

**IN THE MATTER OF THE SECURITIES ACT,  
R.S.O. 1990, c. S.5, AS AMENDED**

**- and -**

**IN THE MATTER OF  
NUVO RESEARCH INC. AND REBECCA E. KEELER**

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**SETTLEMENT AGREEMENT BETWEEN  
STAFF OF THE ONTARIO SECURITIES COMMISSION  
AND NUVO RESEARCH INC.**

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**I. INTRODUCTION**

1. By Notice of Hearing dated April 24, 2007, the Ontario Securities Commission (the "Commission") proposed to hold a hearing pursuant to sections 127 and 127.1 of the *Securities Act*, R.S.O. 1990, c. S.5 (the "Act"), to consider whether it is in the public interest for the Commission to make an order approving this settlement agreement (the "Settlement Agreement") entered into between Staff of the Commission ("Staff") and the Respondent, Nuvo Research Inc.

**II. JOINT SETTLEMENT RECOMMENDATION**

2. Staff recommend settlement of the proceeding initiated in respect of the Respondent in accordance with the terms and conditions set out below. The Respondent consents to the making of an order in the form attached as Schedule "A" based on the facts set out in Part III and the terms set out in Part V of this Settlement Agreement.

3. The terms of this Settlement Agreement and the attached Schedule “A” will be released to the public only if and when the Settlement Agreement is approved by the Commission.

### **III. STATEMENT OF FACTS**

#### **A. Acknowledgement**

4. For the purposes of this Settlement Agreement only, the Respondent agrees with the facts set out in this Part III.

#### **B. The Respondents**

5. Dimethaid Research Inc. (now Nuvo Research Inc. and hereinafter referred to as “Dimethaid”) is a reporting issuer in Ontario and in other Canadian provinces. At all relevant times, Dimethaid’s shares were listed and posted for trading on the Toronto Stock Exchange under the symbol DMX.
6. Dimethaid develops and manufactures pharmaceutical products. During the relevant period, one of Dimethaid’s two leading drugs was Pennsaid, a topical medication used to relieve pain and physical symptoms associated with primary knee osteoarthritis.
7. As of November 2003, Dimethaid had received regulatory approval to market Pennsaid in Canada, the United Kingdom, and certain European countries. Pennsaid was also being marketed and sold in certain Caribbean countries where approval to market was not required.
8. At all relevant times, Rebecca E. Keeler (“Keeler”) was the President, Chief Executive Officer (“CEO”) and Chairman of the board of directors of Dimethaid. Keeler was terminated on September 22, 2004 following the appointment of a new board of directors at Dimethaid’s annual general meeting (“AGM”) on September 21, 2004.

**C. Dimethaid's New Drug Application and the Non-Approvable Letter**

9. On August 7, 2001, Dimethaid filed a new drug application (the "New Drug Application") with the Food and Drug Administration ("FDA") to obtain approval to market Pennsaid in the United States.
10. One year later, by letter dated August 7, 2002, the FDA rejected Dimethaid's application for Pennsaid as "not approvable" under FDA legislation on the basis that the clinical data presented by Dimethaid in support of the application was insufficient to determine if Pennsaid was safe and effective under the proposed conditions of use (the "Non-Approvable Letter").
11. The particular deficiencies, as summarized in the Non-Approvable Letter, were with respect to the pharmacokinetic data, and the efficacy and safety data submitted by Dimethaid.
12. Upon receipt of the Non-Approvable Letter, Dimethaid provided notice to the FDA of its intention to file an amended New Drug Application for consideration.
13. The Non-Approval Letter expressly stated that any amendment by Dimethaid "should respond to all the deficiencies listed" and that the FDA would not process a partial reply by the company nor would the review clock be reactivated until all deficiencies have been addressed.

**D. Design of Protocols and Additional Clinical Trials**

14. Between August 2002 and November 2003, Keeler and others internally from Dimethaid met with representatives of the FDA to discuss and negotiate protocols for additional clinical trials.
15. In that period, two pharmacokinetic protocols and a safety and efficacy protocol were designed by Dimethaid in an effort to address the deficiencies outlined in the Non-Approvable Letter.

16. The pharmacokinetic protocols were submitted by Dimethaid in December 2002 and to the FDA and found to be adequate. The studies were then carried out and completed by March 2003.
17. The safety and efficacy protocol, known as PEN-03-112 (“Protocol 112”), was provided to the FDA in July 2003 and finalized in November 2003. Two clinical trials were carried out in accordance with Protocol 112. The first trial, designated “Study 112”, began in February 2004 but was not complete until late 2005. The second trial, designated “Study 112E” began in March 2004 but was not complete until early 2006.
18. Approval of Dimethaid’s amended New Drug Application was dependent upon a totality of the data submitted by Dimethaid from Study 112 and Study 112E, data from the pharmacokinetic studies and the data from Dimethaid’s original submissions under the New Drug Application.

**E. Misleading Statements and Omission of Material Facts**

19. On November 26, 2003 and June 24, 2004, Dimethaid filed short form prospectuses with the Commission in respect of two separate special warrant offerings (collectively referred to as the “Prospectuses”).
20. Each of the Prospectuses, certified by Keeler and others as containing full, true and plain disclosure of all material facts relating to the securities offered by the Prospectuses, stated the following with respect to Pennsaid’s status in the United States:
  - (a) that “Pennsaid has completed all clinical studies in Canada and the United States”; and
  - (b) that “the Company’s marketing approval for Pennsaid in the United States is being considered by the United States Food and Drug Administration”.
21. Each of the Prospectuses failed to disclose the following facts which, in isolation or in combination, constituted material facts with respect to Pennsaid’s status in the United States, specifically:

- (a) that, in August 2002, the New Drug Application was rejected as “not approvable” under FDA legislation;
  - (b) that the basis for the FDA’s rejection of the New Drug Application was that the information presented by Dimethaid was insufficient to determine if Pennsaid was safe and effective under the proposed conditions of use;
  - (c) that the FDA would not consider an amended New Drug Application until all of the deficiencies identified by the FDA had been addressed by Dimethaid;
  - (d) that Dimethaid had taken steps to preserve its ability to file an amended New Drug Application for consideration by the FDA;
  - (e) that Dimethaid had not, as of the dates of the Prospectuses, filed an amended New Drug Application;
  - (f) from September 2002 to November 2003, that Dimethaid was in discussions with the FDA to develop study protocols necessary to address the deficiencies identified in the Non-Approvable Letter;
  - (g) that, by March 2003, Dimethaid had completed two studies to address the pharmacokinetic deficiencies identified by the FDA in the Non-Approvable Letter; and
  - (h) that, in July 2003, Dimethaid had submitted Protocol 112 (which was finalized in November 2003) to address the safety and efficacy deficiencies identified by the FDA in the Non-Approvable Letter.
22. With respect to Dimethaid’s prospectus dated June 24, 2004, Dimethaid failed to disclose additional material facts with respect to the status of Pennsaid, specifically:
- (a) that Dimethaid had begun patient enrolment in February 2004 for Study 112;
  - (b) that Dimethaid had begun patient enrolment in March 2004 for Study 112E.

**F. Non-Disclosure to Dimethaid’s Board of Directors**

23. Current management of Dimethaid does not have any information to indicate that Keeler disclosed to its board of directors that Dimethaid had received the Non-Approvable Letter or the consequences of the Non-Approvable Letter prior to the Board’s approval of each of the Prospectuses.

**G. Conduct Contrary to the Public Interest**

24. Dimethaid failed to make disclosure in the Prospectuses of the material facts as set out in paragraphs 21 and 22 above relating to the securities proposed to be distributed; specifically, material facts with respect to status of its New Drug Application with the FDA for marketing approval of Pennsaid in the United States.
25. Dimethaid's conduct was contrary to the public interest.

**V. MITIGATING FACTS AND CHANGES BY DIMETHAID****A. Replacement of Keeler and Board of Directors**

26. At its Annual General Meeting on September 21, 2004, the shareholders of Dimethaid elected to replace Dimethaid's existing board of directors with a new slate proposed by a group of dissident shareholders who were calling for Keeler's removal on the basis of concerns regarding Keeler's leadership and management of the company.
27. On September 22, 2004, the new board of directors terminated Keeler's appointment and employment as President and CEO of Dimethaid.

**B. Press Release and Corrective Disclosure by Dimethaid**

28. On October 6, 2004, under direction of the new board of directors, Dimethaid issued a press release to update the market on the state of Dimethaid's business. Included in the press release was the following statements:

The new board has learned that in August 2002, the U.S. Food and Drug Administration sent the company a complete response letter recommending additional efficacy and long-term safety data, along with an extra, pharmacokinetic study providing more information about how the drug is absorbed and eliminated from the body.

Dimethaid responded within 10 days, indicating it would amend its New Drug Application (NDA). The company agreed to the pharmacokinetic study and completed the work in May 2003.

However, given Dimethaid's limited financial resources and the quality of results already submitted, the company continued to negotiate with the FDA in an effort to persuade the agency that additional efficacy and safety data, or more clinical trials, were unnecessary. In November 2002, the company decided to conduct new clinical trials in accordance with the FDA's suggested design.

Over the past two years, Dimethaid has continued to meet with the FDA to clarify the issues and develop the necessary clinical trials. The company submitted a protocol in November 2003 and following approval, started enrolment in March 2004.

Barring unforeseen delays, we expect to complete the studies by the end of calendar 2005 and submit an amended NDA by mid 2006. According to agency guidelines, the FDA should be expected to respond by early 2007. A positive response at this stage would allow the company to begin marketing Pennsaid three-to-six months later.

### **C. November 2004 Prospectus**

29. On November 9, 2004, under new management, Dimethaid filed a short form prospectus with respect to an offering of convertible debenture units (the "November 2004 prospectus"). With respect to FDA marketing approval of Pennsaid, the November 2004 Prospectus indicates that the New Drug Application had been effectively on hold pending the development of clinical protocols and the completion of the studies contemplated thereby. Specifically, the November 2004 Prospectus states:

Marketing approval for Pennsaid in the United States is being considered by the United States Food and Drug Administration ("FDA"). In August 2002, the FDA sent the Company a complete response letter recommending additional efficacy and long-term safety data, along with an extra, pharmacokinetic study providing more information about how the drug is absorbed and eliminated from the body. In response to this letter, Dimethaid indicated that it would amend its New Drug Application ("NDA") relating to Pennsaid.

Since November 2002, Dimethaid has completed the pharmacokinetic study and continues to meet with the FDA to clarify issues and develop necessary protocols. The Company submitted a clinical trials protocol in November 2003 and, following approval by the FDA, started patient enrolment in March 2004. Under this protocol, the two current Pennsaid trials are being conducted to confirm long-term safety and investigate the drug's use in combination with a conventional NSAID. Barring unforeseen delays, the Company expects to complete the trials by the end

of 2005 and submit an amended NDA by mid 2006. According to agency guidelines, the FDA should be expected to respond by early 2007. A positive response at that stage would allow the Company to begin marketing Pennsaid in the United States three to six months thereafter. See “Risk Factors – Government Regulation”.

**C. Compliance and Operational Initiatives by Dimethaid and the Board**

30. Under new management, Dimethaid implemented a corporate disclosure policy, including the creation of a corporate disclosure committee, in order to improve corporate governance issues with respect to disclosure and to seek to ensure compliance with applicable securities regulations and laws.

**D. Co-operation of Dimethaid**

31. Staff notes that Dimethaid has co-operated with Staff from the outset of its investigation and has assisted Staff in gathering the facts that gave rise to this proceeding. Dimethaid’s co-operation has assisted Staff in its review and analysis of the facts and in the expeditious resolution of this matter.

**IV. TERMS OF SETTLEMENT**

32. The Respondent agrees to the following terms of settlement:
- (a) that, within 30 days of an order approving this settlement, Dimethaid will initiate a review of its disclosure and reporting practices and procedures by an independent third party, acceptable to both Dimethaid and Staff. The review will be undertaken at Dimthaid’s expense;
  - (b) that Dimethaid will implement any recommendations made by the independent third party referred to above that are approved by Staff, within a reasonable period of time as approved by Staff; and
  - (c) that Dimethaid shall pay \$15,000 toward the costs of the investigation of this matter.

**V. STAFF COMMITMENT**

33. If this Settlement Agreement is approved by the Commission, Staff will not initiate any proceeding under Ontario securities law in respect of any conduct or alleged conduct of the Respondent in relation to the facts set out in Part III of this Settlement Agreement, subject to the provisions of paragraph 37 below.

**VI. PROCEDURE FOR APPROVAL OF SETTLEMENT**

34. Approval of this Settlement Agreement shall be sought at a hearing of the Commission on April 26, 2007, or as soon thereafter as a hearing can be held by the Commission.
35. Staff and the Respondent may refer to any part, or all, of the Settlement Agreement at the Settlement Hearing. Staff and the Respondent also agree that if this Settlement Agreement is approved by the Commission, it will constitute the entirety of the evidence to be submitted respecting the Respondent in this matter, and the Respondent agrees to waive its rights to a full hearing, judicial review or appeal of the matter under the Act.
36. Staff and the Respondent agree that if this Settlement Agreement is approved by the Commission, neither Staff nor the Respondent will make any public statement inconsistent with this Settlement Agreement.
37. If this Settlement Agreement is approved by the Commission and, at any subsequent time, the Respondent fails to honour any of the terms of settlement set out in Part IV herein, Staff reserve the right to bring proceedings under Ontario securities law against the Respondent based on, but not limited to, the facts set out in Part III of the Settlement Agreement, as well as the breach of the Settlement Agreement.
38. If, for any reason whatsoever, this Settlement Agreement is not approved by the Commission or an Order in the form attached as Schedule "A" is not made by the Commission, each of Staff and the Respondent will be entitled to all available proceedings, remedies and challenges, including proceeding to a hearing of the allegations in the Statement of Allegations, unaffected by this Settlement Agreement or the settlement negotiations.
39. Whether or not this Settlement Agreement is approved by the Commission, the Respondent agrees that it will not, in any proceeding, refer to or rely upon this Settlement Agreement or the negotiation or process of approval of this Settlement

Agreement as the basis for any allegation against the Commission of lack of jurisdiction, bias, appearance of bias, unfairness, or any other remedy or challenge that may otherwise be available.

**VII. DISCLOSURE OF AGREEMENT**

- 40. The terms of this Settlement Agreement will be treated as confidential by all parties hereto until approved by the Commission, and forever if, for any reason whatsoever, this Settlement Agreement is not approved by the Commission, except with the written consent of both the Respondent and Staff or as may be required by law.
- 41. Any obligations of confidentiality shall terminate upon approval of this Settlement Agreement by the Commission.

**VIII. EXECUTION OF SETTLEMENT AGREEMENT**

- 42. This Settlement Agreement may be signed in one or more counterparts which together shall constitute a binding agreement.
- 43. A facsimile copy of any signature shall be effective as an original signature.

**DATED** this 23<sup>rd</sup> day of April, 2007.

**Nuvo Research In.**

“John C. London”

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John C. London, Vice Chairman

I have authority to bind the corporation.

**DATED** this 24<sup>th</sup> day of April, 2007.

**STAFF OF THE ONTARIO SECURITIES  
COMMISSION**

“Michael Watson”

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Michael Watson

Director of Enforcement