITMENT**

- 85. If the Commission approves this Settlement Agreement, Staff will not commence any proceeding against Biovail under Ontario securities law in relation to the facts alleged in the Notice of Hearing.
- 86. If the Commission approves this Settlement Agreement and Biovail fails to comply with any of the terms of the Settlement Agreement, Staff may bring proceedings under Ontario securities law against Biovail. These proceedings may be based on, but are not limited to, the facts alleged in the Notice of Hearing as well as the breach of the Settlement Agreement.

## **VII. PROCEDURE FOR APPROVAL OF SETTLEMENT**

- 87. The parties will seek approval of this Settlement Agreement at a public hearing before the Commission according to the procedures set out in this Settlement Agreement and the Commission’s Rules of Practice.
- 88. Staff and Biovail agree that this Settlement Agreement will form all of the agreed facts that will be submitted at the settlement hearing, unless the parties agree that additional facts should be submitted at the settlement hearing.
- 89. If the Commission approves this Settlement Agreement, Biovail agrees to waive all rights to a full hearing, judicial review or appeal of this matter under the Act.

90. If the Commission approves this Settlement Agreement, neither party will make any public statement that is inconsistent with this Settlement Agreement or with any additional agreed facts submitted at the settlement hearing.
91. Whether or not the Commission approves this Settlement Agreement, Biovail will not use, in any proceeding, this Settlement Agreement or the negotiation or process of approval of this agreement as the basis for any attack on the Commission's jurisdiction, alleged bias, alleged unfairness, or any other remedies or challenges that may otherwise be available.

#### **PART VIII – DISCLOSURE OF SETTLEMENT AGREEMENT**

92. If the Commission does not approve this Settlement Agreement or does not make the order attached as Schedule "A" to this Settlement Agreement:
- (a) this Settlement Agreement and all discussions and negotiations between Staff and Biovail before the settlement hearing takes place will be without prejudice to Staff and Biovail; and
  - (b) Staff and Biovail will each be entitled to all available proceedings, remedies and challenges, including proceeding to a hearing of the allegations contained in the Notice of Hearing. Any proceedings, remedies and challenges will not be affected by this Settlement Agreement, or by any discussions or negotiations relating to this agreement.
93. Both parties will keep the terms of the Settlement Agreement confidential until the Commission approves the Settlement Agreement. At that time, the parties will no longer have to maintain confidentiality. If the Commission does not approve the Settlement Agreement, both parties must continue to keep the terms of the Settlement Agreement confidential, unless they agree in writing not to do so or if required by law.

**PART IX – EXECUTION OF SETTLEMENT AGREEMENT**

94. The parties may sign separate copies of this agreement. Together, these signed copies will form a binding agreement.
95. A fax copy of any signature will be treated as an original signature.

DATED AT Toronto, this 7<sup>th</sup> day of January, 2009

**STAFF OF THE ONTARIO SECURITIES COMMISSION**

By: “Peggy Dowdall-Logie”

Name: Peggy Dowdall-Logie

Title: Executive Director

**BIOVAIL CORPORATION**

By: “Wendy Kelley”

Name: Wendy Kelley

Title: General Counsel & Corporate Secretary

I have authority to bind the corporation

**SCHEDULE – “A” – DRAFT ORDER**

**IN THE MATTER OF THE SECURITIES ACT,  
R.S.O. 1990, c.S.5, as amended**

**- and -**

**IN THE MATTER OF BIOVAIL CORPORATION, EUGENE N. MELNYK,  
BRIAN H. CROMBIE, JOHN R. MISZUK and KENNETH G. HOWLING**

**ORDER  
(Sections 127 and 127.1)**

**WHEREAS** on March 24, 2008 the Ontario Securities Commission (the “Commission”) issued a Notice of Hearing and related Statement of Allegations (the “Notice of Hearing”) against Biovail Corporation (“Biovail”), Eugene N. Melnyk , Brian H. Crombie, John R. Miszuk and Kenneth G. Howling;

**AND WHEREAS** Biovail has entered into a settlement agreement with Staff of the Commission dated January 7, 2009 (the “Settlement Agreement”) in relation to the matters set out in the Notice of Hearing;

**UPON** reviewing the Notice of Hearing and Settlement Agreement, and upon hearing submissions from counsel for Biovail and for Staff of the Commission;

**AND WHEREAS** the Commission is of the opinion that it is in the public interest to make this Order;

**IT IS HEREBY ORDERED** that:

1. The Settlement Agreement is approved.
2. Biovail is reprimanded.

3. Biovail shall pay an administrative penalty of CAN\$5,000,000.00 to be paid to or for the benefit of third parties designated by the Commission, pursuant to section 3.4(2) of the Act.
4. Biovail shall pay CAN\$1,500,000.00 in respect of a portion of the costs of the investigation and hearing in relation to his matter.
5. Pursuant to a Consent Final Judgment entered in the United States District Court for the Southern District of New York in *Securities and Exchange Commissions v. Biovail Corporation, et al.*, dated March 18, 2008, Biovail has retained a consultant (the “Consultant”) to conduct a comprehensive examination and review of Biovail’s internal accounting controls, policies and procedures, training, ethics and compliance policies and procedures and other matters (the “Review”). The terms of reference for the Consultant are attached to the Settlement Agreement as Schedule “C”. The Consultant is required to provide reports from time to time to Biovail’s board of directors, audit committee and the United States Securities and Exchange Commission. Biovail will provide Staff with copies of any such reports.
6. Biovail shall retain a further consultant acceptable to Staff (the “Ontario Consultant”) to examine and report on Biovail’s training of its personnel concerning compliance with the financial and other reporting requirements of Ontario securities law (the “Ontario Review”). In conducting the Ontario Review, the Ontario Consultant shall consider the investigations carried out by, and the reports prepared by, the Consultant pursuant to the Review, and may conduct such further investigations as are reasonably necessary. The terms of reference for the Ontario Review are attached to the Settlement Agreement as Schedule “D”.
7. Biovail shall use its best efforts to ensure that individuals who are current or former Biovail employees, and whom Staff wishes to interview, or call to testify at the hearing in this proceeding, are made available as Staff may reasonably require. Biovail shall use its best efforts to provide such additional documentation as Staff may reasonably require for the purposes of this proceeding.

Dated at Toronto this            day of January, 2009.

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**SCHEDULE “B” – BIOVAIL’S PUBLIC DISCLOSURE**

<b>Document Description</b>	<b>Content</b>	<b>Filing Date</b>
Form 20-F – For the year ended December 31, 2001	AIF, Cdn. and U.S. GAAP MD&A and financial statements	21-May-2002
Form 20-F – For the year ended December 31, 2002	AIF, Cdn. and U.S. GAAP MD&A and financial statements	20-May-2003
Form 6K – For the quarter ended September 30, 2001	U.S. GAAP MD&A and financial statements	13-Nov-2001
Third Quarter 2001 Interim Report - For Canadian Regulatory Purposes	Cdn. GAAP MD&A and financial statements	13-Nov-2001
Form 6K - For the quarter ended March 31, 2002	Cdn. and U.S. GAAP MD&A and financial statements	30-May-2002
Form 6K - For the quarter ended June 30, 2002	Cdn. and U.S. GAAP MD&A and financial statements	29-Aug-2002
Form 6K - For the quarter ended September 30, 2002	Cdn. and U.S. GAAP MD&A and financial statements	26-Nov-2002
Shelf Prospectus	----	05-Nov-2001
Prospectus Supplement	----	14-Nov-2001
Prospectus Supplement	----	26-Mar-2002

**SCHEDULE “C” – TERMS OF REFERENCE FOR THE CONSULTANT**

5. Defendant agrees to comply with the following undertakings:

A. Retention of a Consultant

i. Biovail shall retain, pay for, and enter into an agreement with an independent consultant ("Consultant"), not unacceptable to the Commission staff, to conduct a comprehensive examination and review of the areas specified below and to make recommendations to Biovail's board of directors and the Commission staff. The Consultant's compensation and expenses shall be borne exclusively by Biovail, and shall not be deducted from any amount due under the provisions of the Final Judgment.

ii. The agreement with the Consultant ("Agreement") shall provide that the Consultant examine:

a. Biovail's internal accounting controls and its internal controls over financial reporting, provided, however, that the Consultant may, if appropriate, rely on Biovail's independent accountant's attestation and report on management's assessment of the effectiveness of Biovail's internal control structure and procedures pursuant to Section 404 of the Sarbanes-Oxley Act;

b. The policies, procedures, and effectiveness of Biovail's regulatory and compliance functions, including the operations of any committees or other mechanisms established to review and approve transactions or for the purpose of preventing the recording of transactions or financial reporting results in a manner that is not in compliance with U.S. generally accepted accounting principles;

c. Biovail's training of its accounting staff concerning financial reporting and U.S. generally accepted accounting principles;

d. Biovail's ethics and compliance policies, including the adequacy and effectiveness of any whistleblower procedures designed to allow employees and others to report confidentially matters that may bear on Biovail's financial reporting obligations;

e. Biovail's records management and retention policies and procedures, including without limitation such procedures with respect to e-mail and other electronically stored information;

f. The functioning of Biovail's audit committee, including the audit committee's policies and procedures and the methods for the selection of its members;

g. Biovail's policies and procedures with respect to compliance with Rule 302(b) of Regulation S-T;

h. Biovail's investor relations and public affairs functions, including policies and procedures designed to enhance the quality and accuracy of Biovail's press releases, investor conference calls, and other similar public disclosures;

i. Biovail's policies and procedures concerning its communications with its outside auditors.

**B. Consultant's Reporting Obligations**

i. The Consultant shall issue a report to Biovail's board of directors, its audit committee, and to the Commission staff within three months of appointment, provided however, that the Consultant may seek to extend the period of review for one additional three-month term by requesting such an extension from the Commission's staff. The Commission's staff, after consultation with Biovail, shall have discretion to grant such extension for the period requested if deemed reasonable and warranted.

ii. The Consultant's report shall address the Consultant's review of the areas specified in paragraph 5.A.ii above and shall include a description of the review performed, the conclusions reached, the Consultant's recommendations for any changes or improvements to Biovail's policies and procedures as the Consultant reasonably deems necessary to conform to the law and best practices, and a procedure for implementing the recommended changes or improvements.

iii. Biovail shall adopt all recommendations contained in the Consultant's report, provided, however, that within forty-five days of its receipt of the report, Biovail shall in writing advise the Consultant and the Commission staff of any recommendation that it considers to be unnecessary or inappropriate. With respect to any recommendation that Biovail considers unnecessary or inappropriate, Biovail need not adopt that recommendation at that time but shall propose in writing an alternative policy, procedure, or system designed to achieve the same objective or purpose.

iv. As to any recommendations of the Consultant with respect to which Biovail and the Consultant do not agree, such parties shall attempt in good faith to reach an agreement within ninety days of the issuance of the Consultant's report. In the event Biovail and the Consultant are unable to agree on an alternative proposal, Biovail shall abide by the determinations of the Consultant.

v. Biovail shall retain the Consultant for a period of twelve months from the date of appointment in accordance with paragraph 5.C below. After the Consultant's recommendations become final pursuant to paragraph 5.B above, the Consultant shall oversee the implementation of such recommendations and provide a report to Biovail's board of directors, its audit committee, and to the Commission staff twelve months after appointment concerning the progress of the implementation. If, at the conclusion of this twelve-month period, less than all the recommendations of the consultant (to the extent deemed significant by the Commission staff) have been substantially implemented for at least two successive fiscal quarters, the Commission staff may, in its discretion, direct Biovail to extend the Consultant's term of appointment until such time as all recommendations (to the extent deemed significant by the Commission staff) have been substantially implemented for at least two successive fiscal quarters.

vi. In addition to the reports identified above, the Consultant shall provide Biovail's board of directors, its audit committee, and the Commission staff with such documents or other information concerning the areas specified in paragraph 5.A.ii above as any of them may request during the pendency or at the conclusion of the

review.

C. Terms of Consultant's Retention

i. Within forty-five days after the date of entry of the Final Judgment, Biovail will submit to the Commission staff a proposal setting forth the identity, qualifications, and proposed terms of retention of the Consultant. The Commission staff, within thirty days of such notice, will either (a) deem Biovail's choice of Consultant and proposed terms of retention not unacceptable or (b) require Biovail to propose an alternative Consultant and/or revised proposed terms of retention within fifteen days. This process will continue, as necessary, until the proposed Consultant and retention terms are not unacceptable to the Commission staff.

ii. The Consultant shall have reasonable access to all of Biovail's books and records and the ability to meet privately with Biovail's personnel. Biovail shall instruct and otherwise encourage its officers, directors, and employees to cooperate fully with the review conducted by the Consultant, and inform its officers, directors, and employees that failure to cooperate with the review may be grounds for dismissal, other disciplinary actions, or other appropriate actions.

iii. The Consultant shall have the right, as reasonable and necessary in his or her judgment, to retain, at Biovail's expense, attorneys, accountants, and other persons or firms, other than officers, directors, or employees of Biovail, to assist in the discharge of the Consultant's obligations. Biovail shall pay all reasonable fees and expenses (as reasonably documented) of any persons or firms retained by the Consultant.

iv. The Consultant shall make and keep notes of interviews conducted, and keep a copy of documents gathered, in connection with the performance of his or her responsibilities, and require all persons and firms retained to assist the Consultant to do so as well.

iv. If the Consultant determines that he or she has a conflict with respect to one or more of the areas described in paragraph 5.A.ii above, he or she shall delegate his or her responsibilities with respect to that subject to a person who is chosen by the Consultant and who is not unacceptable to the Commission staff.

vi. For the period of engagement and for a period of two years from completion of the engagement, the Consultant shall not enter into any employment, consultant, attorney-client, auditing, or other professional relationship with Biovail, or any of its present or former affiliates, directors, officers, employees, or agents acting in their capacity as such, and shall require that any firm with which the Consultant is affiliated or of which the Consultant is a member, or any person engaged to assist the Consultant in performance of the Consultant's duties under the Final Judgment not, without prior written consent of the Commission staff, enter into any employment, consultant, attorney-client, auditing, or other professional relationship with Biovail, or any of its present or former affiliates, directors, officers, employees, or agents acting in their capacity as such for the period of the engagement and for a period of two years after the engagement.

**SCHEDULE “D” – TERMS OF REFERENCE FOR  
THE ONTARIO REVIEW**

A. Retention of the Ontario Consultant

- i. The Ontario Consultant's compensation and expenses shall be borne exclusively by Biovail.

B. The Ontario Consultant's Reporting Obligations

- i. The Ontario Consultant shall issue a report to Biovail's board of directors, its audit committee, and to Staff within three months of appointment, provided however, that the Ontario Consultant may seek to extend the period of review for one additional three-month term by requesting such an extension from Staff. Staff, after consultation with Biovail, shall have discretion to grant such extension for the period requested if deemed reasonable and warranted.
- ii. The Ontario Consultant's report shall address the Ontario Consultant's review of the areas specified in paragraph 84(f) of the Settlement Agreement and shall include a description of the review performed, the conclusions reached, the Ontario Consultant's recommendations for any changes or improvements to Biovail's policies and procedures as the Ontario Consultant reasonably deems necessary to conform to the law and best practices, and a procedure for implementing the recommended changes or improvements.
- iii. Biovail shall adopt all recommendations contained in the Ontario Consultant's report, provided, however, that within forty-five days of its receipt of the report, Biovail shall in writing advise the Ontario Consultant and Staff of any recommendation that it considers to be unnecessary or

inappropriate. With respect to any recommendation that Biovail considers unnecessary or inappropriate, Biovail need not adopt that recommendation at that time but shall propose in writing an alternative policy, procedure, or system designed to achieve the same objective or purpose.

- iv. As to any recommendations of the Ontario Consultant with respect to which Biovail and the Ontario Consultant do not agree, such parties shall attempt in good faith to reach an agreement within ninety days of the issuance of the Ontario Consultant's report. In the event Biovail and the Ontario Consultant are unable to agree on an alternative proposal, Biovail shall abide by the determinations of the Ontario Consultant.
- v. Biovail shall retain the Ontario Consultant for a period of twelve months from the date of appointment. After the Ontario Consultant's recommendations become final pursuant to paragraph iv above, the Ontario Consultant shall oversee the implementation of such recommendations and provide a report to Biovail's board of directors, its audit committee, and to Staff twelve months after appointment concerning the progress of the implementation. If, at the conclusion of this twelve-month period, less than all the recommendations of the consultant (to the extent deemed significant by Staff) have been substantially implemented for at least two successive fiscal quarters, Staff may, in its discretion, direct Biovail to extend the Ontario Consultant's term of appointment until such time as all recommendations (to the extent deemed significant by Staff) have been substantially implemented for at least two successive fiscal quarters.
- vi. In addition to the reports identified above, the Ontario Consultant shall provide Biovail's board of directors, its audit committee, and Staff with such documents or other information concerning the areas specified in paragraph 84(f) of the Settlement Agreement as any of them may request during the pendency or at the conclusion of the review.

C. Terms of the Ontario Consultant's Retention

- v. Within forty-five days after the approval of the Settlement Agreement, Biovail will submit to Staff a proposal setting forth the identity, qualifications, and proposed terms of retention of the Ontario Consultant. Staff, within thirty days of such notice, will either (a) deem Biovail's choice of Ontario Consultant and proposed terms of retention not unacceptable or (b) require Biovail to propose an alternative Ontario Consultant and/or revised proposed terms of retention within fifteen days. This process will continue, as necessary, until the proposed Ontario Consultant and retention terms are not unacceptable to Staff.
- vi. The Ontario Consultant shall have reasonable access to all of Biovail's books and records and the ability to meet privately with Biovail's personnel. Biovail shall instruct and otherwise encourage its officers, directors, and employees to cooperate fully with the review conducted by the Ontario Consultant, and inform its officers, directors, and employees that failure to cooperate with the Ontario Review may be grounds for dismissal, other disciplinary actions, or other appropriate actions.
- vii. The Ontario Consultant shall have the right, as reasonable and necessary in his or her judgment, to retain, at Biovail's expense, lawyers, accountants, and other persons or firms, other than officers, directors, or employees of Biovail, to assist in the discharge of the Ontario Consultant's obligations. Biovail shall pay all reasonable fees and expenses (as reasonably documented) of any persons or firms retained by the Ontario Consultant.
- iv. The Ontario Consultant shall make and keep notes of interviews conducted, and keep a copy of documents gathered, in connection with the performance

of his or her responsibilities, and require all persons and firms retained to assist the Ontario Consultant to do so as well.