Ontario Securities Commission | Commission des valeurs mobilières de l'Ontario | P.O. Box 55, 19th Floor 20 Queen Street West Toronto ON M5H 3S8 | CP 55, 19e étage 20, rue queen ouest Toronto ON M5H 3S8

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

SETTLEMENT AGREEMENT BETWEEN STAFF OF THE ONTARIO SECURITIES COMMISSION AND REBECCA E. KEELER

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 certain orders against the Respondent, Rebecca E. Keeler ("**Keeler**"), by reason of the allegations set out in the Statement of Allegations dated April 24, 2007.

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 VI 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, Keeler 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, 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 Complete Response 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 "**Complete Response Letter**").

11. The particular deficiencies, as summarized in the Complete Response Letter, were with respect to the pharmacokinetic data, and the efficacy and safety data submitted by Dimethaid.

12. Upon receipt of the Complete Response Letter, Dimethaid provided notice to the FDA of its intention to file an amended New Drug Application for consideration.

13. The Complete Response 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 had 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 Complete Response Letter.

16. The pharmacokinetic protocols were submitted by Dimethaid in December 2002 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. 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, 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 Complete Response Letter;

(g) that, by March 2003, Dimethaid had completed two studies to address the pharmacokinetic deficiencies identified by the FDA in the Complete Response 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 Complete Response 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. Keeler did not disclose to Dimethaid's board of directors that Dimethaid had received the Complete Response Letter or the consequences of the Complete Response Letter prior to the Board's approval of each of the Prospectuses.

24. Furthermore, during the due diligence process for the offerings, Keeler made statements to Dimethaid's counsel and to counsel for the underwriters that were misleading or untrue by claiming that Dimethaid's last written communication with the FDA in respect of the New Drug Application was July 23, 2002 and, further, that Dimethaid was not aware of any unresolved issues for Pennsaid.

G. Replacement of Keeler and Board of Directors

25. 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.

26. On September 22, 2004, the new board of directors terminated Keeler's appointment and employment as President and CEO of Dimethaid.

H. Press Release and Corrective Disclosure by Dimethaid

27. 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 were 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.

IV. RESPONDENT'S POSITION

28. After Dimethaid submitted its initial New Drug Application, dated August 7, 2001, but before the FDA issued the Complete Response Letter, the FDA changed certain aspects of its method of analyzing the new drug application from what it had discussed with Dimethaid. Keeler understood that the non-approvable status given Pennsaid in the Complete Response Letter was a result of that change in the FDA's method of analysis. After receiving the Complete Response Letter, Keeler spoke to the Director of the FDA and understood from that conversation that another then-ongoing study by Dimethaid (Study 110), if successful, would be sufficient to meet the FDA's efficacy requirements. Based on these factors, Keeler treated the Complete Response Letter as an interim step in the review process. Notwithstanding what she believed at the time, Keeler acknowledges that she was not duly diligent in this matter and that it was not reasonable to treat the Complete Response Letter as an interim step.

29. Keeler did not make any profit or avoid any loss as a result of her conduct. In fact, Keeler continued to invest in Dimethaid after receiving the Complete Response Letter, and as a result incurred portfolio losses exceeding CDN $300,000 in relation to her holdings in Dimethaid, as of the date of this settlement.

30. Keeler has provided Staff with evidence that she has not acted as the director or officer of a reporting issuer since her dismissal from Dimethaid in September 2004, and that she has not acted as the director or officer of any non-reporting issuer, except acting as a director and officer for two related and now-dormant companies that never offered securities publicly or privately. The only shareholders of the two companies were two members of Keeler's immediate family and their business partner and the companies were not profitable. Keeler received no direct or indirect compensation for acting as a director and officer for those companies.

31. Keeler has provided Staff with evidence that she has been unemployed since her dismissal from Dimethaid in September of 2004.

32. Keeler has shown and continues to show remorse.

33. Keeler has co-operated with Staff in its investigation. Keeler's co-operation has assisted Staff in its review and analysis of the facts and in resolving this matter.

V. CONDUCT CONTRARY TO THE PUBLIC INTEREST

34. The facts relating to the status of Dimethaid's application with the FDA for marketing approval of Pennsaid in the United States were material facts relating to the securities proposed to be distributed by Dimethaid. The Prospectuses failed to provide full, true and plain disclosure of these facts, contrary to section 56 of the Act and contrary to the public interest.

35. Keeler's certification that the Prospectuses contained full, true and plain disclosure of all material facts relating to the securities being offered was misleading, was in breach of the Act and was contrary to the public interest.

36. Keeler's failure to provide the Complete Response Letter to Dimethaid's board of directors or to counsel for Dimethaid's underwriters was contrary to the public interest.

37. By her certification in the Prospectuses and by her further conduct as described above, Keeler authorized, permitted or acquiesced in Dimethaid's failure to provide full, true and plain disclosure in the Prospectuses, contrary to section 129.2 of the Act and contrary to the public interest.

VI. TERMS OF SETTLEMENT

38. Keeler agrees to the following terms of settlement:

(a) Keeler shall be prohibited from acting as a director or officer of any reporting issuer for a period of 2 years from the date of an order of the Commission approving this Settlement Agreement;

(b) Prior to acting in any capacity as a director or officer of any reporting issuer in the future, Keeler shall complete an education program, acceptable to both Keeler and Staff, relating to the obligations of officers and directors of reporting issuers. The education program will be undertaken at Keeler's expense;

(c) Keeler is reprimanded pursuant to s. 127(1)6 of the Act; and,

(d) Immediately upon this Settlement Agreement being approved, Keeler shall pay to the Commission an administrative penalty of $5,000 pursuant to s. 127(1)9 of the Act.

VII. STAFF'S POSITION

39. It is Staff's position, and the Respondent concurs, that the 2 year duration of the prohibition and the amount of the administrative penalty to be imposed are only appropriate in light of the period of time the Respondent has remained voluntarily absent from the capital markets while settlement negotiations were ongoing and the financial losses she suffered as a result of her own conduct.

VIII. STAFF COMMITMENT

40. 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 41, below.

IX. PROCEDURE FOR APPROVAL OF SETTLEMENT

41. Approval of this Settlement Agreement shall be sought at a hearing of the Commission on December 12, 2011, or as soon thereafter as a hearing can be held by the Commission.

42. 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.

43. 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.

44. 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 VI 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.

45. 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.

46. 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.

X. DISCLOSURE OF AGREEMENT

47. 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.

48. Any obligations of confidentiality shall terminate upon approval of this Settlement Agreement by the Commission.

XI. EXECUTION OF SETTLEMENT AGREEMENT

49. This Settlement Agreement may be signed in one or more counterparts which together shall constitute a binding agreement.

50. A facsimile copy of any signature shall be effective as an original signature.

DATED this 30th day of November, 2011.

REBECCA E. KEELER

Rebecca E. Keeler

WITNESS

DATED this 1st day of December 2011.

STAFF OF THE ONTARIO SECURITIES COMMISSION

Schedule "A"

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

- and -

IN THE MATTER OF A SETTLEMENT AGREEMENT
BETWEEN STAFF OF THE ONTARIO SECURITIES COMMISSION
AND REBECCA E. KEELER

ORDER

WHEREAS on April 24, 2007, the Commission issued a Notice of Hearing pursuant to section 127 of the *Securities Act* (the "Act") in respect of Rebecca Keeler ("Keeler" or the "Respondent");

AND WHEREAS on April 24, 2007, Staff of the Commission ("Staff") filed a Statement of Allegations;

AND WHEREAS the Respondent entered into a Settlement Agreement dated •, 2011, (the "Settlement Agreement") in relation to the matters set out in the Amended Statement of Allegations;

AND WHEREAS the Commission issued a Notice of Hearing dated December •, 2011, announcing that it proposed to consider the Settlement Agreement;

UPON reviewing the Settlement Agreement, the Notice of Hearing and the Statement of Allegations, and upon considering submissions from the Respondent through her counsel and from 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:

1. the Settlement Agreement is hereby approved;

2. pursuant to clause 8 of subsection 127(1) of the *Act*, Keeler shall be prohibited from acting as a director or officer of any reporting issuer for a period of 2 years from the date of an order of the Commission approving this Settlement Agreement, and that prior to acting in any capacity as a director or officer of any reporting issuer in the future, Keeler shall complete an education program, acceptable to both Keeler and Staff, relating to the obligations of officers and directors of reporting issuers, and undertaken at Keeler's expense;

3. pursuant to clause 6 of subsection 127(1) Keeler is reprimanded; and,

4. pursuant to clause 9 of subsection 127(1), immediately upon this Settlement Agreement being approved, Keeler shall pay to the Commission an administrative penalty of $5,000.

DATED at Toronto this _____ day of December, 2011.