NUVO RESEARCH® INC.

ANNUAL INFORMATION FORM

February 19, 2015

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CERTAIN REFERENCES

Unless otherwise noted, the information contained in this Annual Information Form (AIF) is provided as at December 31, 2014 or for the period ended December 31, 2014 as applicable.

For an explanation of key terms, please refer to the "Glossary of Terms" at the end of this AIF. Unless otherwise noted, or indicated by context, "Nuvo Research Inc.", "Nuvo", the "Company", "our" and "we" refers to Nuvo Research Inc. and its direct and indirect subsidiaries.

All dollar amounts are expressed in Canadian dollars unless otherwise noted.

FORWARD-LOOKING INFORMATION

Certain statements in this AIF constitute forward-looking statements within the meaning of applicable securities laws. Forward-looking statements include, but are not limited to, statements made under the headings "General Development of the Business", "Risk Factors" and other statements concerning the Company's future objectives, strategies to achieve those objectives, as well as statements with respect to management's beliefs, plans, estimates, and intentions, and similar statements concerning anticipated future events, results, circumstances, performance or expectations that are not historical facts. Forward-looking statements generally can be identified by the use of forward-looking terminology such as "outlook", "objective", "may", "will", "expect", "intend", "estimate", "anticipate", "believe", "should", "plans" or "continue", or similar expressions suggesting future outcomes or events. Such forward-looking statements reflect management's current beliefs and are based on information currently available to management. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those contemplated by such statements. Factors that could cause such differences include general business and economic uncertainties and adverse market conditions as well as other risk factors included in this AIF under the heading "Risks Factors" and as described from time to time in the reports and disclosure documents filed by the Company with Canadian securities regulatory agencies and commissions. This list is not exhaustive of the factors that may impact the Company's forward-looking statements. These and other factors should be considered carefully and readers should not place undue reliance on the Company's forward-looking statements. As a result of the foregoing and other factors, no assurance can be given as to any such future results, levels of activity or achievements and neither the Company nor any other person assumes responsibility for the accuracy and completeness of these forward-looking statements. The factors underlying current expectations are dynamic and subject to change. Although the forward-looking information contained in this AIF is based upon what management believes are reasonable assumptions, there can be no assurance that actual results will be consistent with these forward-looking statements. Certain statements included in this AIF may be considered "financial outlook" for purposes of applicable securities laws, and such financial outlook may not be appropriate for purposes other than this AIF. All forward-looking statements in this AIF are qualified by these cautionary statements. The forward-looking statements contained herein are made as of the date of this AIF and except as required by applicable law, the Company undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

NUVO RESEARCH INC. STRUCTURE

Corporate Structure

Nuvo Research Inc. was incorporated on August 22, 1983 under the laws of the Province of Ontario as Clark Pharmaceutical Laboratories Ltd. On November 14, 1990, the articles were

amended to change the name of the Company from Clark Pharmaceutical Laboratories Ltd. to Dimethaid Research Inc. On September 30, 2005, the articles were further amended to change the name of the Company from Dimethaid Research Inc. to Nuvo Research Inc. On January 1, 2007, the Company completed a short-form amalgamation with Akorn Pharmaceuticals Canada Limited, Excelpharm Inc., Femina Inc., Dimethaid Management Inc. and Dimethaid Manufacturing Inc., including certain of its subsidiaries. The amalgamated entity continues as Nuvo Research Inc. No new securities of the Company were issued in connection with the amalgamation and securities of the Company prior to the amalgamation continue to represent securities of the amalgamated entity.

The Company's registered office and principal place of business is located at 7560 Airport Road, Unit 10, Mississauga, Ontario L4T 4H4. The Company's telephone number is (905) 673-6980 and the web address is www.nuvoresearch.com. The Company also operates a manufacturing and research and development (R&D) facility in Varennes, Québec where it manufactures Pennsaid®, Pennsaid 2% and the bulk drug substance for the heated lidocaine/tetracaine patch (HLT Patch).

Dimethaid Immunology Inc. (Dimethaid Immunology)

In 1993, Dimethaid Immunology was incorporated under the federal laws of Canada as a wholly owned subsidiary of the Company. It is responsible for the Canadian marketing and distribution of WF10™ and other related products. Dimethaid Immunology currently has limited activity as WF10 and related products are not currently approved for sale in Canada.

Dimethaid (UK) Ltd.

In 1999, Dimethaid (UK) Ltd. was incorporated as a British company that holds the marketing authorization for Pennsaid in the United Kingdom and several European Union countries. Dimethaid (UK) Ltd. is a wholly owned subsidiary of Nuvo Research Inc.

Nuvo Research AG, Nuvo Manufacturing GmbH and Nuvo Research GmbH

In 2002, the Company completed the acquisition of Oxo Chemie, a Swiss company headquartered in Fribourg, Switzerland from Dr. F.W. Kühne (Dr. Kühne). Oxo Chemie owned the intellectual property rights related to WF10. The assets acquired by Nuvo included the manufacturing plant, equipment and inventory in Wanzleben, Germany and the marketing rights for WF10 in Thailand.

Upon completion of the acquisition of Oxo Chemie, it was restructured into Nuvo Research AG, Nuvo Manufacturing GmbH and Dimethaid (Thailand) Limited. Nuvo Research AG retained all rights related to the WF10 patents and intellectual property. Nuvo Manufacturing GmbH was incorporated as a new, wholly owned German subsidiary of the Company overseeing the manufacturing facility in Wanzleben. Dimethaid (Thailand) Limited was registered in Thailand as a wholly owned subsidiary of Nuvo.

In 2004, the Company restructured the relationship with Dr. Kühne and entered into an agreement effective May 31, 2005, to reflect these restructured arrangements. Pursuant to this new agreement, the Company transferred all shares of Nuvo Manufacturing GmbH to Nuvo Research AG, establishing Nuvo Manufacturing GmbH as a wholly owned subsidiary of Nuvo Research AG. Dimethaid (Thailand) Limited, which never commenced operations, transferred its WF10 marketing rights for Thailand to Dr. Kühne and the Company transferred a 40% ownership interest in Nuvo Research AG to Dr. Kühne. The Company retained the right to repurchase this

ownership interest for US$18.5 million, plus accumulated interest at the rate of 6% per annum. The agreement also provided Dr. Kühne with the rights to receive 6% of all WF10 worldwide licensing fees and royalties received by Nuvo Research AG.

In 2007, Dimethaid (Thailand) Limited was dissolved.

In 2008, Nuvo Research AG established a wholly owned subsidiary, Nuvo Research GmbH (NRG). NRG's office and operations are located in Leipzig, Germany where it conducts and coordinates the R&D activities related to WF10.

In 2011, the Company reacquired Dr. Kühne's 40% ownership interest in Nuvo Research AG in exchange for 0.5 million Nuvo common shares with an agreed upon value of US$1.7 million. Under the terms of the acquisition, Dr. Kühne retained his right to receive 6% of money received by the Company from the outlicensing of WF10 and is eligible to receive 6% of any proceeds received by the Company if it sells all or any portion of its interest in Nuvo Research AG.

Nuvo Research US, Inc. (Nuvo US)

In 2005, the Company acquired all of the common shares of fqubed, Inc. (fqubed), a company based in San Diego, California. fqubed was subsequently renamed Nuvo Research US, Inc. and incorporated in the State of Delaware. Nuvo US developed screening capabilities to identify innovative formulations that efficiently deliver active therapeutics into and through the skin. Nuvo used this technology to develop a portfolio of early stage drug formulations for topical administration. In January 2011, Nuvo closed its operations in San Diego, but maintained much of the capability, technology and know-how by transferring key equipment and knowledge to other Nuvo facilities.

ZARS Pharma, Inc. (ZARS)

In 2011, the Company acquired all of the shares of ZARS, a company based in Salt Lake City, Utah and incorporated in the State of Delaware. ZARS was a specialty pharmaceutical company focused on the development and commercialization of topically administered drugs, primarily for the treatment of pain, using its proprietary drug delivery technologies.

ZARS (UK) Limited (ZARS UK)

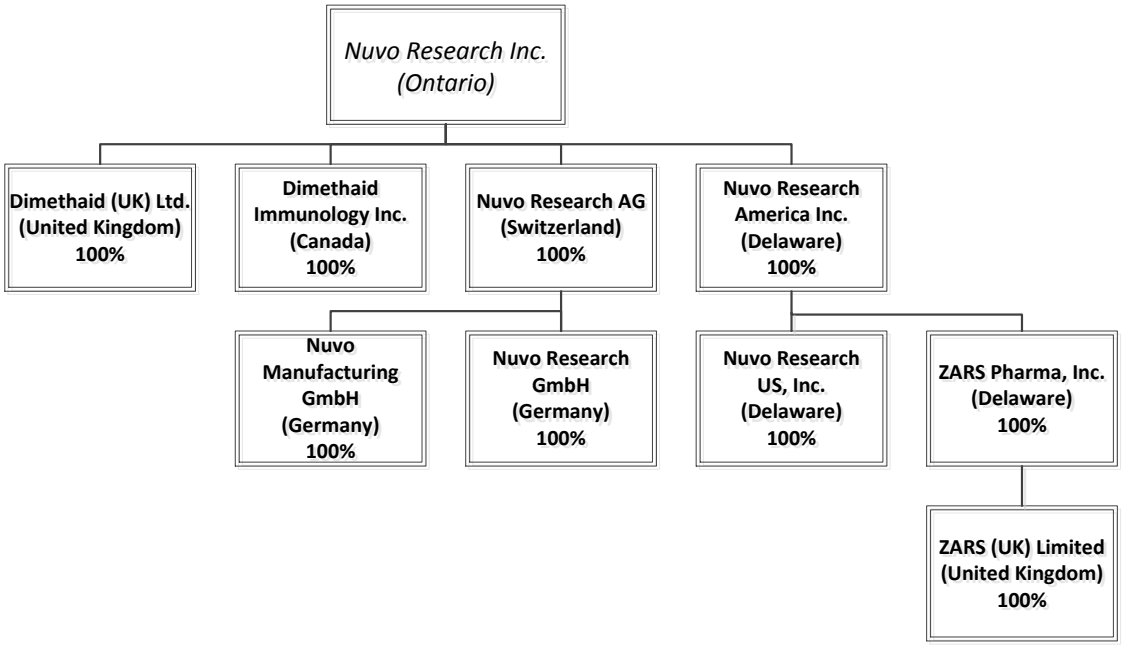
ZARS UK was incorporated in the U.K. and submitted the Pliaglis Marketing Authorization Application (MAA) in the E.U. and upon approval, subsequently transferred the MAA to Galderma Pharma S.A. (Galderma), a global pharmaceutical company specialized in dermatology. ZARS UK is a wholly owned subsidiary of ZARS. ZARS UK was acquired by the Company through the acquisition of ZARS.

Nuvo Research America Inc. (Nuvo America)

In July 2011, Nuvo America was incorporated in the State of Delaware as a wholly owned subsidiary of the Company. In December 2011, the Company completed transactions that transferred ownership of its wholly owned subsidiaries, Nuvo US and ZARS, to Nuvo America in exchange for additional shares of Nuvo America.

Organizational Chart

The following chart illustrates Nuvo's relationship to its subsidiaries, their respective jurisdictions of incorporation, as well as the percentage ownership as at December 31, 2014.



GENERAL DEVELOPMENT OF THE BUSINESS

Nuvo is a publicly traded, Canadian specialty pharmaceutical company with a diverse portfolio of products and technologies. The Company operates two distinct business units: the Topical Products and Technology (TPT) Group and the Immunology Group. The TPT Group has four commercial products, a pipeline of topical and transdermal products focusing on various therapeutic areas including pain and dermatology and multiple drug delivery platforms that support the development of patented formulations that can deliver actives into or through the skin. The Immunology Group has two commercial products and an immune system modulation platform that supports the development of drug products that modulate chronic inflammation processes resulting in a therapeutic benefit.

The Company's products have been commercialized in a number of countries:

Pennsaid 2% is a topical non-steroidal anti-inflammatory drug (NSAID) containing 2% diclofenac sodium compared to 1.5% for original Pennsaid. It is more viscous than original Pennsaid, is supplied in a metered dose pump bottle and has been approved in the U.S. for twice daily dosing compared to four times a day for Pennsaid. On January 16, 2014, Pennsaid 2% was approved in the U.S. for the treatment of the pain of osteoarthritis (OA) of the knee. The sales and marketing rights in the U.S. were originally licensed to Mallinckrodt Inc. (Mallinckrodt). In September 2014, the Company reached a settlement related to its litigation with Mallinckrodt. See "Narrative Description of the Business – Litigation". Under the terms of the settlement agreement, Mallinckrodt paid US$10.0 million to settle the claims and returned the sales and marketing rights for Pennsaid 2% to Nuvo. In October 2014, the Company sold the U.S. rights to Pennsaid 2% to Horizon Pharma plc (Horizon) for US$45.0 million. See "General Development

of the Business – Recent Financings and Corporate Transactions". In January 2015, Horizon launched its commercial sale and marketing of Pennsaid 2% in the U.S.

Pennsaid is a topical NSAID containing 1.5% diclofenac sodium and is used to treat the signs and symptoms of OA of the knee and is approved for sale and marketing in several European countries and Canada where it is licensed to Paladin Labs Inc. (Paladin). As a result of the litigation settlement with Mallinckrodt, the U.S. rights to Pennsaid were returned to the Company. Under the terms of the agreement with Horizon for the sale of the Pennsaid 2% rights, the Company agreed to discontinue the manufacture, sale and marketing of Pennsaid in the U.S. Pennsaid is no longer available in the U.S. as a branded pharmaceutical product, although generic versions of Pennsaid are available. Pennsaid was available in the U.S. market from April 2010 to December 2014.

Pliaglis is a topical local anaesthetic cream that provides safe and effective local dermal analgesia on intact skin prior to superficial dermatological procedures. The Company has licensed worldwide marketing rights to Galderma. Pliaglis is approved for sale and marketing in the U.S., several Western European countries, Argentina, Brazil and Canada. Galderma launched the commercial sale and marketing of Pliaglis in the U.S. and in the E.U. in 2013 and in Brazil in March 2014. In Argentina, Pliaglis has been sold and marketed since 2011. The Company expects Galderma to launch the sale of Pliaglis in Canada and other territories in 2015 and 2016.

The HLT Patch is a topical patch that combines lidocaine, tetracaine and heat. The HLT Patch is approved in the U.S. to provide local dermal analgesia for superficial venous access and superficial dermatological procedures and is marketed by Galen US Incorporated (Galen) under the brand name Synera. In Europe, the HLT Patch is approved for surface anaesthesia of normal intact skin and is marketed by the Company's licensing partner, Eurocept International B.V. (Eurocept) under various brand names including Rapydan.

WF10 is an immune system modulating drug containing chlorite and chlorate ions that is approved in Thailand under the brand name Immunokine as an adjunct in the treatment of cancer to relieve post radiation therapy syndromes and as an adjunct therapy for diabetic foot ulcers, but is not otherwise approved for marketing and sale elsewhere.

Oxoferin™, a topical wound healing agent, contains the active ingredient in WF10, but at a lower concentration. Oxoferin is marketed by Nuvo and its partners in parts of the E.U., Asia and South America as a topical wound healing agent under the trade names Oxoferin and Oxovasin™.

Three Year History

Important events which have occurred in the last three fiscal years and the period subsequent to December 31, 2014 up to the date of filing this 2014 AIF on SEDAR include the following:

Fiscal 2015 to AIF filing date

- In January, the Company announced top line results of its Phase 2 clinical trial to investigate the safety and efficacy of WF10 in patients with refractory allergic rhinitis. As expected, the WF10 arm reduced allergy symptoms as evidenced by recorded patient Total Nasal Symptom Scores (TNSS). The placebo arm demonstrated an unexpected reduction in patient TNSS scores that was not only greater than the

placebo arm in the Company's 2010 Phase 2 proof-of-concept clinical study but also lasted much longer. While the WF10 arm and the 2 separate arms that included constituent elements of WF10 all performed better than placebo, the differences were not statistically significant.

The Company is continuing to conduct a detailed review of the data with its external experts and expects to release further information and analysis of the trial including information on secondary endpoints when the analysis is completed. Please see "Narrative Description of the Business – Immunology Group" for more information on the results of this trial.

Fiscal 2014

- In January, Mallinckrodt received U.S. Food and Drug Administration (FDA) approval for the sale and marketing of Pennsaid 2% in the U.S. and launched the product in the U.S. in February;

- In March, the Company raised $3.1 million in a non-brokered private placement to which 1,390,000 units of the Company were issued at a price of $2.25 per unit (Private Placement). Each unit consisted of one common share of the Company and one-half of one common share purchase warrant of the Company. See "General Development of the Business – Recent Financings and Corporate Transactions";

- In March, Galderma launched the commercial sale and marketing of Pliaglis in Brazil. See "Narrative Description of the Business – Topical Products and Technology Group – Pliaglis";

- In April, the Company entered into a collaboration involving Ferndale Laboratories, Inc. (Ferndale) and a leading Contract Research Organization (CRO) to develop two topical dermatology products based on Nuvo's patented Multiplexed Molecular Penetration Enhancer (MMPE™) technology;

- In September, the Company completed enrolment of its 16-week, double-blind, placebo-controlled, Phase 2 clinical trial to investigate the safety and efficacy of WF10 in patients with refractory allergic rhinitis;

- In September, the Company reached a full settlement with Mallinckrodt of Nuvo's claims and Mallinckrodt's counterclaim relating to the right to sell and market Pennsaid and Pennsaid 2% in the U.S. Under the terms of the settlement agreement, Mallinckrodt returned all U.S. rights to Pennsaid and Pennsaid 2% to Nuvo and paid US$10.0 million. See "Narrative Description of the Business – Litigation";

- In October, the Company sold the Pennsaid 2% U.S. rights to Horizon for US$45.0 million. The Company will manufacture Pennsaid 2% for Horizon pursuant to a long-term supply agreement. See "General Development of the Business – Recent Financings and Corporate Transactions". Horizon launched the sale and marketing of Pennsaid 2% in January 2015;

- In October, the Company paid $3.7 million to Paladin to settle its outstanding loan. All obligations of Nuvo and the other obligors under the loan agreement were satisfied and all security was released and discharged. See "General Development of the Business – Recent Financings and Corporate Transactions";

- In November, the Company announced its plan to conduct a Phase 3 clinical study in Germany for Pennsaid 2% for the treatment of acute pain to support regulatory approval applications for Pennsaid 2% in international jurisdictions. Commencement of the study, which is subject to German regulatory approval, is expected in Q2 2015 with top-line results anticipated in Q4 2015;

  In November, the Company reacquired the Pennsaid 2% marketing rights to South America, Central America, South Africa and Israel. As consideration for these rights, the Company provided its authorization to Paladin to market, sell and distribute an authorized generic version of Pennsaid in Canada;

- In December, 179 patients completed the Phase 2 WF10 clinical trial for the treatment of refractory allergic rhinitis; and

- In December, the United States Patent and Trademark Office (USPTO) granted U.S. Patent No. 8,911,797, relating to the use of formulations that include chlorite ions (such as WF10) to treat or inhibit allergy-like symptoms that include conjunctivitis in patients suffering from or at risk of developing allergic asthma, allergic rhinitis or atopic dermatitis. The patent expires in 2028.

Fiscal 2013

- In January, the Company and Mallinckrodt entered into a settlement agreement with Apotex Inc. and Apotex Corp. (together Apotex) respecting patent infringement litigation brought by Nuvo and Mallinckrodt in response to Apotex's filing of an abbreviated new drug application (ANDA) with the FDA seeking approval to market a generic version of Pennsaid (Apotex Settlement Agreement). Under the terms of the Apotex Settlement Agreement, Nuvo and Mallinckrodt granted a license to Apotex that permitted Apotex, upon approval of its ANDA by the FDA, to launch its generic version of Pennsaid on a date that is the earlier of 45 days after Mallinckrodt or Nuvo makes a first commercial shipment of Pennsaid 2% in the U.S. and April 1, 2014, or earlier under certain circumstances. Apotex launched its generic version of Pennsaid in May 2014;

- In March, Galderma launched the commercial sale and marketing of Pliaglis in the U.S. See "Narrative Description of the Business – Topical Products and Technology Group – Pliaglis";

- In March, Mallinckrodt received a Complete Response Letter (CRL) to its New Drug Application (NDA) for Pennsaid 2% in which the FDA confirmed the only substantive additional requirement was the completion of a pharmacokinetic (PK) study comparing Pennsaid 2% to original Pennsaid. In July, Mallinckrodt advised Nuvo that it successfully completed the PK study required by the FDA in the CRL. In August, Mallinckrodt advised Nuvo that the FDA accepted for filing and review the NDA for Pennsaid 2%, submitted by Mallinckrodt on August 7, 2013. On January 16, 2014, Mallinckrodt received FDA approval for the sale and marketing of Pennsaid 2% in the U.S.;

- In April, Galderma launched the commercial sale and marketing of Pliaglis in the E.U. See "Narrative Description of the Business – Topical Products and Technology Group – Pliaglis";

- In May, the USPTO granted U.S. Patent No. 8,435,568 for the treatment of allergic asthma, allergic rhinitis and atopic dermatitis, using the existing formulation of WF10 and derivative formulations;

- In May, the Company completed a share consolidation on the basis of 65 pre-consolidation common shares for one post-consolidation common share reducing the number of common shares outstanding to 8.7 million;

- In July, the Company sold the exclusive rights to sell and market Synera in the U.S. for its current indication to Galen for US$4.5 million received on closing (Galen Upfront Payment), royalties of 10% of net sales and sales milestones of US$5.0 million upon gross annual U.S. sales reaching US$25.0 million and an additional US$5.0 million upon gross annual U.S. sales reaching US$50.0 million. See "General Development of the Business – Recent Financings and Corporate Transactions";

- In July, the Company amended its loan arrangements with Paladin; whereby, the Company drew upon the second $4.0 million loan tranche and could draw an additional third tranche of $4.0 million upon the achievement of predefined milestones (Amended Paladin Debt). The loan was repaid in full in October 2014. See "General Development of the Business – Recent Financing and Corporate Transactions";

- In August, the Company commenced legal action against Mallinckrodt asserting that it had breached its contractual obligations to Nuvo as set out in a licensing agreement pursuant to which Nuvo licensed to Mallinckrodt the rights to sell and market Pennsaid and to develop, sell and market Pennsaid 2% in the U.S. The Company sought damages of not less than US$100 million and a declaration that it was entitled to terminate the licensing agreement which would result in the rights to sell and market Pennsaid and/or Pennsaid 2% in the U.S. reverting to the Company. This matter was settled in September 2014. See "Narrative Description of the Business – Litigation";

- In October, Galderma received approval for the sale and marketing of Pliaglis in Brazil. The Company received a US$2.0 million milestone payment which related to the regulatory approval of Pliaglis in Brazil; and

- In December, the Company signed a supply and distribution agreement providing NovaMedica LLC (NovaMedica) with the exclusive rights to sell and market Pennsaid and Pennsaid 2% in Russia and some of the Community of Independent States (CIS). See "General Development of the Business – Recent Financings and Corporate Transactions".

Fiscal 2012

- In February, the Company launched Synera in the U.S. targeting interventional pain doctors with a small contract sales force. In September, the Company terminated its agreement with its contract sales organization (CSO) and refocused its resources on large national accounts such as dialysis centers, infusion centers and blood diagnostic laboratories;

- In February, Galderma submitted a Supplemental New Drug Application (sNDA) for Pliaglis with the FDA that addressed a number of manufacturing issues, including the transfer of manufacturing to Galderma. The FDA accepted the submission and set a

Prescription Drug User Fee Act (PDUFA) date of April 16, 2012. On April 16, 2012, Galderma received a CRL from the FDA that outlined additional information the FDA required before it would approve the sNDA for Pliaglis. In May 2012, Galderma submitted additional information that addressed all of the FDA's issues. On October 18, 2012, the FDA approved the sNDA;

- In May, the Company received notice of a positive opinion from the European decentralized procedure for the approval of Pliaglis from the German Federal Institute for Drugs and Medical Devices (BfArM). The Company received US$6.0 million in total milestone payments related to the regulatory approval of Pliaglis in Europe;

- In May, the Company completed a loan agreement with Paladin; whereby, the Company became eligible to borrow up to $8.0 million. The loan consisted of two equal tranches of $4.0 million each. One tranche was received by the Company on closing of the loan agreement in May 2012 and the second tranche could be drawn by the Company, at its option, upon the achievement of predefined milestones. The loan bore interest at 15% per annum and was to mature on May 25, 2016. The loan was later amended in July 2013 and repaid in full in October 2014. See "General Development of the Business – Recent Financings and Corporate Transactions";

- In July, the Company expanded its existing partnerships with the Development Bank of Saxony (SAB), the University of Leipzig and the Fraunhofer Institute for Cell Therapy and Immunology IZI (Fraunhofer Institute) to continue the development of WF10. The SAB committed to continue funding a portion of the cost of developing WF10 by way of €4.4 million of non-repayable funding. Total funding from the SAB to-date is €6.6 million towards a €10.8 million development program for WF10 with the Company providing the balance;

- In July, the USPTO issued Patent No. 8,217,078 relating to a method of using Pennsaid with an expiry date of July 10, 2029. Mallinckrodt listed the Pennsaid Patent in the FDA Orange Book;

- In August, the USPTO issued U.S. Patent No. 8,252,838 relating to compositions and methods of using Pennsaid 2% that expires on April 21, 2028; and

- In August, the USPTO granted U.S. Patent No. 8,252,343 relating to WF10 for the treatment of allergic asthma, allergic rhinitis and atopic dermatitis, creating a potential commercial opportunity for the existing formulation of WF10.

Recent Financings and Corporate Transactions

In the past three years, the Company has raised approximately $8.0 million from the issuance of debt and $4.1 million from the issuance of equity. The Company has also received approximately $57.6 million in upfront payments from product licensing and sale agreements, $11.2 from the settlement of the litigation with Mallinckrodt and $0.3 million from the sale of excess land in Varennes. The Company is continuing to explore further financing opportunities in order to develop existing drugs in its product pipeline or new drugs utilizing the Company's proprietary drug delivery platforms and to support general corporate initiatives.

Fiscal 2014

Pennsaid 2% U.S. Asset Sale

On October 17, 2014, the Company entered into an asset purchase agreement with Horizon pursuant to which the Company sold the sales and marketing rights, intellectual property and other assets with respect to Pennsaid 2% in the U.S. (Pennsaid 2% U.S. Sale Agreement) for cash consideration of US$45.0 million received on the closing date.

Under the terms of the Pennsaid 2% U.S. Sale Agreement, the Company sold the sales and marketing rights and other assets related to Pennsaid 2% in the U.S. including, among other things: the investigational new drug application (IND) and the NDA for Pennsaid 2%, the Company's interests in patents covering Pennsaid 2% in the U.S. and certain regulatory documentation, promotional materials and records related to Pennsaid 2%. Horizon launched the sale and marketing for Pennsaid 2% in the U.S. in early January 2015 and is now responsible for all matters related to Pennsaid 2% in the U.S.

Also pursuant to the Pennsaid 2% U.S. Sale Agreement, Nuvo agreed to discontinue the manufacture, sale and marketing of Pennsaid in the U.S. and is prohibited, for a period of ten years, from developing, manufacturing or commercializing any diclofenac sodium product for topical uses in humans in the U.S.

In connection with the Pennsaid 2% U.S. Sale Agreement, the Company also entered into a long-term supply agreement with Horizon. Pursuant to the supply agreement, the Company agreed to supply Pennsaid 2% to Horizon from its Varennes, Québec manufacturing facility for commercialization in the U.S. The initial term of the supply agreement expires December 31, 2022 and, unless terminated, will automatically renew for successive two-year terms, thereafter. The supply agreement may be terminated earlier by either party for any uncured material breach or other customary conditions. Under the supply agreement, Nuvo is obligated to supply Pennsaid 2% to Horizon and Horizon is obligated to obtain 100% of its requirements for Pennsaid 2% from Nuvo and will pay to Nuvo an agreed-upon transfer price under the supply agreement. The transfer price is subject to semi-annual adjustments based on Nuvo's raw material costs and annual adjustments based upon changes in the national manufacturing cost for pharmaceutical products. The supply agreement also provides for the selection and qualification of alternate suppliers of Pennsaid 2% and its active pharmaceutical ingredient (API). Following the approval by the FDA of a selected alternate supplier, and subject to certain limitations, the Company is required to enter into a supply agreement with the alternate supplier with respect to Pennsaid 2% or its API. To the extent that maintaining regulatory approvals for an alternative supplier requires the Company to purchase of minimum quantities of drug product or API from the alternate supplier, the Company is obligated to purchase such minimum quantities, subject to Horizon's obligation to reimburse the Company for any excess cost compared to our cost to otherwise obtain such drug product or API.

Litigation Settlement

On September 4, 2014, the Company reached a full settlement with Mallinckrodt of Nuvo's claims and Mallinckrodt's counterclaim related to Nuvo's license to Mallinckrodt to sell and market Pennsaid and Pennsaid 2% in the U.S. Under the terms of the settlement agreement, Mallinckrodt returned all U.S. rights to Pennsaid and Pennsaid 2% to Nuvo and paid the Company US$10.0 million as settlement for all claims. See "Narrative Description of the Business – Litigation".

Ferndale Collaboration

In April 2014, the Company entered into a collaboration agreement with Ferndale and a leading CRO to develop two topical dermatology products based on Nuvo's patented MMPE technology. The Company is currently developing both formulations. Under the terms of the collaboration agreement, Nuvo will utilize its proprietary MMPE technology to formulate two patented topical dermatology product candidates. Once the formulations are complete, Ferndale, in collaboration with the CRO, will oversee and fund the formulations' advancement through Phase 2 clinical studies. It is anticipated that the product candidates will then be made available for out-licensing. Licensing revenues, including upfront payments, milestone payments and royalties will be shared by the parties based on a calculation that includes compensation to Nuvo for contributing the patented formulations.

Private Placement

On March 31, 2014, the Company completed a non-brokered private placement, pursuant to which an aggregate of 1,390,000 units of the Company were issued at a price of $2.25 per unit for gross proceeds of $3.1 million ($2.9 million net of issuance costs). Each unit consisted of one common share of the Company and one-half of one common share purchase warrant of the Company (Unit). The Company issued 695,000 common share purchase warrants (Private Placement Warrants).

The Private Placement Warrants entitle the holder to purchase one common share of the Company at a price of $3.00 for a 24-month period. The Private Placement Warrants are subject to an acceleration feature, where the Company at its option, can force the exercise of the Private Placement Warrants following a specified date if the ten-day volume weighted share price for the Company's common shares is equal to or exceeds $3.50 on the Toronto Stock Exchange (TSX) at any time during the warrant term. If the Company elects to trigger the acceleration feature, any Private Placement Warrants that are not exercised prior to such date will expire. In the year ended December 31, 2014, 429,999 of the Private Placement Warrants were exercised and 15,650 were issued upon the exercise of 31,300 Broker Warrants.

In connection with the Private Placement, finder's fees were paid consisting of (a) a 6% cash commission totalling $0.2 million, and (b) broker warrants to purchase Units at a price of $2.54 per Unit (Broker Warrants), equal to 6% of the number of Units issued. The finder's fee was paid on Units purchased by new investors and not on Units purchased by management or its advisors. The Company issued 78,233 Broker Warrants.

Fiscal 2013

Pennsaid Russia Licensing Agreement

In the fourth quarter of 2013, the Company entered into a supply and distribution agreement providing NovaMedica with the exclusive rights to sell and market Pennsaid and Pennsaid 2% in Russia and some of the CIS. Under the terms of the agreement, NovaMedica made an upfront payment to Nuvo of US$0.5 million and Nuvo will manufacture and supply Pennsaid and Pennsaid 2% to NovaMedica and will share in the profits. NovaMedica is responsible for conducting required clinical studies and obtaining regulatory approval for the products in the licensed territories. The Company is entitled to receive a milestone payment of US$0.5 million when predefined sales targets for Pennsaid 2% have been achieved.

Synera U.S. Licensing Agreement

In July 2013, the Company sold the exclusive rights to sell and market Synera throughout the U.S. for its current indication to Galen. Under the terms of the product acquisition and license agreement, Nuvo received the Galen Upfront Payment on closing and Nuvo receives royalties of 10% of net sales and is eligible to receive a US$5.0 million milestone payment upon gross annual sales reaching US$25.0 million and a further US$5.0 million upon gross annual sales reaching US$50.0 million.

Paladin Loan

In July 2013, the Company completed an amendment to the May 2012 loan agreement with Paladin. The amended arrangement included a provision to borrow an additional $4.0 million (the Third Tranche) upon the achievement of predefined milestones increasing the total debt available under the agreement to $12.0 million. The second tranche of $4.0 million was advanced on closing of the Amended Paladin Debt arrangement. Under the terms of the Amended Paladin Debt, when the second tranche was drawn by Nuvo, Paladin was issued warrants to acquire 50,000 Nuvo common shares at $1.82 per share which represented 130% of the 5-day trailing value weighted average trading price (VWAP) of Nuvo common shares on the TSX. The warrants expire on July 10, 2016 and no warrants have been exercised to date. If Nuvo had exercised its option to draw down the Third Tranche of the loan, Paladin would have been entitled to warrants to acquire an additional 50,000 Nuvo common shares at 130% of the 5-day trailing VWAP of Nuvo common shares, as of the date that Nuvo draws the Third Tranche.

Under the terms of the Amended Paladin Debt, the Company was required to make payments on account of the Paladin debt equal to 10% of all royalty payments and milestones received by the Company on the sale of Synera in the U.S. by Galen, excluding the Galen Upfront Payment for the acquisition of the U.S. rights for Synera.

In October 2014, the Company paid $3.7 million to Paladin to settle the outstanding loan. All obligations of Nuvo and the other obligors under the loan agreement were satisfied and all security was released and discharged.

Fiscal 2012

In May 2012, the Company entered into a license and supply agreement with Paladin granting Paladin exclusive Canadian rights to sell and market the HLT Patch upon regulatory approval. Under the terms of the agreement, Nuvo will receive a double digit royalty on net sales of the HLT Patch in Canada and will supply the HLT Patch to Paladin. Paladin is responsible for obtaining regulatory approval for the HLT Patch in Canada.

In addition, Paladin agreed to loan Nuvo $8.0 million in two equal tranches of $4.0 million each (Paladin Debt). The first tranche was advanced on closing and the second tranche could be drawn by Nuvo, at its option, upon the achievement of predefined milestones. The loan bore interest at a rate of 15% per annum and would have matured on May 25, 2016. Under the terms of the May 2012 loan agreement, the Company paid 10% of all royalty payments received by the Company on the sale of Pennsaid and Pennsaid 2% in the U.S.; 10% of all royalty and milestone payments received by the Company on the sale of Pliaglis; and Paladin offset and retained 100% of the royalties payable to the Company on Canadian distribution of Pennsaid. The loan was secured by a charge over Nuvo's assets, excluding the Immunology Group's assets and was repaid in full in October 2014.

NARRATIVE DESCRIPTION OF THE BUSINESS

Nuvo is a publicly traded, Canadian specialty pharmaceutical company with a diverse portfolio of products and technologies. The Company operates two distinct business units: the TPT Group and the Immunology Group. The TPT Group has four commercialized products, a pipeline of topical and transdermal products focusing on various therapeutic areas including pain and dermatology and multiple drug delivery platforms that support the development of patented formulations that can deliver actives into or through the skin. The Immunology Group has two commercial products and an immune system modulation platform that supports the development of drug products that modulate chronic inflammation processes resulting in a therapeutic benefit.

Topical Products and Technology Group

The TPT Group is developing drugs for a variety of therapeutic areas with a focus on delivering drugs topically into and through the skin directly to the desired site or transdermally into the bloodstream with resulting systemic activity, if desirable. Unlike oral medications, the Company's commercial topical products aim to reach affected parts of the body without relying on delivery to the bloodstream by offering site-specific treatment while limiting systemic exposure to the active drug; thereby, reducing the potential for systemic side effects, adverse events and potential drug-drug interactions.

The Company's commercial topical products include Pennsaid, Pennsaid 2%, the HLT Patch and Pliaglis. The Company has multiple proprietary drug delivery platforms which include MMPE and DuraPeel™. These platforms are the focus of the development of the topical pipeline products.

Pennsaid 2%

Pennsaid 2% is the follow-on product to original Pennsaid. Pennsaid 2% is an NSAID containing 2% diclofenac sodium compared to 1.5% for original Pennsaid. It is more viscous than original Pennsaid, is supplied in a metered dose pump bottle and has been approved for twice daily dosing compared to four times a day for Pennsaid. This provides Pennsaid 2% with advantages over Pennsaid and other competitor products, and with patent protection. Pennsaid 2% has received marketing approval in the U.S.

Pennsaid 2% was approved on January 16, 2014 in the U.S. and launched by Mallinckrodt in February 2014 for the treatment of pain of OA of the knee. OA is the most common joint disease affecting middle-age and older people. It is characterized by progressive damage to the joint cartilage and causes changes in the structures around the joint. These changes can include fluid accumulation, bony overgrowth and loosening and weakness of muscles and tendons, all of which may limit movement and cause pain and swelling. In the U.S. market, Pennsaid 2% was originally licensed to Mallinckrodt. In September 2014, the Company reached a settlement related to its litigation with Mallinckrodt. See "Narrative Description of the Business – Litigation". Under the terms of the settlement agreement, Mallinckrodt returned the U.S. sales and marketing rights to Pennsaid 2% to Nuvo. In October 2014, the Company sold the U.S. rights to Pennsaid 2% to Horizon for US$45.0 million. Under the terms of this agreement, the Company earns revenue from product sales of Pennsaid 2% to Horizon. See "General Development of the Business – Recent Financings and Corporate Transactions". In January 2015, Horizon launched its commercial sale and marketing of Pennsaid 2% in the U.S.

Paladin has exclusive rights to market and sell Pennsaid 2% in Canada. In November 2014, the Company reacquired from Paladin the rights to market Pennsaid 2% in South America,

Central America, South Africa and Israel. As consideration for these rights, the Company provided its authorization to Paladin to market, sell and distribute an authorized generic version of Pennsaid in Canada.

NovaMedica has exclusive rights to sell and market Pennsaid and Pennsaid 2% in Russia and some of the CIS. NovaMedica has assumed responsibility for conducting all studies that may be required to obtain approval of Pennsaid 2% in those countries for which it has marketing rights. NovaMedica has advised that they will be conducting these studies in 2015.

In January 2014, the European Patent Office issued European Patent No. 2 086 504 that provides protection for the Pennsaid 2% formulation and its use. In 2014, the patent was validated in 9 European countries.

Additional clinical and non-clinical studies may be required to support applications for the regulatory approval of Pennsaid 2% in other countries in which the Company, or other licensees and distributors, could potentially market the product. The Company plans to conduct a Phase 3 clinical study in Germany using Pennsaid 2% for the treatment of acute sprains and strains to support regulatory approval applications for Pennsaid 2% in international jurisdictions. Commencement of the study, which is subject to German regulatory approval, is expected in Q2 2015 with top-line results anticipated in Q4 2015. There can be no assurance that the current and future trials and studies will be sufficient for regulatory authorities in any jurisdiction or that all studies will yield successful results or that the required regulatory approvals will be obtained.

A number of existing pharmaceutical products treat the pain associated with OA. The goal, according to the American College of Rheumatology, is “control of pain and improvement in function and health-related quality of life, with avoidance, if possible, of toxic effects of therapy”. There are many products available to address this condition with those available in the U.S. generally fall into one of the following categories:

- over-the-counter (OTC) oral medications that are accessible without a doctor’s prescription, such as acetaminophen (Tylenol) and low-dose NSAIDs such as ibuprofen (Advil, Motrin) and naproxen (Aleve);
- oral, full-dose, NSAIDs which are available by prescription only;
- oral, full-dose, NSAIDs combined with proton pump inhibitors (PPI) to reduce certain side effects common to NSAIDs, such as VIMOVO which combines naproxen, an NSAID, with esomeprazole magnesium, a PPI, which are available by prescription only;
- topical NSAIDs, which are available by prescription only;
- oral COX-2 selective NSAIDs which are available by prescription only; and
- oral opioid analgesics which are available by prescription only.

For the year ended December 31, 2014, the Company recorded $5.3 million in revenue related to Pennsaid 2% representing 40% of the Company’s total revenue [December 31, 2013 - $nil million or nil%].

Pennsaid

Pennsaid, the Company's first commercialized topical pain product, is used to treat the signs and symptoms of OA of the knee. Pennsaid combines a transdermal carrier (containing dimethyl sulfoxide, popularly known as DMSO) with diclofenac sodium, a leading NSAID and delivers the active drug through the skin at the site of pain. While conventional oral NSAIDs expose patients to potentially serious systemic side effects such as gastrointestinal bleeding and cardiovascular risks, Nuvo's clinical trials suggest that some of these systemic side effects occur less frequently with topically applied Pennsaid.

The Company enters into marketing and/or distribution agreements with third-party partners that have sales and marketing capabilities. Nuvo earns revenue from its partners in the form of product sales. In Canada, the Company also earns a royalty on Canadian net sales. As of December 31, 2014, the Company no longer earns a royalty on Pennsaid sales in the U.S., as Pennsaid is no longer sold in the U.S. market.

The Company has conducted multiple clinical studies on more than 1,600 subjects that demonstrated both the safety and efficacy of Pennsaid in the treatment of OA of the knee. Pennsaid is the only topical NSAID approved by the FDA with the indication for the treatment of the signs and symptoms of OA of the knee.

United States

Since 2012, four patents related to Pennsaid have been issued by the USPTO with expiry dates in 2029 and 2030 (Pennsaid Patents) and are listed in the FDA's Orange Book. The Orange Book listing required any ANDA applicant seeking FDA approval for a generic version of Pennsaid, prior to expiration of the patent, to provide a certification notice to Nuvo and Mallinckrodt of its ANDA before it can obtain FDA approval. Subsequent to the Orange Book listing, Nuvo and Mallinckrodt received Paragraph IV certification notices from several companies advising Nuvo and Mallinckrodt that they each filed an ANDA with the FDA seeking approval to market a generic version of Pennsaid prior to expiration of the Pennsaid Patents, and consequently, Nuvo and Mallinckrodt filed patent infringement complaints with the courts, and settled with a majority of generic companies.

In January 2013, Nuvo and Mallinckrodt entered into the Apotex Settlement Agreement. Under the terms of the Apotex Settlement Agreement, Nuvo and Mallinckrodt granted a license to Apotex that permits Apotex, upon approval of its ANDA by the FDA, to launch its generic version of Pennsaid on or after April 1, 2014. Apotex received approval for their generic version of Pennsaid in May 2014 and launched in late May 2014.

In September 2014, the Company settled its litigation with Mallinckrodt and under the terms of the settlement, Mallinckrodt agreed to return the U.S. rights to Pennsaid and Pennsaid 2% to Nuvo (see "Narrative Description of the Business – Litigation"). In October 2014, the Company sold the U.S. rights to Pennsaid 2% to Horizon (see "General Development of the Business – Recent Financings and Corporate Transactions"). Under the terms of the Pennsaid 2% U.S Sale Agreement, the Company agreed to discontinue the manufacture, sale and marketing of Pennsaid in the U.S.

In December 2014, a second generic version of Pennsaid launched in the U.S., which entitled the Company to earn an up-front, non-refundable milestone payment of US$0.5 million ($0.6 million). In a patent infringement complaint against this generic company, the Company, along with Mallinckrodt, entered into a settlement agreement whereby this generic company

would agree to pay an up-front, non-refundable milestone of US$0.5 million upon the launch of its generic version of Pennsaid, and agree to pay royalties calculated at 50% of gross profits from subsequent product sales until which time a third generic version of Pennsaid was launched in the U.S. and then the royalty rate would decrease to 10% of its gross profits from product sales. This generic agreement was assigned to the Company as part of the settlement agreement with Mallinckrodt.

Canada

In February 2014, Taro Pharmaceutical Industries, Ltd. received approval in Canada for a generic version of Pennsaid which they launched in March. In the fourth quarter of 2014, this generic started to have an impact on the net sales that Paladin earns from Pennsaid, thereby reducing the Company's royalty income in Canada. In addition, there is a second generic version of Pennsaid that is approved in Canada that has not launched. It is not known if, or when, this generic version of Pennsaid will be sold in the Canadian market.

Rest of World

Pennsaid is also approved for sale and marketing in Greece, Italy and the U.K. Nuvo does not directly market Pennsaid in these jurisdictions.

In 2013, the Company licensed the exclusive rights to sell and market Pennsaid and Pennsaid 2% in Russia and some of the CIS to NovaMedica. NovaMedica is responsible for conducting required clinical studies and obtaining regulatory approval for the products in the licensed territories.

For the year ended December 31, 2014, the Company recorded $6.0 million in revenue related to Pennsaid representing 46% of the Company's total revenue [December 31, 2013 - $9.6 million or 52%].

Pliaglis

Pliaglis is a topical local anaesthetic cream that provides safe and effective local dermal anaesthesia on intact skin prior to superficial dermatological procedures, such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing and laser-assisted tattoo removal. This product contains lidocaine and tetracaine and utilizes proprietary phase-changing topical cream Peel technology. The Peel technology consists of a drug-containing cream which, once applied to a patient's skin, dries to form a pliable layer that releases drug into the skin. Pliaglis should be applied to intact skin for 20 to 30 minutes prior to superficial dermatological procedures and for 60 minutes prior to laser-assisted tattoo removal. Following the application period, Pliaglis forms a pliable layer that is easily removed from the skin allowing the dermatological procedure to be performed with minimal to no pain.

Galderma holds the worldwide sales and marketing rights for Pliaglis. Under the terms of the licensing agreement, the Company earns royalties on the net sales of Pliaglis and is eligible to earn and receive milestone payments when certain specified approvals are obtained and launches occur. The Company has earned all milestone payments as per the terms of the agreement. Galderma is responsible for manufacturing Pliaglis.

Pliaglis was launched in the U.S. market in March 2013 and in the E.U. in April 2013. In the E.U., the regulatory approval required a post-approval commitment study, the cost of which will be shared equally by Galderma and Nuvo. In South America, Pliaglis is approved and marketed in Brazil and Argentina. Pliaglis was launched in Brazil in March 2014. Pliaglis is also approved in Canada, but has not been launched in this market. The Company expects Galderma to file for marketing approval in other countries around the world, including other South American countries, select Asian countries, South Africa and Australia.

Pliaglis was initially approved by the FDA in June 2006 and launched by Galderma, but was voluntarily removed from the U.S. market in 2008, due to manufacturing issues at a former third party contract manufacturing organization (CMO). As a result, Galderma negotiated an amendment to the licensing agreements. Under the terms of this amendment ZARS received a cash payment of US$6 million in exchange for agreeing to a downward adjustment to the royalty rates it was to receive on the global net sales of Pliaglis. These reduced royalty rates continue until such time as Pliaglis achieves a predetermined monetary milestone that is based on the cumulative aggregate sales of Pliaglis and the difference between the original and the adjusted royalty rates. In addition, if this milestone is not achieved by April 2015, the royalty rates will be reduced further until such time as the target is reached, subject to a minimum annual royalty rate being paid to the Company. Upon the sales thresholds being met, the royalty rates revert back to the amounts specified under the original agreements. The cumulative aggregate sales of Pliaglis to-date have not achieved the predefined monetary milestone and the Company anticipates that the royalty rate will decline in April 2015.

Pliaglis has been studied in 2,048 adult and geriatric subjects in 28 studies evaluating its efficacy and safety including 14 Phase 2 studies and 12 placebo-controlled, Phase 3 clinical studies. Eleven of the 12 studies clearly demonstrated the efficacy of Pliaglis in providing highly statistically significant and clinically meaningful levels of topical local anaesthesia prior to a painful dermal procedure in a variety of locations on the body of adult and geriatric subjects.

For the year ended December 31, 2014, the Company recorded $0.2 million in revenue related to Pliaglis representing 2% of the Company's total revenue [December 31, 2013 - $2.2 million or 12%].

HLT Patch

The HLT Patch is a topical patch that combines lidocaine, tetracaine and heat, using Nuvo's proprietary Controlled Heat-Assisted Drug Delivery (CHADD™) technology. The CHADD unit generates gentle heating of the skin and in a well-controlled clinical trial has demonstrated that it contributes to the efficacy of the HLT Patch by improving the flux rate of lidocaine and tetracaine through the skin. The HLT Patch resembles a small adhesive bandage in appearance and for its currently approved indication is applied to the skin 20 to 30 minutes prior to painful medical procedures, such as venous access, blood draws, needle injections and minor dermatologic surgical procedures.

In the U.S., the HLT Patch is marketed under the brand name Synera by Galen. Synera is approved in the U.S. to provide local dermal analgesia for superficial venous access and superficial dermatological procedures, such as excision, electrodessication and shave biopsy of skin lesions. In July 2013, the Company sold the rights to sell and market Synera in the U.S. to Galen for its current indication. See "General Development of the Business – Recent Financings and Corporate Transactions". Under the terms of the license agreement, the Company earns royalties on the net sales of Synera and is eligible to receive sales milestones. The HLT Patch has FDA Orange Book listed patents, the latest of which expires in July 2020. In September

2012, the Company successfully completed a study to provide data to support an application for the removal of the “not for home use” condition included on the U.S. label of Synera. The Company filed a prior approval supplement (PAS) with the FDA in May 2013 requesting removal of the “not for home use” condition from the label. In March 2014, the FDA approved the PAS that requested the removal of the “not for home use” condition from the label. In December 2014, the Company entered into a three-party agreement, which included a covenant from the Company not to sue one of the parties for patent infringement. As consideration, Nuvo will receive a total of US$175,000, to be paid in five equal non-refundable instalments based upon the timeline provided in the agreement.

In most E.U. countries, the HLT Patch is marketed under the trade name Rapydan and is approved for surface anaesthesia of normal intact skin in connection with needle punctures in adults and children from 3 years of age and for use in cases of superficial surgical procedures on normal intact skin in adults. The Company has licensed the sales and marketing rights to Eurocept for: all countries in Europe, Israel and the People’s Republic of China. Eurocept has responsibility for all commercialization activities and costs, including marketing, selling and medical education in the aforementioned countries. Under the terms of the license agreement, the Company earns royalties on the net sales of Rapydan and is eligible to receive sales milestones.

The HLT Patch is manufactured by a CMO for Galen and Eurocept. Currently, the Company manufactures the bulk drug substance for both parties.

In May 2012, the Company entered into a license and supply agreement granting Paladin exclusive Canadian rights to market and sell the HLT Patch, upon regulatory approval. Under the terms of the agreement, the Company will receive a double digit royalty on net sales of the HLT Patch in Canada and will supply the HLT Patch to Paladin. The HLT Patch has not yet been approved by Canadian regulatory authorities for sale and marketing in Canada.

The Company holds the sales and marketing rights for the HLT Patch in Mexico, South America, Australia, Africa and most regions in Asia. The Company is looking for licensing partners in these territories. The HLT Patch is not approved in any of these territories.

The HLT Patch has been studied extensively on more than 1,400 subjects in 26 clinical trials. Trials on the HLT Patch have been conducted in pediatric, adult and geriatric patient populations with PK trials, toxicology studies in animals and dermal safety studies in humans supporting the safe use of the HLT Patch. In a controlled clinical trial that compared Synera to EMLA Cream (EMLA), the HLT Patch showed significantly reduced patient-reported pain intensity as compared to EMLA for venous access procedures following application times of 10, 20 and 30 minutes. The p-values for each time point were 0.010, 0.042 and 0.001.

For the year ended December 31, 2014, the Company recorded $0.3 million in revenue related to the HLT Patch representing 2% of the Company’s total revenue [December 31, 2013 - $5.5 million or 30%].

Pipeline Expansion and Early Stage Drug Development

The Company has a broad portfolio of development stage products and proprietary platform technologies, MMPE and DuraPeel. These platforms are the focus of the development of topical products for a variety of therapeutic areas. The Company is actively seeking co-development partners to advance its pipeline products.

The following table summarizes our key product candidates:

Product	Therapeutic Area	Stage of Development	Intellectual Property[1]
Pennsaid 2%	Acute strains & sprains	Phase 3 clinical trials	Patents granted in AU, CH, DE, DK, FR, GB, GR, IE, IT, NL, HK, JP, MX, NZ, RU, ZA, expiring in 2027. Application allowed in Canada and pending in 6 countries.
Mical (1) [2]	Psoriasis	Preclinical	Patent granted in the U.S. expiring in 2027.
Mical (2) [2]	Women's skin care	Preclinical	Patent granted in the U.S. expiring in 2027.
HLT Patch (lidocaine 70mg / tetracaine 70mg)	Acute Musculoskeletal Pain	Phase 2 clinical trial	Patent granted in JP and pending in 8 other countries including U.S. and EP with latest anticipated expiry date in 2031.
Flexicaine (lidocaine 7%/ tetracaine 7% cream)	Postherpetic Neuralgia	Phase 2 clinical trial	Patents granted in AU and CN, with latest expiring in 2031. Applications allowed in RU and the U.S. and pending in 9 other countries including EP. Latest anticipated expiry date is 2031.
TAC DuraPeel (Triamcinolone Acetonide 0.5%)	Hand Dermatitis	Phase 2 clinical trial	Patents granted in AU, CN, CA and the U.S. with the latest anticipated expiry date in 2026. Applications allowed in EP, CN and pending in 7 other countries including U.S. Latest anticipated expiry in 2031.
Ropivacaine DuraPeel (6.5% Ropivacaine)	Neuropathic Pain	Phase 2 clinical trial	Patents granted in AU, CN, CA and the U.S. with the latest anticipated expiry date in 2027. Applications pending in U.S., EP and JP.
Alprazolam Patch (1% alprazolam)	Anxiety Disorder	Multiple Phase 1 clinical trials	Patent granted in the U.S. and application pending in EP. Anticipated expiry date is 2029.
Risperidone Patch (2% risperidone)	Schizophrenia	Pre-clinical	Applications pending in EP and U.S. Latest anticipated expiry date is 2028.
Ibuprofen Foam (5% ibuprofen)	Acute Pain	Pre-clinical	Applications pending in EP, CA and U.S. Anticipated expiry date is 2031.
Terbinafine solution (terbinafine 10% solution)	Onychomycosis	Pre-clinical	Application allowed in AU and pending in 5 other countries including U.S. and EP. Latest anticipated expiry date is 2030.

[1] Region and country abbreviations defined as follows: Australia (AU), Canada (CA), China (CN), Denmark (DK), Europe (EP), France (FR), Germany (DE), Great Britain (GB), Greece (GR), Ireland (IE), Italy (IT), Netherlands (NL), Hong Kong (HK), Japan (JP), Mexico (MX), New Zealand (NZ), Russian Federation (RU), South Africa (ZA), Switzerland (CH), United States (U.S.).

[2] Mical is a product being developed under the Ferndale collaboration (see Recent Financings and Corporate Transactions – 2014 - Ferndale Collaboration).

Immunology Group

The Immunology Group, based in Leipzig, Germany, is focused on developing drug products that modulate chronic inflammation processes resulting in a therapeutic benefit. Such pathological, inflammatory processes play an important role in the onset of several diseases including allergic rhinitis, allergic asthma, rheumatoid arthritis and inflammatory bowel diseases.

WF10

WF10 is an immune system modulating drug containing chlorite and/or chlorate ions including its derivative formulations and dosage forms as formulated or developed by the Company. The immune system provides an essential defence to micro-organisms, cancer and substances it sees as foreign and potentially harmful.

It is believed that WF10 focuses on supporting the immune system by targeting the macrophage, a type of white blood cell that coordinates much of the immune system, to regulate normal immune function. Normally functioning macrophages can alternate between one of two basic states: phagocytic and inflammatory. Phagocytic macrophages digest invading organisms, such as viruses, and initiate a biological defence pathway. Inflammatory macrophages induce a variety of reactions including fever, sweating, swollen glands, malaise and appetite loss, the common, uncomfortable signs of illness. Such responses, while entirely normal, must be turned on and off in a controlled manner. If left unchecked, pathogens can overdrive the system toward the inflammatory state creating an imbalance that may lead to such medical disorders as chronic inflammation, immune deficiency, organ damage and tumour proliferation.

It is believed that WF10's mode of activity is based on how macrophages regulate the immune system. Research suggests that, in some cases, WF10 may rebalance improperly functioning immune systems. The drug has potential applications in adjuvant cancer therapy, diseases related to immune deficiencies and the management of chronic viral infections.

Based on the concept that WF10 may rebalance improperly functioning immune systems, the Company's scientists have hypothesized that it may be effective for the treatment of conditions such as allergic rhinitis, where the body's immune system inappropriately responds to the presence of foreign allergens and rheumatoid arthritis, where autoimmunity plays a pivotal role in the progression of cartilage destruction in the joints. Autoimmunity is the failure of the body to recognize its own cells and tissues and; therefore, the body initiates an immune response against its own cells and tissues.

WF10 is approved in Thailand under the name Immunokine as an adjunct in the treatment of cancer to relieve post radiation therapy syndromes and as adjunctive therapy for diabetic foot ulcers.

WF10 Development for the Treatment of Allergic Rhinitis

What is Allergic Rhinitis?

Allergic rhinitis is a highly prevalent condition characterized by nasal symptoms (runny, blocked, or itchy nose; chronic sneezing) triggered by an inappropriate immune response to one or more allergens such as pollens, house dust mites and pet dander. Refractory allergic rhinitis patients usually show strong symptoms and do not respond adequately to common forms of treatment such as antihistamines or inhaled corticosteroids. It is estimated that there are 82 million allergy patients in the U.S. of which approximately 10 million suffer from allergic rhinitis that is refractory.

Clinical Studies

Single-Centre Phase 2a Study

In 2010, the Company conducted a Phase 2 proof-of-concept clinical trial to evaluate WF10 as a treatment for persistent allergic rhinitis. The trial was a 60-subject, randomized, double-blind, placebo-controlled, single-centre trial to assess the efficacy and safety of a regimen of five daily WF10 infusions. The trial met its primary endpoint as measured by the change in Total Nasal Symptom Score (TNSS) from baseline to assessment after three weeks comparing the WF10 group with the placebo group. The trial also met its secondary endpoints as measured by the change in TNSS at six, nine and twelve weeks and in the Total Ocular Symptom Score (TOSS) from baseline to assessment after three, six, nine and twelve weeks. The TNSS and TOSS are validated scales to measure nasal and ocular symptoms associated with allergic rhinitis. The results were statistically significant as the p-value for all primary and secondary endpoints with p-values less than 0.001 except for the change in TOSS after three weeks for which the p-value was less than 0.003. WF10 was very well tolerated with a favourable safety profile. This trial also demonstrated that a short course of treatment (5 days) with WF10 resulted in a long-term treatment effect that persisted for the duration of the 12 week clinical trial. In an anecdotal follow-up 12 months after treatment, most of the patients that received WF10 reported that they were still obtaining relief from their allergic rhinitis symptoms.

Multi-Centre Phase 2b Study

In December 2013, the BfArM, authorized the Company to execute another Phase 2 clinical trial. This clinical trial was a 16-week, double-blind, placebo-controlled, Phase 2 clinical trial conducted in Germany to compare the safety and efficacy of WF10 and its main constituents (sodium chlorite and sodium chlorate) with saline in patients with refractory allergic rhinitis and to compare the safety and efficacy of WF10 and its main constituents. The trial measured TNSS and other secondary endpoints and was completed in December 2014 with 179 patients completing the trial of 184 patients who enrolled in the trial at 15 sites in Germany. The trial included three active arms (the Active Arms):

a) WF10;

b) WF10 with chlorate and sulphate removed; and

c) WF10 with chlorite and sulphate removed.

Each of the Active Arms was compared to a placebo arm in which patients received saline. Active or placebo treatments were administered by five intravenous infusions given once per day during the first five days of the trial. The primary endpoint was change in TNSS from baseline to assessment after three weeks comparing the Active Arms with the placebo arm.

Topline Findings of the trial are:

- The WF10 arm demonstrated a reduction in TNSS over the course of the observation period, similar to the reduction in TNSS demonstrated in the WF10 arm in the Company's previous 2010 Phase 2 proof-of-concept study;

- The placebo arm demonstrated a reduction in TNSS over the course of the observation period that was significantly greater than demonstrated in the placebo arm of the Company's 2010 Phase 2 proof-of-concept study;

- Each of the Active Arms demonstrated a greater reduction in TNSS than placebo; however,

    a. the difference between the WF10 arm and the placebo arm did not achieve statistical significance 3 weeks after commencement of the trial which was the trial's primary endpoint; and

    b. the difference between the Active Arms and the placebo arm did not achieve statistical significance at measured time points over the course of the observation period.

- Treatments administered in the Active Arms were well tolerated with favourable safety profiles.

The Company is conducting a detailed review of the data and expects to release further information and analysis of the data including information on secondary endpoints when the analysis is completed.

A number of additional studies would need to be conducted before WF10 could be submitted for regulatory approval for the treatment of allergic rhinitis or any other disease and there can be no assurance that the results of these additional studies would be favourable or that regulators would approve WF10 for these or other purposes. Any such studies and approvals would be expected to take a number of years.

Funding

In July 2012, the SAB agreed to provide the Company with €4.4 million of funding to support a number of preclinical studies relating to both WF10 and improved reformulated versions of WF10 (Reformulated WF10). These studies were conducted by the Company in partnership with the University of Leipzig and the Fraunhofer Institute and were focused on demonstrating the efficacy, safety and stability of Reformulated WF10. The total cost of this development program is estimated to be €6.3 million and the SAB committed to provide up to €4.4 million in funding to support these projects, €3.7 million of which will be provided to the Company's co-operative partners and €0.7 million of which will be provided directly to the Company. The funding was in the form of a non-repayable reimbursement of specific development monies expended by the Company until October 2014.

Intellectual Property

WF10

In August 2012, the USPTO granted U.S. Patent No. 8,252,343 for the treatment of allergic asthma, allergic rhinitis and atopic dermatitis using the existing formulation of WF10. Similar patent applications are pending in Canada and allowed in Europe.

In May 2013, the USPTO granted Patent No. 8,435,568, for the treatment of allergic asthma, allergic rhinitis and atopic dermatitis using the existing formulation of WF10 and derivative formulations.

In December 2014, the USPTO granted U.S. Patent No. 8,911,797, related to the use of formulations that include chlorite ions (such as WF10) to treat or inhibit allergy-like symptoms

that include conjunctivitis in patients suffering from or at risk of developing allergic asthma, allergic rhinitis or atopic dermatitis.

The Company's three U.S. patents will expire in 2028. Additional patent applications are pending.

Reformulated WF10

In December 2011, the Company filed a new U.S. provisional patent application for reformulated versions of WF10. In December 2012, the Company filed an international Patent Cooperation Treaty (PCT) application and a U.S. patent application claiming priority to the December 2011 U.S. provisional application. The PCT application was nationalised in Australia in 2013 and subsequently allowed on October 8, 2014. The PCT application was additionally nationalised in 13 other countries in 2014.

Oxoferin

Oxoferin, a topical wound healing agent, contains the same active ingredient as WF10, but at a lower concentration. Chronic, hard-to-heal wounds are a serious problem with an increasing incidence. Chronic wounds can be caused by such conditions as burns, pressure sores and poor circulation in the lower extremities. Co-morbid conditions, such as diabetes and atherosclerosis, reduce blood flow to the extremities and also increase the likelihood of developing chronic wounds such as diabetic foot ulcers and venous ulcers.

Oxoferin is marketed by Nuvo Manufacturing GmbH and its partners in parts of Europe, Asia and South America as a topical wound healing agent under the names Oxoferin and Oxovasin. The product is licensed to Ranbaxy Laboratories Limited (Ranbaxy) for Malaysia, the Philippines, Vietnam, Singapore and other Indochina countries and Algeria, Tunisia and Morocco. In 2014, Ranbaxy received approval to market Oxoferin in Morocco, Malaysia and the Philippines and has launched in these territories. The product has not been approved or marketed in any of the other territories and Ranbaxy is at various stages in pursuing marketing approvals in these jurisdictions. In 2014, a licensing agreement for Russia was terminated.

The Company's patents associated with Oxoferin have expired and the Company is exploring improved formulations of this product for which the Company has filed 9 patent applications that cover a new version of Oxoferin. See "Narrative Description of the Business — Intellectual Property".

For the year ended December 31, 2014, the Company recorded $0.6 million in revenue related to Oxoferin and WF10 representing 5% of the Company's total revenue [December 31, 2013 - $0.6 million or 3%].

Manufacturing and Facilities

The Company has a manufacturing facility in Varennes, Québec that produces Pennsaid, Pennsaid 2% and the bulk drug products for the HLT Patch. The Company manufactures these products for all of its global partners for all markets where the products are sold. The facility is in compliance with current Good Manufacturing Practices (GMP). In September 2012 and February 2013, the plant passed two FDA inspections as part of the U.S. Pennsaid 2% NDA review and U.S. Synera sNDA review.

The Company has a small manufacturing facility in Wanzleben, Germany that produces the active ingredient in WF10 and Oxoferin.

Intellectual Property

Patents

Pennsaid

The Canadian and U.S. composition of matter patents for Pennsaid have expired. However, upon FDA approval of Pennsaid in the U.S., the product received a three-year period of marketing exclusivity from the date of approval pursuant to the "Hatch-Waxman Act", and Code of Federal Regulations (C.F.R.) 314.108(b)(4) which provide that a product filed as a 505(b)(2) application and supported by sponsor initiated clinical studies required as a condition of approval is entitled to three years of marketing exclusivity starting from the effective date of approval. This period of marketing exclusively prohibited the sale of generic versions of Pennsaid in the U.S. until November 2012, three years from the effective date of approval. As such market exclusivity has now expired, there are generic versions of Pennsaid available in the U.S. market.

In July 2012, the USPTO issued the first Pennsaid Patent with an expiry date of July 10, 2029. Three additional Pennsaid Patents were issued on October 1, 2013, December 31, 2013 and June 3, 2014 with expiry dates ranging from July 10, 2029 to August 9, 2030. The Pennsaid Patents are listed in the FDA Orange Book. In addition, there are additional U.S. patent applications relating to methods of using Pennsaid that are currently pending. The Company sold the Pennsaid Patents and applications to Horizon in October 2014 pursuant to the Pennsaid 2% U.S. Sale Agreement.

The European composition of matter patent for Pennsaid (covering Austria, Belgium, France, Germany, Italy, Liechtenstein, Luxembourg, Netherlands, Sweden, Switzerland and the U.K.) expired in June 2006. In Italy, the Supplementary Protection Certificate that extended the life of this patent expired in March 2011. See “Risk Factors – Patents, Trademarks and Proprietary Technology”.

Pennsaid 2%

The Company has filed patent applications to cover Pennsaid 2% and other related formulations in a number of jurisdictions worldwide. The Australian, European, Hong Kong, Japanese, Mexican, Russian, South African and New Zealand patents covering Pennsaid 2% are granted and the Canadian patent application was allowed in 2014. In addition, the USPTO issued U.S. Patent No. 8,252,838, U.S. Patent No. 8,563,613 and U.S. Patent No. 8,871,809 relating to compositions and methods of using Pennsaid 2% on August 28, 2012, October 22, 2013 and October 28, 2014, respectively. In addition, there are U.S. patent applications for Pennsaid 2% that are currently pending. The Company sold the U.S. Pennsaid 2% patents and applications to Horizon in October 2014 pursuant to the Pennsaid 2% U.S. Sale Agreement.

There are additional patent applications pending in Brazil, China, Europe, Hong Kong, India and Israel that relate to the Pennsaid 2% franchise.

Pliaglis

The Company owns two patent families which cover Pliaglis. Claims are directed to compositions of matter and methods of use. A number of patents have been issued in Austria, Belgium, Canada, China, Cyprus, Denmark, Finland, France, Germany, Great Britain, Greece, Ireland, Italy, Luxemburg, Monaco, Netherlands, Portugal, Spain, Sweden, Switzerland, and the U.S. Of the two patent families, the latest expiry date is 2019 in the U.S. and 2020 in countries outside of the U.S.

The Company pays royalties to two companies for 1% and 1.5% of net sales of Pliaglis.

HLT Patch

The Company owns several patent families covering the HLT Patch, methods of manufacture and methods of use. One family specifically covers the HLT Patch with composition of matter claims, manufacture claims and method of use claims (prescribed indications). In this family, a number of patents have been issued in Austria, Belgium, Canada, China, France, Germany, Great Britain, Italy, Netherlands, Spain, Sweden, Switzerland, and the U.S. Of the several patent families, the latest expiry date is 2020 worldwide. Additionally, two patent families directed to new methods of use are currently pending in 8 countries and granted in Japan. The latest anticipated expiry date is 2031.

The Company pays royalties to two companies for 1% and 1.5% of net sales of the HLT Patch.

Flexicaine

The Company owns two distinct patent families relating to its Flexicaine formulation. Both families include composition of matter claims and method of use claims for treating neuropathic pain. The first family has patents granted in Australia and China and applications allowed in Russia and the U.S. Additional applications are pending in 5 other countries. The second family has a patent granted in Australia and is pending in 7 other countries.

Topical Antifungals

The Company has an allowed application in Australia and 5 pending applications in other jurisdictions that cover the Company's novel onychomycosis product candidate.

MMPE Technology

A U.S. patent claiming certain combinations of particular molecular penetration enhancers (MPEs) together with certain active drugs in topical formulations was issued on September 14, 2010 as U.S. Patent No. 7,795,309. Two related U.S. patents covering alternative topical formulations were issued on January 1, 2013 as U.S. Patent No. 8,343,962 and August 20, 2013 as U.S. Patent No. 8,513,304. In addition, U.S. patent applications covering other topical formulations were filed in 2013 and 2014. The Company also holds a royalty-free license for devices useful in assessing MPEs on the barrier properties of membranes which are covered by an issued U.S. patent.

DuraPeel Technology

The Company holds several patent families covering the DuraPeel technology platform. Claims are directed to composition of matter and methods of use in the treatment of pain, dermatitis and other conditions. Worldwide, there are 8 patent applications pending and 14 issued patents. There are also 2 allowed and 7 pending applications in various jurisdictions drawn to an improved topical composition for the treatment of dermatitis.

WF10

With the acquisition of Oxo Chemie on May 31, 2002, the Company acquired patents relating to the immune regulation technology underlying WF10, some of which have since expired. The Company does not hold composition of matter patents on WF10 itself or on all its potential uses, but does hold patents and has filed patent applications for particular prescribed uses of WF10. For example, the Company has three issued patents in the U.S. related to a method of using WF10 and derivative formulations to treat allergic asthma, allergic rhinitis and atopic dermatitis. In 2011, the Company conducted research with a view to developing an improved version of WF10. These research efforts led to the filing of a new U.S. provisional patent application in December 2011. In 2012, an international PCT application and a U.S. patent application were filed claiming priority to this provisional application. An Australian patent application was filed in 2013 and was subsequently allowed on October 8, 2014. The PCT application was additionally nationalised in 13 other countries in 2014.

Oxoferin

All Oxoferin composition of matter patents have expired. The Company is conducting research with a view to developing an improved version of Oxoferin with enhanced wound healing abilities. The Company has 9 patent applications in various jurisdictions that cover a new version of Oxoferin.

Trademarks

The Company holds certain registered trademarks and trademark applications that cover its pipeline and commercial products.

Confidential Information and Trade Secrets

In addition to patent protection, the confidential nature of the Company's expertise and its trade secrets provides a period of exclusivity with respect to processes or products developed by, or for, the Company and its exclusive benefit. The Company believes it has taken steps reasonably necessary to protect the confidentiality of its commercially sensitive activities.

Technology

The Company has multiple drug delivery platforms that support the development of patented formulations that can deliver actives into or through the skin. The most significant platforms are:

DuraPeel

The DuraPeel technology is self-occluding, film-forming cream/gel formulations that provide extended release delivery to the site of application. The cream/gel contains a drug

applied to a patient's skin forming a pliable layer that releases drug into the skin for up to 12 hours. The benefits of the DuraPeel technology include proven compatibility with a variety of APIs, self-occluding film reduces product transference risk, fast drying time and easy application and removal and application to large and irregular skin surfaces. Patents have been issued in Australia, Canada, China, Japan and the U.S. with the latest expiry in 2027. Patent applications are pending in Australia, Canada, Brazil, China (allowed), Europe (allowed), India, Japan, Hong Kong and the U.S. through 2031.

MMPE

The MMPE technology uses synergistic combinations of pharmaceutical excipients included on the FDA's Inactive Ingredient Guide (IIG) for improved topical delivery of actives into or through the skin. The benefits of this technology include the potential for increased penetration of Active Pharmaceutical Ingredients (API) with the possibility of improved efficacy, lower API concentration and/or reduced dosing. Issued U.S. patents provide intellectual property protection through March 6, 2027.

Employees

As at February 19, 2015, the Company had 66 full-time employees. Nuvo employees are not subject to any collective bargaining agreements and are not unionized.

Specialized Skill and Knowledge

The Company specializes in drug development and relies on its ability to design and conduct clinical studies, navigate the regulatory pathway in Canada, the U.S. and Europe and outlicense its products in development. The Company from time-to-time will enlist the support of experienced clinical trial, regulatory and legal consultants and will use this and its own expert knowledge to assist in the successful development of its products and the protection of its intellectual property.

Competitive Conditions

The pharmaceutical industry is characterized by evolving technology and intense competition. Many companies, including major pharmaceutical and specialized biotechnology companies, are engaged in activities focused on medical conditions that are the same as or similar to those targeted by the Company. The Company's success depends upon maintaining its competitive position in the R&D and commercialization of its products. Competition from pharmaceutical, chemical and biotechnology companies, as well as universities and research institutes, is intense and is expected to increase. Many of these organizations have substantially greater R&D, experience in manufacturing, marketing, financial and managerial resources and they represent significant competition.

The Company's branded products may face competition from generic versions. Generic versions are generally significantly cheaper than the branded version, and, where available, may be required or encouraged in preference to the branded version under third-party reimbursement programs or substituted by pharmacies for branded versions by law. The entrance of generic competition to the Company's branded products generally reduces the market share and adversely affects the Company's profitability and cash flows. Generic competition with the Company's branded products would be expected to have a material adverse effect on net sales and profitability of the branded product and of the Company.

Regulatory Environment and Drug Development Process

The research, development, manufacture and marketing of pharmaceutical products are subject to regulation by the FDA in the U.S., the Therapeutic Products Directorate (TPD) in Canada, the European Medicines Agency (EMA) in Europe and comparable regulatory authorities in other foreign countries. These agencies and other federal, state, provincial and local entities regulate the testing, manufacture, safety and promotion and sale of the Company's products.

For a pharmaceutical company to launch a new prescription or non-prescription drug, whether innovative (original) or a generic version of a known drug, it must demonstrate to the national regulatory authorities in the countries in which it intends to market the new drug that the drug is both effective and safe for its intended use and population. Depending upon the circumstances surrounding the clinical evaluation of a drug candidate, the Company may undertake clinical and nonclinical animal studies, contract clinical trial activities to contract research organizations or rely upon future partners for such development. Approval of a product by one regulatory authority does not necessarily imply that it can or will be approved by a regulatory authority responsible for a different jurisdiction.

Although only the jurisdictions of the U.S., the E.U. and Canada are discussed in this section, the Company also intends to seek regulatory approval in other jurisdictions in the future and will initiate clinical studies where appropriate and cost effective.

Canada

In Canada, all drugs are regulated under the Food and Drugs Act and are enforced by the TPD of the Government of Canada's Department of Health and Welfare. Activities that are regulated include all non-clinical and clinical trials used in support of marketing approval. In addition, the regulations state that GMP must be adhered to during production of all products intended for human use and to some degree during the development process. The regulatory pathway for a potential drug candidate begins by conducting initial proof-of-concept and preliminary safety studies both in the laboratory and in animals (preclinical studies). After the preclinical studies are completed, applications to conduct human clinical trials with the drug candidate must be submitted to the TPD. This application is referred to as a Clinical Trial Application (CTA). The CTA includes information about the methods of manufacture of the drug and controls associated therewith, and preclinical studies demonstrating safety and potential efficacy of the drug candidate. The TPD has 30 days in which to notify the Company if the application is satisfactory by issuance of a No Objection Letter (NOL), after which the Company may proceed with clinical trials. In addition, before a clinical trial can commence at each participating clinical trial site, the site's institutional review board (IRB)/research ethics board (REB) must approve the clinical trial protocol and other related documents.

After completing all required preclinical and clinical trials, and prior to selling a novel drug in Canada, the Company must submit a New Drug Submission (NDS) to the TPD and receive a Notice of Compliance (NOC) to sell the drug. The information contained within the NDS describes the new drug, including the drug's generic and proposed names under which it will be sold, a list describing the quantities and qualities of the ingredients, the method of manufacturing, processing and packaging of the drug, controls in place during the manufacturing operations to determine safety, potency and purity, stability information, results of non-clinical and clinical trials, intended indications for use of the new drug and the effectiveness of the new drug when used as intended. If, upon review of the NDS by the TPD, the NDS meets the requirements of Canada's Food and Drugs Act and the regulations thereunder, the TPD will issue the NOC. The TPD has

the authority to impose certain post-approval requirements, such as post-market surveillance clinical trials. TPD approval can be withdrawn for failure to comply with any post-marketing requirements or for other reasons, such as the discovery of significant adverse effects.

United States

In the U.S., all drugs are regulated under the C.F.R. which is enforced by the FDA. The regulations require that non-clinical and clinical studies be conducted to demonstrate the safety and effectiveness of products before marketing and that the manufacturing be conducted according to GMP. Subsequent to the completion of certain preclinical studies, the application to conduct human clinical trials with the drug candidate is submitted to the FDA. It is referred to as an IND application. This application contains similar information to the Canadian CTA, and the FDA has 30 days in which to notify the Company if the application is unsatisfactory. If the application is not deemed unsatisfactory, then the Company may proceed with administering the medication to humans in clinical studies. As in Canada, before any clinical trial can commence at each participating clinical trial site, the site's IRB/REB must approve the clinical protocol and other related documents.

After completing all required preclinical and clinical trials, and prior to selling a drug in the U.S., the Company must also comply with NDA procedures required by the FDA. The NDA procedure includes the submission of a package containing similar information to that required in the NDS in Canada to indicate safety and efficacy of the drug and describe the manufacturing processes and controls. FDA approval of the submission is required prior to commercial sale or shipment of the product in the U.S. Pre and/or post-approval inspections of manufacturing and testing facilities are necessary. The FDA may also conduct inspections of the clinical trial sites and the preclinical laboratories conducting pivotal safety studies to ensure compliance with Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) requirements. Similar to the TPD, the FDA has the authority to impose certain post-marketing requirements, such as post-market surveillance clinical and preclinical trials. In addition, FDA approval can be withdrawn for failure to comply with any post-marketing requirements or for other reasons, such as the discovery of significant adverse effects.

Europe

In Europe, the evaluation of applications for new medicinal products submitted for European approval is coordinated by the EMA, a body of the E.U. The regulations are similar to those in Canada and the U.S. and require that preclinical and clinical studies be conducted to demonstrate the safety and effectiveness of products before marketing and that the manufacturing will be conducted according to GMP. Subsequent to the preclinical studies and prior to conducting human clinical trials, a CTA must be submitted to the competent authority in the country where the clinical trial will be conducted. This application contains similar information to the Canadian CTA and U.S. IND. In Europe, clinical trials are regulated by the European Clinical Trial Directive (Directive 2001/20/EC of April 4, 2001). As in Canada and the U.S., before a clinical trial can commence at each participating clinical trial site, the site's IRB/REB must approve the clinical protocol and other related documents.

A major difference in Europe, when compared to Canada and the U.S., is with the approval process. In Europe, there are two different procedures that can be used to gain marketing authorization in the E.U. The first procedure is referred to as the Centralized Procedure and requires that a single application be submitted to the EMA which, if approved, allows marketing in all countries of the E.U. The second procedure has two options: the first is referred to as the Mutual Recognition Procedure (MRP) and requires that approval is gained from

one Member State after which a request is made to the other Member States to mutually recognize the approval and the second is referred to as the Decentralized Procedure which requires a member state to act as the RMS through a simultaneous application made to other member states.

Drug Development Process

A potential new drug must first be tested in the laboratory and in several animal species (preclinical or non-clinical studies) before being evaluated in humans (clinical studies). Preclinical studies primarily involve in vitro evaluations of the therapeutic activity of the drug and in vivo evaluations of the PK, metabolic and toxic effects of the drug in selected animal species. Ultimately, based on data generated during preclinical studies, extrapolations will be made to evaluate the potential risks versus the potential benefits of use of the drug in humans under specific conditions of use. Upon successful completion of the preclinical studies, the drug typically undergoes a series of evaluations in humans, including healthy volunteers and patients with the targeted disease.

The activities which must typically be completed prior to obtaining approval for marketing a new drug product in Canada, the U.S. and E.U. may be summarized as follows:

A. *Preclinical Studies*: In the preclinical stage of drug development, an investigational drug must be tested extensively in the laboratory to ensure it will be safe to administer to humans. Testing at this stage must provide data showing that the drug is reasonably safe for use in initial, small-scale clinical studies. Depending on whether the compound has been studied or marketed previously, the sponsor may have several options for fulfilling this requirement including:

(a) compiling existing non-clinical data from past in vitro laboratory or animal studies on the compound;

(b) compiling data from previous clinical testing or marketing of the drug in a country whose population is relevant to the target population; or

(c) undertaking new preclinical studies designed to provide the evidence necessary to support the safety of administering the compound to humans.

During preclinical drug development, a sponsor evaluates the drug's toxic and pharmacologic effects through in vitro and in vivo laboratory animal testing. Genotoxicity screening is performed, as well as investigations on drug absorption, metabolism, the toxicity of the drug's metabolites and the speed with which the drug and its metabolites are excreted from the body. In North America, sponsors are generally asked, at a minimum, to:

(a) develop a pharmacological profile of the drug;

(b) determine the acute toxicity of the drug in at least two species of animals; and

(c) conduct short-term toxicity studies ranging from 2 weeks to 3 months, depending on the proposed duration of use of the substance in the proposed clinical studies.

B. *Filing of an IND or CTA:* The formulation development and preclinical data are submitted to the FDA, TPD or other applicable regulatory body, for review prior to testing in humans.

C. *Clinical Trials*: Clinical trials involve the administration of the drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal, state and local regulations and requirements, under protocols detailing, for example, the objectives of the trial, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated. Clinical trials to support NDAs or NDSs for marketing approval are typically conducted in three sequential phases, but the phases may overlap.

Phase 1 Trials: Phase 1 trials include the initial introduction of an investigational new drug into humans. These studies are closely monitored and may be conducted in patients, but are usually conducted in healthy volunteer subjects. These studies are designed to determine the metabolic and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's PKs and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. In cases where the Phase 1 studies are conducted on patients and not on healthy volunteers, it is possible that these studies may show evidence of efficacy typically not obtained until Phase 2 studies. These are referred to as Phase 1/2 trials.

Phase 2 Trials: Phase 2 trials are controlled clinical studies conducted to obtain some preliminary data on the effectiveness and safety of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine dosage levels, common short-term side effects and risks associated with the drug.

Phase 3 Trials: Phase 3 trials are large controlled and uncontrolled trials. These trials are performed after preliminary evidence suggesting effectiveness and safety of the drug has been obtained in the Phase 2 trials and are intended to gather additional information about effectiveness and safety that is needed to evaluate the overall risk-benefit relationship of the drug. These studies provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labelling.

Filing of an NDA or NDS: An NDA or NDS filing with the relevant regulatory authority in the U.S., Canada, E.U. or other pertinent jurisdiction documents the safety and efficacy of the IND and contains all the information collected during the drug development process including the preclinical studies, chemistry, manufacturing and controls (CMC) and the clinical trials. At the conclusion of successful preclinical, CMC and clinical testing, this series of documents is submitted to the regulatory authority. The application must present substantial evidence that the drug will have the effect it is represented to have when people use it or under the conditions for which it is prescribed, recommended or suggested in the labelling. Obtaining approval to market a new drug typically takes between six months and two years after submission of an application to the applicable regulatory authority.

Once the data is reviewed and approved by the appropriate regulatory authorities, such as the TPD, FDA or EMA, the drug is deemed ready for sale. These authorities and other

applicable regulatory bodies will determine whether the drug will be a prescription or non-prescription product based on factors such as the age and history of the drug, the number of patients having reported adverse effects and how well the drug is documented with respect to safety and efficacy. Given that innovative drugs have no long-term history of public use, it is unlikely that an innovative drug would be approved in the first instance as a non-prescription product.

After marketing approval for a drug has been obtained, further studies and clinical trials may be required or requested by the regulatory authorities. The FDA refers to these as Postmarketing Requirements and Commitments. Post-marketing trials may provide additional data about a product's safety, efficacy or optimal use. Some of the studies and clinical trials may be required; others may be studies or clinical trials a sponsor has committed to conduct. Postmarketing requirements (PMRs) include studies and clinical trials that sponsors are required to conduct under one or more statutes or regulations. Postmarketing commitments (PMCs) are studies or clinical trials that a sponsor has agreed to conduct, but that are not required by a statute or regulation. Failure to conduct or comply with an established timetable for completing PMRs may result in enforcement actions by the FDA that could include charges or civil monetary penalties. In addition, the FDA may prevent the marketing of the product in the U.S.

Litigation

Mallinckrodt

On August 20, 2013, the Company commenced legal action against Mallinckrodt by filing a Complaint in the U.S. District Court for the Southern District of New York (the Action).

The Complaint asserted that Mallinckrodt breached its contractual obligations to Nuvo, as set out in the Pennsaid U.S. Licensing Agreement pursuant to which Nuvo licensed to Mallinckrodt the rights to sell and market Pennsaid and Pennsaid 2% in the U.S. in return for certain obligations undertaken by Mallinckrodt.

The Complaint asserted that Mallinckrodt breached the Pennsaid U.S. Licensing Agreement in several respects, including, among others:

- Mallinckrodt willfully failed to conduct two Phase 3 clinical studies required under the Pennsaid U.S. Licensing Agreement that are critical to a) securing an indication and product label for Pennsaid 2% in the U.S. that is equivalent to those for Pennsaid; b) providing evidence of robust efficacy of Pennsaid 2% for marketing in the U.S. and throughout the world, and c) obtaining regulatory approval for Pennsaid 2% outside the U.S.;

- Mallinckrodt made significant, negligent errors in certain clinical studies for which it was responsible, including failure to properly conduct PK studies which led to the delay of the FDA's approval of Pennsaid 2% in the U.S.;

- Mallinckrodt willfully failed to apply requisite efforts to commercialize Pennsaid in the U.S. resulting in significantly lower sales and royalties payable to the Company; and

- Mallinckrodt willfully refused to pay the full milestone payments due to Nuvo under the Pennsaid U.S. Licensing Agreement.

Nuvo sought damages of not less than US$100 million and a declaration that it was entitled to terminate the Pennsaid U.S. Licensing Agreement which would result in the rights to sell and market Pennsaid and/or Pennsaid 2% in the U.S. reverting to Nuvo. While the litigation was ongoing, Mallinckrodt continued to sell Pennsaid and Pennsaid 2% in the U.S.

On November 1, 2013, Mallinckrodt filed an Answer and Counterclaim in the Action. In its Answer, Mallinckrodt denied Nuvo's assertions. Mallinckrodt's Counterclaim set forth a single cause of action for breach of contract, and sought unspecified damages, as well as declaratory relief. The Company believed that it had substantial defenses to the Counterclaim raised in the Action and intended to vigorously defend against it.

In July 2014, Nuvo amended its Complaint to, among other things, include allegations related to Mallinckrodt's failure to use diligent efforts to launch and market Pennsaid 2%.

Nuvo and Mallinckrodt agreed to a joint discovery schedule in which document discovery was substantially completed by June 2014 and all fact discovery was to be completed by December 2014. The trial would have taken place no sooner than mid-2015.

On September 4, 2014, the Company reached a full settlement with Mallinckrodt of Nuvo's claims and Mallinckrodt's counterclaim relating to Nuvo's license to Mallinckrodt of the right to sell and market Pennsaid and Pennsaid 2% in the U.S. Under the terms of the settlement agreement, Mallinckrodt returned all U.S. rights to Pennsaid and Pennsaid 2% to Nuvo and paid US$10.0 million. Each of Mallinckrodt and the Company also released claims against the other related to the litigation.

RISK FACTORS

An investment in the securities of the Company is speculative and involves a high degree of risk including, but not limited to, the risk factors discussed in this document. Before making an investment decision, investors should carefully consider these risk factors. If any of the factors identified as risks actually occur, the Company's business, results of operations and financial condition could be harmed. However, the risks described below are not the only ones the Company faces. Additional risks not currently known to the Company, or those that it currently believes to be immaterial, may also harm the Company's business.

Need for Additional Financing

The Company has an ongoing need for substantial capital resources to research, develop, commercialize and manufacture its products and technologies as the Company is not generating enough cash to funds its operations. The Company has limited participation in revenues from the commercial products that the Company has outlicensed and these revenues are not sufficient to cover the costs of operating the business. The Company earns revenue from product sales of Pennsaid, Pennsaid 2%, WF10 and Oxoferin, but is dependent on its partners to sell these products in their respective licensed territories. The Company also earns revenue from royalties on the net sales of Pennsaid in Canada, on gross profits from the sales of a generic version of Pennsaid in the U.S., the global net sales of Pliaglis and net sales of the HLT Patch - branded as Synera in the U.S. and Rapydan in Europe. In Canada, royalty revenue for Pennsaid is expected to decline as a generic version of this product has launched in this market. The Company's partner in this market has launched an authorized generic to try to maintain market share. The Company will earn revenues from product sales and royalties related to the authorized generic. Royalties earned from Pliaglis and the HLT Patch are minimal.

Companies in the pharmaceutical R&D industry typically require periodic funding in order to develop drug candidates until such time as at least one drug candidate has been successfully commercialized or until the companies are receiving sufficient revenue to fund their operations. The Company has not yet reached this stage, and; therefore, the Company monitors on a regular basis, its liquidity position, the status of its partners' commercialization efforts, the status of its drug development programs, including cost estimates for completing various stages of development, the scientific progress on each drug candidate and the potential to license or co-develop each drug candidate and it continues to actively pursue fundraising possibilities through various means.

There can be no assurance that the Company will have sufficient capital to fund its ongoing operations or develop or commercialize any further products without future financings. There can be no assurance that additional financing will be available on acceptable terms or at all. If adequate funds are not available, the Company may have to substantially reduce or eliminate planned expenditures, terminate or delay clinical trials for its product candidates, curtail product development programs designed to expand the product pipeline or discontinue certain operations.

Economic Environment

Economic conditions may limit the Company's ability to access capital or may cause the Company's suppliers to increase their prices, reduce their output or change their terms of sale. If the Company's customers' or suppliers' operating and financial performance deteriorates or if they are unable to make scheduled payments or obtain credit, its customers may not be able to pay or may delay payment of accounts receivable owed and its suppliers may restrict credit or impose different payment terms. Any inability of customers to pay the Company for its products or any demands by suppliers for different payment terms, may adversely affect its earnings and cash flow.

The Company has no control over changes in inflation and interest rates, foreign currency exchange rates and controls or other economic factors affecting its businesses or the possibility of political unrest, legal and regulatory changes in jurisdictions in which the Company operates. These factors could negatively affect the Company's future results of operations in those markets.

Dependence on Sales and Marketing Partnerships

The Company has limited sales and marketing experience and lacks financial and other resources necessary to undertake marketing and advertising activities worldwide. Accordingly, the Company relies on marketing arrangements, including joint ventures, licensing or other third-party arrangements, to distribute its products in jurisdictions where it lacks the resources or expertise. The Company faces, and will continue to face, significant competition in seeking appropriate partners and distributors. Moreover, collaboration and distribution arrangements are complex and time consuming to negotiate, document and implement. Therefore, there can be no assurance that the Company will be able to find additional marketing and distribution partners in any jurisdiction or be able to enter into any marketing and distribution arrangements on any terms, acceptable or not. Moreover, there can be no assurance that its partners will dedicate the resources needed to successfully market and distribute the Company's products and maximize sales. In addition, under these arrangements, disputes may arise with respect to payments that the Company or its partners believe are due under such distribution or marketing arrangements, a partner or distributor may develop or distribute products that compete with the Company's products or they may terminate the relationship.

The Company has no influence in sales and marketing activities for Pennsaid and Pennsaid 2% in the markets it is currently available in. Decisions impacting sales and marketing efforts are made by the Company's partners for their respective territories. If one of the Company's partners (especially Paladin in Canada for Pennsaid and Horizon in the U.S. for Pennsaid 2%) was unable to be successful in selling its respective product, it could have an adverse effect on the Company's product sales and cash resources, as well as royalties earned in Canada.

The Company has licensed the rights for the HLT Patch to Galen for the U.S. and Eurocept for the E.U. and certain other territories and has no influence on sales and marketing activities for this product in the licensed territories.

The Company has minimal influence in the worldwide sales and marketing activities for Pliaglis, as these decisions are made by Galderma. Although the Company has three seats on the Joint Steering Committee that was established to monitor the development and commercial activities related to Pliaglis, the Company has no direct control over the technical, regulatory and commercial activities for the product. In addition, Galderma is responsible for the worldwide commercialization of Pliaglis and, as such, the Company will rely on Galderma to successfully execute a worldwide commercialization program. Delays in obtaining the appropriate regulatory approvals for Pliaglis in territories or an unsuccessful launch in any major territory may have an adverse effect on the Company's royalty income and cash flows. In addition, an unsuccessful commercialization program may decrease the royalties and the royalty rate that the Company is eligible to receive and this may impact cash flows. See "Narrative Description of the Business – Topical Products and Technologies – Pliaglis".

The Company depends on all of its partners and licensees to comply with all government legislation and regulations relating to selling the Company's products in their respective territories. If any of our partners do not comply, this could have a material impact on the cash flows of the Company.

Generic Drug Manufacturers

Regulatory approval for competing generic drugs can be obtained without investing in the same level of costly and time-consuming clinical trials that the Company has conducted or might conduct in the future. Due to the substantially reduced development costs, generic drug manufacturers are often able to charge much lower prices for their products than the original developer. The Company faces competition from manufacturers of generic drugs on some of its products that are commercial, since a number of the Company's patents have expired, or if not yet expired, may be ignored by generic drug manufacturers who choose to launch their products "at risk" of a possible patent infringement lawsuit brought by the Company or its licensing partners. Generic competition may impact the prices at which the Company's products are sold, the royalty rates the Company receives and the volume of product sold which may substantially reduce the Company's overall revenues.

In 2014, a generic version of Pennsaid was launched in Canada. The Company's partner in Canada has launched an authorized generic to compete with the generic version of Pennsaid and protect market share. The Company's revenues from royalties and product sales in Canada may be negatively impacted as a result of the launch of these generic versions.

In the U.S., under the "Hatch-Waxman Act", the FDA can approve an ANDA for a generic version of a branded drug or a variation of an existing branded drug, without undertaking the

clinical testing necessary to obtain approval to market a new drug. This is referred to as the "ANDA process". In place of such clinical studies, an ANDA applicant usually needs to submit data and information demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product, in addition to, for example, any data necessary to establish that any difference in inactive ingredients does not result in different safety or efficacy profiles, as compared to the reference drug. The “Hatch-Waxman Act”, in addition to providing brand-name drug manufacturers with periods of marketing exclusivity, such as 3-year “new clinical investigation” exclusivity, requires an applicant for a drug that relies, at least in part, on the FDA’s findings of safety or effectiveness for a branded drug, to notify the sponsor of the branded drug of their application and potential infringement of any patents timely listed in the FDA Orange Book. Upon receipt of this notice, the sponsor of the branded drug has 45 days to bring a patent infringement suit in federal district court against the applicant seeking approval of a product covered by the patent. If such a suit is commenced and the ANDA was filed after the patent had been listed in the FDA Orange Book, then the FDA is generally prohibited from granting approval of the ANDA or Section 505(b)(2) NDA, a type of NDA that relies on information for which the applicant does not have a right of reference, until the earliest of 30 months from the date the FDA accepted the application for filing (the 30-Month Stay), or the conclusion of patent infringement litigation in the generic's favour or expiration of the patent. If an ANDA was filed before the patent had been listed in the FDA Orange Book, the 30-Month Stay does not apply and it is possible that the ANDA holder may launch its generic product “at risk” of patent infringement proceedings initiated by the innovator drug company. If the litigation is resolved in favour of the applicant or the challenged patent expires during the 30-month stay period, the stay is terminated and the FDA may thereafter approve the application based on the standards for approval of ANDAs and Section 505(b)(2) NDAs. Frequently, the unpredictable nature and significant costs of patent litigation leads the parties to settle out of court. Settlement agreements between branded companies and generic applicants may allow, among other things, a generic product to enter the market prior to the expiration of any or all of the applicable patents covering the branded product, either through the introduction of an authorized generic or by providing a license to the patents in suit.

In the U.S., Pennsaid 2% is protected by multiple patents listed in the FDA Orange Book and has received 3-year exclusivity under the “Hatch-Waxman Act”. All of the intellectual property for Pennsaid 2% for the U.S. is owned by Horizon and it is their responsibility to litigate any claims against these patents from generic companies. The approval or launch of generic versions of Pennsaid 2% in the U.S. market could have an adverse effect on the Company’s future revenue from product sales.

Obtaining Government and Regulatory Approvals

The research, testing, manufacturing, packaging, labeling, approval, storage, selling, marketing and distribution of drug products are subject to extensive regulation in the U.S. by the FDA, in Canada by the TPD and by similar regulatory authorities in the E.U., Japan and elsewhere, and regulations and requirements differ from country-to-country. Despite the time and expense exerted by the Company, failure can occur at any stage.

The process of completing a drug development program and obtaining regulatory approval for a drug can be long and may involve significant delays despite the Company’s best efforts and can require substantial cash resources. Even after initial approval has been obtained, further research, including post-marketing studies, may be required to expand indications covered under the product approvals and labelling. Also, regulatory agencies require post-marketing surveillance programs to monitor side effects. Results of post-marketing programs may limit or expand additional marketing of the drug. Moreover, regulations are rigorous, time

consuming and costly and the Company cannot predict the extent to which it may be affected by changes in regulatory developments and its ability to meet such regulations. There is also a risk that the Company's products may be withdrawn from the market and the required approvals suspended as a result of non-compliance with regulatory requirements.

Furthermore, there can be no assurance that the regulators will not require modification to any submissions, which may result in delays or failure to obtain regulatory approvals. Any delay or failure to obtain regulatory approvals could adversely affect the Company's business, financial condition and operational results. Further, there can be no assurance that the Company's products will prove to be safe and effective in clinical trials or receive the requisite regulatory approval in any market.

In addition to the regulatory product approval framework, pharmaceutical companies are subject to a number of other regulations covering occupational safety, laboratory practices, environmental protection and hazardous substance control. They may also be subject to existing and future local, provincial, state, federal and foreign regulation, including possible future regulation of the overall industry.

Failure to obtain necessary regulatory approvals, the restriction, suspension or revocation of existing approvals or any other failure to comply with regulatory requirements, could have a material adverse effect on the Company's business, financial condition and operational results.

United States Regulation

The FDA has substantial discretion in the drug approval process. The FDA may delay, limit or deny approval of a drug candidate for many reasons including:

- a drug candidate may not be deemed safe or effective;
- the FDA may find the data from preclinical studies, CMC and clinical trials insufficient;
- the FDA may change its approval policies or adopt new regulations; or
- third-party products may enter the market and change approval requirements.

Even once drug candidates are approved, these approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. The FDA may require further testing and surveillance programs to monitor the pharmaceutical product that has been commercialized. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, injunction actions and criminal prosecutions.

The process of receiving FDA approval has become more difficult with the requirement to submit a Risk Evaluation and Mitigation Strategy (REMS) as part of the drug application for certain classes of drugs and some individual drug products. In addition, the FDA may require REMS after approving a covered application, including applications approved before the REMS program was initiated.

In addition, the FDA has the authority to regulate the claims the Company's partners make in marketing its prescription drug products to ensure that such claims are true, not misleading, supported by scientific evidence and consistent with the product's approved labelling.

Failure to comply with FDA requirements in this regard could result in, among other things, suspensions or withdrawal of approvals, product seizures and injunctions against the manufacture, holding, distribution, marketing and sale of a product, civil and criminal sanctions.

Canada Regulation

The TPD may deny issuance of a NOC for an NDS if applicable regulatory criteria are not satisfied or may require additional testing. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. The TPD may require further testing and surveillance programs to monitor a pharmaceutical product which has been commercialized. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, injunction actions and criminal prosecutions.

Additional Regulatory Considerations

There is no assurance that problems will not arise that could delay or prevent the commercialization of the Company's products currently under development or that the TPD, FDA or other foreign regulatory agencies will be satisfied with the information submitted by the Company, including results of clinical trials, to approve the marketing of such products. In addition to the regulatory approval process, pharmaceutical companies are subject to regulations under local, provincial, state and federal law, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control and may be subject to other present and future local, provincial, state, federal and foreign regulations, including possible future regulations of the pharmaceutical industry. The Company cannot predict the time required for regulatory approval or the extent of clinical testing and documentation that is required by regulatory authorities. Any delays in obtaining, or failure to obtain regulatory approvals in Canada, the U.S., the E.U. or other foreign countries, would significantly delay the development of the Company's markets and the receipt of revenues from the sale of its products.

Changes in Government Regulation

The business of the Company may be adversely affected by such factors as changes in the regulatory environment with respect to intellectual property, regulation, export controls or product marketing approvals. Such changes remain beyond the Company's control and have an unpredictable impact.

Manufacturing and Supply Risks

The Company purchases key raw materials necessary for the manufacture of its products and finished products from a limited number of suppliers around the world and in some cases relies on its licensing partners to manufacture its products.

In the case of Pennsaid and Pennsaid 2%, the Company has a supply agreement with a single supplier based in the U.S. to purchase all of the Company's requirements for pharmaceutical grade DMSO (one of the key ingredients in Pennsaid and Pennsaid 2%) until December 31, 2022 using the supplier's patented process. It may be difficult to find another manufacturer if the supplier is unable to supply the Company with a sufficient amount of DMSO or if the Company is forced for any other reason to find another supplier. It could take another supplier a significant period of time to develop and certify the necessary processes to manufacture the product on terms acceptable to the Company or the related regulatory authority.

There may not be suppliers who are able to meet the Company's volume or quality requirements at a price that is as favourable as the current supplier. Any operating, production or quality problems experienced by these suppliers that result in a reduction or interruption in supply could significantly delay the manufacture and sale of the Company's products.

In addition, since WF10 and Oxoferin are manufactured by CMOs, the Company has limited ability to control the manufacturing process or costs related to this process. Increases in the prices paid to the CMO, price increases from suppliers of any component of the product, interruptions in supply of product or lapses in quality could adversely impact the Company's margins, profitability and cash flows. The Company is reliant on its third-party CMOs to maintain the facilities at which it manufactures the Company's products in compliance with FDA, EMA, state and local regulations or other countries' regulatory authorities. If the CMO fails to maintain compliance with regulatory authorities, they could be ordered to cease manufacturing, which would have a material adverse impact on the Company's business, results of operations, financial condition and cash flows. In addition to FDA regulations, violation of standards enforced by the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA), and their counterpart agencies at the state level, could slow down or curtail operations of the CMO or any of its suppliers.

If the relationships with the CMO or any of the single-sourced suppliers is discontinued or, if any manufacturer is unable to supply or produce required quantities of product on a timely basis or at all, or if a supplier ceases production of an ingredient or component, the operations would be negatively impacted and the business would be harmed.

Under the terms of the Pliaglis license agreements, Galderma has the sole right to manufacture Pliaglis and; therefore, the Company does and will depend on Galderma as the only qualified supplier of the product for all global markets. Pliaglis also contains the active drugs lidocaine and tetracaine and in the past the form of tetracaine used in the product has, at times, been difficult to procure. The Company is reliant on Galderma to maintain the facilities at which it manufactures Pliaglis in compliance with FDA, EMA, state and local regulations and other regulatory agencies. If Galderma fails to maintain compliance with FDA, EMA or other critical regulations, they could be ordered to cease manufacturing, which would have a material adverse impact on the Company's business, results of operations, financial condition and cash flows. In addition to FDA regulations, violation of standards enforced by the EPA, the OSHA and their counterpart agencies at the state level, could slow down or curtail operations of Galderma.

For the HLT Patch, Galen and Eurocept are responsible for manufacturing the patch and both rely on the same CMO in the U.S. The Company does and will depend on Galen and Eurocept to ensure the CMO remains a qualified supplier of the product for all global markets and will have limited ability, if any, to control the manufacturing process. The HLT Patch also contains the active drugs lidocaine and tetracaine and in the past, the form of tetracaine used in the product has, at times, been difficult to procure. The Company is reliant on Galen and Eurocept to ensure that the CMO maintains the facility at which it manufactures the HLT Patch in compliance with FDA, EMA, state and local regulations and other regulatory agencies. If the CMO fails to maintain compliance with FDA, EMA or other critical regulations, they could be ordered to cease manufacturing which would have a material adverse impact on the Company's business, results of operations, financial condition and cash flows. In addition to FDA regulations, violation of standards enforced by the EPA, the OSHA, and their counterpart agencies at the state level, could slow down or curtail operations of the CMO.

In addition, the FDA and other regulatory agencies require that raw material manufacturers comply with all applicable regulations and standards pertaining to the

manufacture, control, testing and use of the raw materials as appropriate. For the Active Pharmaceutical Ingredients (API) or critical raw materials depending on the drug product, this means compliance to current GMPs for APIs and submission of all data related to the manufacture, control and testing of the API for quality, purity, identity and stability, as well as a complete description of the process, equipment, controls and standards used for the production of the API. This is usually submitted to the FDA in the form of a Drug Master File (DMF) by the manufacturer and referenced by the sponsor of the NDA. The DMF information and data is reviewed by the FDA as a critical component of the approvability of the NDA.

As a result, in the case where only one supplier of a particular API or critical raw material meets all of the FDA's (or other regulatory agencies) requirements and has a DMF (or similar filing) on file with the FDA, the Company is at risk should a supplier violate GMP, fail an FDA inspection, terminate access to its DMF, be unable to manufacture product, choose not to supply the Company or decide to increase prices. For DMSO and tetracaine, the Company has only one approved supplier for all jurisdictions in which Pennsaid and the HLT Patch has been approved. For Pennsaid and Pennsaid 2%'s API, diclofenac sodium, the Company has two approved suppliers for Canada and the E.U., but only one approved supplier for the U.S. For some of the Company's other raw materials required to manufacture Pennsaid, the bulk substance for the HLT Patch, Oxoferin and WF10, the Company currently has only one approved supplier.

In addition, the Company could be subject to various import duties applicable to both finished products and raw materials and it may be affected by other import and export restrictions, as well as developments with an impact on international trade. Under certain circumstances, these international trade factors could affect manufacturing costs, which will in turn affect the Company's margins, as well as the wholesale and retail prices of manufactured products.

The Company's current internal manufacturing capabilities are limited to its site in Varennes, Québec, which is the sole manufacturer of Pennsaid, Pennsaid 2% and the bulk drug product for the HLT Patch for all markets and its site in Wanzleben, Germany that produces the active ingredient in WF10 and Oxoferin. The Company has never achieved capacity in these facilities. This exposes the Company to the following risks, any of which could delay or prevent the commercialization of its products, result in higher costs or deprive it of potential product revenues:

- The Company may encounter difficulties in achieving volume production, quality control and quality assurance, as well as relating to shortages of qualified personnel. Accordingly, the Company might not be able to manufacture sufficient quantities to meet its clinical trial needs or to commercialize its products;

- The Company's manufacturing facilities are required to undergo satisfactory current GMP inspections prior to regulatory approval and are obliged to operate in accordance with FDA, E.U. and other nationally mandated GMP, which govern manufacturing processes, stability testing, record keeping and quality standards. Failure to establish and follow GMPs and to document adherence to such practices, may lead to significant delays in the availability of material for clinical studies and may delay or prevent filing or approval of marketing applications for the Company's products; and

- Changing manufacturing locations would be difficult and the number of potential manufacturers is limited. Changing manufacturers generally requires re-validation

of the manufacturing processes and procedures in accordance with FDA, E.U. and other nationally mandated GMPs. Such re-validation may be costly and would be time consuming. It would be difficult or impossible to quickly find replacement manufacturers on acceptable terms, if at all.

The Company's manufacturing facilities are subject to ongoing periodic unannounced inspection by the FDA and corresponding agencies, including E.U. and Canadian agencies, and may be subject to inspection by local, state, provincial and federal authorities from various jurisdictions to ensure strict compliance with GMPs and other government regulations. Failure by the Company to comply with applicable regulations could result in sanctions being imposed on it, including fines, injunctions, civil penalties, failure of the government to grant review of submissions or market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions, facility closures and criminal prosecutions, any of which could harm the Company's business.

Patents, Trademarks and Proprietary Technology

There can be no assurance as to the breadth or degree of protection that existing or future patents or patent applications may afford the Company or that any patent applications will result in issued patents or that the Company's patents or trademarks will be upheld if challenged. It is possible that the Company's existing patent or trademark rights may be deemed invalid. Although the Company believes that its products do not, and will not, infringe valid patents or trademarks or violate the proprietary rights of others, it is possible that use, sale or manufacture of its products may infringe on existing or future patents, trademarks or proprietary rights of others. If the Company's products infringe the patents or proprietary rights of others, the Company may be required to stop selling or making its products, may be required to modify or rename its products or may have to obtain licenses to continue using, making or selling them. There can be no assurance that the Company will be able to do so in a timely manner, upon acceptable terms and conditions, or at all. The failure to do any of the foregoing could have a material adverse effect upon the Company. In addition, there can be no assurance that the Company will have sufficient financial or other resources to enforce or defend a patent infringement or proprietary rights violation action. Moreover, if the Company's products infringe patents, trademarks or proprietary rights of others, the Company could, under certain circumstances, become liable for substantial damages which could also have a material adverse effect.

Regardless of the validity of the Company's patents, there can be no assurance that others will be unable to obtain patents or develop competitive non-infringing products or processes that permit such parties to compete with the Company. The Company may not be able to protect its intellectual property rights throughout the world as filing, prosecuting and defending patents and trademarks on all of the Company's product candidates, products and product names, when and if they exist, in every jurisdiction would be prohibitively expensive and can take several years. Competitors may manufacture, sell or use the Company's technologies and use its trademarks in jurisdictions where the Company or its partners have not obtained patent and trademark protection. These products may compete with the Company's products, when and if it has any, and may not be covered by any of its or its partners' patent claims or other intellectual property rights.

The laws of some countries do not protect intellectual property rights to the same extent as the laws of Canada and the U.S. and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain

countries, particularly certain developing countries, do not favour the enforcement of patents, trademarks and other intellectual property protection, particularly those protections relating to biotechnology and pharmaceuticals, which could make it difficult for the Company to stop the infringement of its patents. Proceedings to enforce patent rights in foreign jurisdictions could result in substantial cost and divert efforts and attention from other aspects of the business.

The discovery, trial and appeals process in patent litigation can take several years. Should the Company commence a lawsuit against a third party for patent infringement or should there be a lawsuit commenced against the Company with respect to the validity of its patents or any alleged patent infringement by the Company, the cost of such litigation, as well as the ultimate outcome of such litigation, if commenced, whether or not the Company is successful, could have a material adverse effect on its business, results of operations, financial condition and cash flows.

Ability to Protect Know How and Trade Secrets

The ability of the Company to maintain the confidentiality of its expertise and trade secrets is essential to success. Disclosure and use of the Company's expertise and trade secrets, not otherwise protected by patent, are generally controlled under agreements with the parties involved. There can be no assurance however, that all confidentiality agreements are legally enforceable or will be honoured, that others will not independently develop equivalent or competing technology, that disputes will not arise over the ownership of intellectual property or that disclosure of the Company's trade secrets will not occur. To the extent that consultants or other research collaborators use intellectual property owned by others while working with the Company, disputes may also arise over the rights to related or resulting expertise or inventions.

Inability to Achieve Drug Development Goals within Expected Time Frames

From time-to-time, the Company sets targets and makes public statements regarding its expected timing for achieving drug development goals. These include targets for the commencement and completion of preclinical and clinical trials, studies and tests and anticipated regulatory filing and approval dates. These targets are set based on a number of assumptions that may not prove to be accurate. The actual timing of these forward-looking events can vary dramatically from the Company's estimates or they might not be achieved at all, due to factors such as delays or failures in clinical trials or preclinical work, scheduling changes at CROs, the need to develop additional data required by regulators as a condition of approval, the uncertainties inherent in the regulatory approval process, delays in achieving manufacturing or marketing arrangements necessary to commercialize product candidates and limitations on the funds available to the Company. If the Company does not meet these targets, including those which are publicly announced, the ultimate commercialization of its products may be delayed and, as a result, its business could be harmed.

Also, there can be no assurance that such trials and studies will be sufficient for regulatory authorities or that the required regulatory approvals will be obtained.

Uncertainty of Drug Research and Development

There can be no assurance that any of the Company's product candidates will be successfully developed in a timely manner or that they will prove to be more effective than products based on existing or new technologies or that a sufficient number of medical professionals will recommend their use. The risk that a product candidate may fail clinical trials, the Company may be unable to successfully complete development or a decision for financial or

other reasons to halt development of any product candidate, particularly in instances where significant capital expenditures have already been made, could have a material adverse effect on the Company.

In January 2015, the Company announced that it failed to meet the primary endpoint in its 16 week, double-blind, placebo controlled, Phase 2 clinical trial to investigate the safety and efficacy of WF10 in patients with refractory allergic rhinitis. Please see "Narrative Description of the Business – Immunology Group" for more information on the results of this trial. The return on the Company's investment in Nuvo Research AG depends on the successful development of WF10 for allergic rhinitis or other conditions, the successful completion of reformulation activities, attaining new intellectual property protection, clinical development, regulatory approvals and subsequent commercialization of WF10. At this time, the Company is conducting a detailed review of the data from the Phase 2 clinical trial that missed its primary endpoints and expects to release further information and analysis of the data including information on secondary endpoints when the analysis is completed. The review of this data will determine the future pathway for WF10. If the Company decides to continue investing in WF10, its reformulation efforts, future clinical trials and preclinical and clinical development programs with WF10 for allergic rhinitis and other disease indications and the pursuit of new intellectual property protection could yield additional disappointing or negative results. Such results could further diminish or eliminate the Company's ability to commercialize WF10 or recover its investment in Nuvo Research AG.

The Company has product candidates that are at an early stage in the drug development process and have not progressed to the clinical trial phase of development. There can be no assurance that preclinical or clinical testing of the Company's product candidates will yield sufficiently positive results to enable progress toward commercialization and any such trials will take significant time to complete. Unsatisfactory results may prompt the Company to reduce or abandon future testing or commercialization of particular product candidates and this may have a material adverse effect on the Company.

Due to the inherent risk associated with R&D efforts in the pharmaceutical industry, particularly with respect to new drugs, the Company's R&D expenditures may not result in the successful introduction of government approved new pharmaceutical products. Also, after submitting a drug candidate for regulatory approval, the regulatory authority may require additional studies, and as a result, the Company may be unable to reasonably predict the total R&D costs to develop a particular product.

Risk Related to Clinical Trials

The Company and its drug development partners must demonstrate through preclinical studies and clinical trials that the product being developed is safe and efficacious before obtaining regulatory approval for the commercial sale of such product. The results of preclinical studies and previous clinical trials are not necessarily predictive of future results and the Company's current product candidates may not have favourable results in later testing or trials. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study PK and pharmacodynamics and to understand the side effects of products at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful and such success is not necessarily predictive of final results. Favourable results in early trials may not be repeated in later trials and positive interim results do not ensure success in final results. Even after the completion of Phase 3 clinical trials, the FDA, TPD, EMA or other regulatory authorities may disagree with the clinical trial design and interpretation of data and may require additional clinical trials to demonstrate the efficacy of product candidates.

A number of companies in the biotechnology and pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials and preclinical studies. The Company suffered a similar setback with the recent results of its Phase 2 clinical trial using WF10 for the treatment of allergic rhinitis where WF10 failed to meet its primary endpoint (see Narrative Description of the Business – Immunology Group). In many cases where clinical results were not favourable, were perceived negatively or otherwise did not meet expectations, the share prices of these companies declined significantly. Failure to complete clinical trials successfully and to obtain successful results on a timely basis could have an adverse effect on the Company's future business and its common share price.

Patient Enrolment May Not be Adequate for Current Trials or Future Clinical Trials

The Company's future prospects could suffer if it, or any of its drug development partners, fails to develop and maintain sufficient levels of patient enrolment in its current or future clinical trials. Delays in planned patient enrolment may result in increased costs, delays or termination of clinical trials, which could materially harm the Company's future prospects.

Rapid Technological Change Could Make Products or Drug Delivery Technologies Obsolete

Pharmaceutical technologies are subject to rapid and significant technological change. The Company expects its competitors will develop new technologies and products that may render the Company's products and drug delivery technologies uncompetitive or obsolete. The products and drug delivery technologies of its competitors may be more effective than the products and drug delivery technologies developed by the Company. As a result, the Company's products may become obsolete before it recovers expenses incurred in connection with their development or realizes revenues from any commercialized products.

Reliance on Third Parties to Conduct Clinical and Preclinical Studies

The Company and its drug development partners rely on third parties such as CROs, medical institutions and clinical investigators to enroll qualified patients, conduct, supervise and monitor its clinical trials, conduct preclinical studies and complete CMC work. The reliance on these third parties for clinical development activities reduces its control over these activities. The reliance on these third parties; however, does not relieve the Company or its drug development partners of their regulatory responsibilities, including ensuring that its clinical trials are conducted in accordance with GCPs and that its preclinical studies are conducted in accordance with GLPs. Furthermore, these third parties may have relationships with other entities, some of which may be competitors. In addition, they may not complete activities on schedule or may not conduct preclinical studies or clinical trials in accordance with regulatory requirements or the Company's trial design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, the Company's ability to obtain regulatory approvals for product candidates may be delayed or prevented.

Prolonged Development Time

It takes considerable time to develop new prescription or over-the-counter drug products, to obtain the necessary regulatory approvals permitting sales, to establish appropriate distribution channels and market acceptance and to obtain insurer reimbursement approvals. This time period is generally from five to more than ten years and it exposes the Company to significant risks, including the development of competing products, loss of investor interest, shifting consumer preferences, changes in personnel and new regulatory requirements. During this

lengthy period, the Company often incurs significant development-related costs without generating offsetting revenues.

Competition

The pharmaceutical industry is characterized by evolving technology and intense competition. The Company is engaged in areas of research where developments are expected to continue at a rapid pace. Many companies, including major pharmaceutical and specialized biotechnology companies, are engaged in activities focused on medical conditions that are the same as or similar to those targeted by the Company. The Company's success depends upon maintaining its competitive position in the R&D and commercialization of its products. Competition from pharmaceutical, chemical and biotechnology companies, as well as universities and research institutes, is intense and is expected to increase. Many of these organizations have substantially greater R&D, experience in manufacturing, marketing, financial and managerial resources and they represent significant competition. If the Company fails to compete successfully in any of these areas, its business, results of operations, financial condition and cash flows could be adversely affected.

The intensely competitive environment of the branded products business requires an ongoing, extensive search for medical and technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety and value of branded products for their intended uses to healthcare professionals in private practice, group practices and managed care organizations. There can be no assurance that the Company and its drug development partners will be able to successfully develop medical or technological innovations or that the Company and its licensing partners will be able to effectively market the Company's existing products or any future products.

The Company's branded products may face competition from generic versions. Generic versions are generally significantly cheaper than the branded version, and, where available, may be required or encouraged in preference to the branded version under third-party reimbursement programs or substituted by pharmacies for branded versions by law. The entrance of generic competition to the Company's branded products generally reduces the market share and adversely affects the Company's profitability and cash flows. Generic competition with the Company's branded products would be expected to have a material adverse effect on net sales and profitability of the branded product and of the Company.

Additionally, the Company competes to acquire the intellectual property assets that are required to continue to develop and broaden its product portfolio. In addition to in-house R&D efforts, the Company seeks to acquire rights to new intellectual property through corporate acquisitions, asset acquisitions, licensing and joint venture arrangements. Competitors with greater resources may acquire assets that the Company seeks, and even if the Company is successful, competition may increase the acquisition price of such assets. If the Company fails to compete successfully, its growth may be limited.

Competition for Pennsaid and Pennsaid 2%

Several major pharmaceutical companies have developed oral COX-2 selective NSAIDs designed to reduce gastrointestinal side effects associated with other types of NSAIDs. Many of these products have been taken off the market or drug development has stopped in response to safety concerns. Those that remain represent competition for market share. While the Company believes that topical administration gives Pennsaid and Pennsaid 2% a better safety profile than all oral NSAIDs, including those with PPIs and COX-2 selective medications, it may be subject to

regulations and regulatory decisions of governing bodies, such as the FDA in the U.S., including label warnings that apply to NSAIDs generally.

Pennsaid 2% faces competition in the U.S. from at least two other topically applied diclofenac drug products available by prescription that were approved for marketing by the FDA, as well as numerous OTC products. The FLECTOR Patch, which contains the NSAID diclofenac epolamine was approved by the FDA for the topical treatment of acute pain due to minor strains, sprains and contusions and is marketed by one of the largest healthcare companies in the world. The second drug product, Novartis' Voltaren Gel which contains the NSAID diclofenac sodium was approved by the FDA for the relief of the pain of OA of joints amenable to topical treatment, such as the knees and those of the hand and is marketed by Endo Pharmaceuticals Inc. Both of these topical products have achieved respectable sales levels and they provide significant competition for market share. If patients and practitioners believe these competing products provide pain relief, it may be difficult for our partner to convince them to use Pennsaid 2% or conversely, if they do not believe that they provide pain relief this may create a perception that all topically applied products have similar efficacy, making it more difficult to convince physicians and their patients of the value of Pennsaid 2%.

In Canada, a competitor's generic version of Pennsaid was launched in 2014. In addition, our partner launched an authorized generic to protect market share. The launch of these generic versions of Pennsaid may have an adverse impact on the Company's future revenue from Canada. A topical diclofenac product, Novartis' Voltaren Emulgel (1.16% w/w diclofenac diethylamine) has been available in Canada as an OTC since October 2008. In August 2014, Voltaren Emulgel Extra Strength (2.32% w/w diclofenac diethylamine) was approved in Canada as an OTC product and was launched by Novartis in October 2014. In the E.U., several major pharmaceutical companies market oral and topical NSAIDs that compete against Pennsaid in countries where it is marketed.

In addition to recently approved products, there may be other companies that are developing topical NSAID products for the U.S. and other markets that may present additional competition in the future. Like Pennsaid and Pennsaid 2%, these drugs may be efficacious yet reduce the incidence of some of the side effects associated with oral NSAIDs.

The impact of competitive branded products and generic products could have a significant adverse effect on Pennsaid 2% product sales in the U.S. market, as well as the resulting level of royalties earned and product sales in Canada from Pennsaid sales.

Competition for the HLT Patch and Pliaglis

The HLT Patch and Pliaglis face competition in all markets from other topically applied local anaesthetic drug products such as compounded anaesthetic creams that are available from certain pharmacies, EMLA Cream (a eutectic mixture of lidocaine 2.5% and prilocaine 2.5%), and L.M.X 4 and L.M.X.5 Anorectal Creams that are available OTC.

Products May Fail to Achieve Market Acceptance

Any products successfully developed by the Company may not achieve market acceptance and, as a result, may not generate significant revenues. Market acceptance of the Company's products by physicians or patients will depend on a number of factors, including:

- availability, cost and effectiveness of products when compared to competing products and alternative treatments;

- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- the acceptance of competing products;
- pricing, which may be subject to regulatory control;
- effectiveness of marketing and distribution partners' sales and marketing strategies; and
- the ability to obtain sufficient third-party insurance coverage or reimbursement.

If any product commercialized by the Company does not provide a treatment regimen that is as beneficial as the current standard of care or otherwise does not provide patient benefit, there is the potential that it will not achieve market acceptance. This may result in a shortfall in revenues and an inability to achieve or maintain profitability.

Publications of Negative Study or Clinical Trial Results

The publication of negative results of studies or clinical trials related to the Company's products, or the therapeutic areas in which its products compete, may adversely affect sales, the prescription trends for the products, the reputation of the products and the price of the Company's common shares. From time-to-time, studies or clinical trials on various aspects of pharmaceutical products are conducted by the Company, academics or others, including government agencies. The results of these studies or trials, when published, may have a dramatic effect on the market for the pharmaceutical product that is the subject of the study. In the event of the publication of negative results of studies or clinical trials related to the Company's marketed products or the therapeutic areas in which these products compete, the business, financial condition, results of operations and cash flows of the Company may be adversely affected.

Reimbursement and Product Pricing

There can be no assurance that Pennsaid, Pennsaid 2%, Pliaglis or the HLT Patch will be successfully commercialized in current markets or that the additional regulatory approvals necessary to commercialize Pennsaid, Pennsaid 2%, Pliaglis and the HLT Patch in markets where they are not currently approved will be obtained.

In Canada, private health coverage insurers have generally approved reimbursement of Pennsaid costs, but government health authorities have not approved such reimbursement. Obtaining reimbursement approval for a product from each government or other third-party payer is a time consuming and costly process that could require the Company to provide supporting scientific, clinical and cost effectiveness data for the use of its products to each payer. In certain territories, this process is the responsibility of the licensee and the Company will have little financial impact from this process except to the extent the licensees are forced to provide significant discounts or rebates which would affect the level of net sales of the product and reduce the amount of royalties the Company earns. The Company may not have or be able to provide data sufficient to gain acceptance with respect to reimbursement. Even when a payer determines that a product is eligible for reimbursement, they may impose coverage limitations

that preclude payment for some approved uses or that full reimbursement may not be available for the Company's products.

Furthermore, even after approval for reimbursement for the Company's products is obtained from private health coverage insurers or government health authorities, it may be removed at any time. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products and there can be no assurance that third-party coverage will be sufficient to give the Company an appropriate return on its investment in developing existing or new products. Increasingly, government and other third-party payers are attempting to contain expenditures for new therapeutic products by limiting or refusing coverage, limiting reimbursement levels, imposing high co-pays, requiring prior authorizations and implementing other measures. Inadequate coverage or reimbursement could adversely affect market acceptance of the Company's products. Third-party payers increasingly challenge the pricing of pharmaceutical products. Moreover, the trend toward managed healthcare in the U.S., the growth of organizations such as health maintenance organizations and reforms to healthcare and government insurance programs, could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for the Company's products.

In the U.S., each third-party payer plan is organized into tiers and the number of tiers will vary. Each tier represents a different reimbursement level. There is no guarantee that the Company's products will be reimbursed even at tiers where the reimbursement amounts are minimal.

In some countries, particularly the countries of the E.U., the pricing of prescription pharmaceuticals is subject to government control. In these countries, pricing negotiations with governmental authorities can take considerable time and delay the introduction of a product to the market. To obtain reimbursement or pricing approval in some countries, the Company may be required to conduct a clinical trial that compares the cost effectiveness of its product candidate to other available therapies. If reimbursement of the Company's product is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, its business could be adversely affected. In addition, any country could pass legislation or change regulations affecting the pricing of pharmaceuticals before or after a regulatory agency approves any of its product candidates for marketing in ways that could adversely affect the Company. While the Company cannot predict the likelihood of any legislative or regulatory changes, if any government or regulatory agency adopts new legislation or new regulations, the Company's business could be harmed.

Potential Product Liability

The Company may be subject to product liability claims associated with the use of its products either after their approval or during clinical trials and there can be no assurance that liability insurance will continue to be available on commercially reasonable terms or at all. Product liability claims might also exceed the amounts or fall outside of such coverage. Product liability claims against the Company, regardless of their merit or potential outcome, could be costly and divert management's attention from other business matters or adversely affect its reputation and the demand for its products.

In addition, certain drug retailers and distributors require minimum liability insurance as a condition of purchasing or accepting products for retail or wholesale distribution. Failure to satisfy such insurance requirements could impede the ability of the Company or its potential

partners in achieving broad retail distribution of its products, resulting in a material adverse effect on the Company.

There can be no assurance that a product liability claim or series of claims brought against the Company would not have an adverse effect on its business, financial condition, results of operations and cash flows. If any claim is brought against the Company, regardless of the success or failure of the claim, there can be no assurance that the Company will be able to obtain or maintain product liability insurance in the future on acceptable terms or with adequate coverage against potential liabilities or the cost of a recall can be given.

Hazardous Materials and Environmental

The Company's products involve the use of potentially hazardous materials, and as a result, it is exposed to potential liability claims and costs associated with complying with laws regulating hazardous waste. R&D and manufacturing activities involve the use of hazardous materials, including chemicals, and are subject to federal, provincial and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. However, accidental injury or contamination from these materials may occur. In the event of an accident, the Company could be held liable for any damages, which could exceed its available financial resources. In addition, the Company may be required to incur significant costs to comply with environmental laws and regulations in the future.

Operating Losses

The Company had an accumulated deficit at December 31, 2014 of $192.9 million. The Company expects expenditures and the accumulated deficit to increase as it proceeds with its development programs to advance the products in its pipeline and to seek regulatory approvals. The Company does not expect to attain sustained profitability for the foreseeable future. The Company does not expect to achieve sustained profits until such time as product sales and royalty payments generate sufficient revenues to fund our continuing operations, if ever. The Company may never achieve profitability. Even if it achieves profitability, it may not remain profitable. The Company's inability to become and remain profitable could depress the market price of its shares and could impair its ability to raise capital, expand its business, expand its product pipeline or continue its operations.

There can be no assurance that the Company will achieve significant revenues from its commercial products (i.e. Pennsaid, Pennsaid 2%, Pliaglis, the HLT Patch and WF10) or achieve profitability or that it will obtain additional marketing approvals for its products in other jurisdictions. There can be no assurance that the Company will successfully develop and obtain regulatory approval for any other therapeutic product or that it will successfully commercialize such product if it is developed and approved.

Quarterly Fluctuations

The Company's quarterly and annual operating results are likely to fluctuate in the future. These fluctuations could cause our stock price to decline. The nature of the Company's business involves variable factors, such as the timing of launch and market acceptance of the Company's products, the timing and costs associated with the research, development and regulatory submissions of our products in development, the costs of maintaining manufacturing facilities operating below capacity and the costs associated with public company and other regulatory compliance. As a result, in some future quarters or years, the Company's clinical, financial or

operating results may not meet the expectations of securities analysts and investors which could result in a decline in the price of Nuvo's stock.

Personnel

The Company depends upon certain key members of its scientific and management teams. The loss of any of these individuals could have a material adverse effect on the Company. The Company does not maintain key-man insurance on any employee.

The Company's success depends, in large part, on its ability to continue to attract and retain qualified scientific, manufacturing and management personnel. The Company faces intense competition for such personnel. It may not be able to attract and retain qualified management, manufacturing and scientific personnel in the future. Also, it must provide training for its employee base due to the highly specialized nature of pharmaceutical products.

Further, the Company expects that its growth and potential expansion into specific areas and activities requiring new or additional expertise, such as in the areas of R&D, preclinical studies, CMC work, clinical trials and regulatory approvals will place additional requirements on management, operational and financial resources. The Company expects these demands will require an increase in the number of management and scientific personnel and development of additional expertise by existing personnel. The failure to attract and retain such personnel, or to develop such expertise, could materially adversely affect prospects for its success. In addition, to attract qualified personnel, the Company may be required to establish offices in different locations. Failure of personnel in different locations to work effectively together could materially adversely affect the Company's success.

Given these potential challenges, current personnel may be unable to adapt or may not have the appropriate skills and the Company may fail to assimilate and train new employees. Highly skilled employees with the education and training required, especially employees with significant experience and expertise in drug delivery systems, are in high demand. Once trained, the Company's employees may be hired by its competitors.

Information Technology Infrastructure

Despite the implementation of security measures, the Company's information systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruption of our operations. The Company's business depends on the efficient and uninterrupted operation of computer and communications systems and networks, hardware and software systems and other information technology. If systems were to fail or the Company was unable to successfully expand the capacity of these systems or was unable to integrate new technologies into its existing systems, its operations and financial results could suffer.

Litigation and Regulation

From time-to-time, during the ordinary course of business, the Company is threatened with, or is named as a defendant in various legal proceedings, including lawsuits based upon product liability, patent infringement, personal injury, breach of contract and lost profits or other consequential damage claims.

A significant judgment against the Company or the imposition of a significant fine or penalty or a finding that the Company has failed to comply with laws or regulations or a failure to settle any dispute on satisfactory terms, could have a significant adverse impact on the Company's ability to continue operations. Additionally, lawsuits and investigations can be expensive to defend, whether or not the lawsuit or investigation has merit, and the defense of these actions may divert the attention of the Company's management and other resources that would otherwise be engaged in running the Company's business.

On August 20, 2013, the Company commenced legal action against Mallinckrodt by filing a Complaint in the U.S. District Court for the Southern District of New York. This lawsuit was settled in September 2014. See "Narrative Description of the Business – Litigation".

Acquisition and Integration of Complementary Technologies or Businesses

The Company may pursue product or business acquisitions that could complement or expand its business. However, it may not be able to identify appropriate acquisition candidates in the future. If an acquisition candidate is identified, the Company may not be able to successfully negotiate the terms of any such acquisition or finance such acquisition. Any such acquisition could result in unanticipated costs or liabilities, diversion of management's attention from the core business, the expenditure of resources and the potential loss of key employees, particularly those of the acquired organizations. In addition, the Company may not be able to successfully integrate any businesses, products, technologies or personnel that it might acquire in the future, which may harm its business.

To the extent the Company issues common shares or other rights to finance any acquisition, existing shareholders may be diluted. In connection with an acquisition, the Company may acquire goodwill and other long-lived assets that are subject to impairment tests, which could result in future impairment charges.

Inability to Achieve Expected Savings from Restructurings

The Company may, from time-to-time, seek to restructure its operations, which may require it to incur restructuring charges and it may not be able to achieve the level of benefits that it expects to realize from any restructuring activities or it may not be able to realize these benefits within the expected time frames. Furthermore, upon the closure of any facilities in connection with restructuring efforts, the Company may not be able to divest such facilities at a fair price or in a timely manner. Changes in the amount, timing and character of charges related to restructurings and the failure to complete or a substantial delay in completing any restructuring plan could have a material adverse effect on the Company's business.

Losses Due to Foreign Currency Fluctuations

The Company anticipates that the majority of the revenue from commercialization of its product candidates may be in currencies other than Canadian dollars. Fluctuation in the exchange rate of the Canadian dollar relative to these other currencies could result in the Company realizing a lower profit margin on sales of its product candidates than anticipated at the time of entering into such commercial agreements. Adverse movements in exchange rates could have a material adverse effect on the Company's financial condition and results of operations.

International Operations

The Company has operations outside of Canada, primarily in the E.U. and the U.S., in order to research, develop, market, distribute and manufacture certain of its products and potential products. The Company may expand such operations further in the future. Participation in international markets requires resources and management's attention and subjects the Company to business risks, including the following:

- different regulatory requirements for approval of its product candidates;
- dependence on local distributors;
- longer payment cycles and problems in collecting accounts receivable;
- adverse changes in trade and tax regulations;
- absence or substantial lack of legal protection for intellectual property rights;
- difficulty in managing widespread operations;
- political and economic instability;
- increased costs and complexities associated with financial reporting; and
- currency risks.

The occurrence of any of these or other factors may cause the Company's international operations to be unsuccessful, could lower the prices at which it can sell its products or otherwise have an adverse effect on its operating results.

Taxes

The Company is a multinational corporation with global operations. As such, it is subject to the tax laws and regulations of Canadian federal, provincial and local governments, the U.S. and many international jurisdictions, including transfer pricing laws and regulations between many of these jurisdictions.

Significant judgment is required in determining the Company's provision for income taxes and claims for investment tax credits (ITCs) related to qualifying Scientific Research and Experimental Development (SR&ED) expenditures in Canada. Various internal and external factors may have favourable or unfavourable effects on future provisions for income taxes and the Company's effective income tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, results of audits by tax authorities, changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, future levels of R&D spending and changes in overall levels of income before taxes. Furthermore, new accounting pronouncements or new interpretation of existing accounting pronouncements can have a material impact on the Company's effective income tax rate.

The Company could be impacted by certain tax treatments for various revenue streams in different tax jurisdictions. The Company was subject to withholding taxes on certain of its revenue streams. The withholding tax rates that were used were based on the interpretation of specific tax acts and related treaties. If a tax authority has a different interpretation from the Company's, it could potentially impose additional taxes, penalties or fines. This would potentially reduce the amounts of revenue ultimately received by the Company.

The Company, from time-to-time, has executed multiple reorganization transactions impacting its tax structure. If a tax authority has a different interpretation from the Company's, it could potentially impose additional taxes, penalties or fines.

Volatility of Share Price

Market prices for pharmaceutical related securities, including those of the Company, have been historically volatile and subject to substantial fluctuations. The stock market, from time-to-time, experiences significant price and volume fluctuations unrelated to the operating performance of particular companies. Future announcements concerning the Company or its competitors, including the results of testing, technological innovations, new commercial products, marketing arrangements, government regulations, developments concerning regulatory actions affecting the Company's products and its competitors' products in any jurisdiction, developments concerning proprietary rights, litigation, additions or departures of key personnel, cash flow, public concerns about the safety of the Company's products and economic conditions and political factors in the U.S., the E.U., Canada or other regions may have a significant impact on the market price of the common shares. In addition, there can be no assurance that the common shares will continue to be listed on the TSX.

Dilution from Further Equity Financing and Declining Share Price

If the Company raises additional funding or completes an acquisition or merger by issuing additional equity securities, such issuance may substantially dilute the interests of shareholders of the Company and reduce the value of their investment. The market price of the Company's common shares could decline as a result of issuances of new shares or sales by existing shareholders of common shares in the market or the perception that such sales could occur. Sales by shareholders might also make it more difficult for the Company itself to sell equity securities at a time and price that it deems appropriate.

Issue of Preference Shares

The Company's Board of Directors has the authority to issue undesignated preference shares in one or more series and, before issue, to fix the designation of, and the rights and restrictions attached to, the preference shares of each series, without consent from holders of common shares. Preference shares could be issued with voting, dividend, liquidation, dissolution, winding-up and other rights superior to those of the holders of common shares.

Absence of Dividends

The Company has not paid dividends on its common shares and does not anticipate declaring any dividends in the near future. As a result, the return on an investment in the Company's common shares will depend upon any future appreciation in value. There is no guarantee that the common shares will appreciate in value or even maintain the price at which they were purchased.

Active Trading Market for Common Shares

The Company's common shares are listed for trading on the TSX. There can be no assurance that an active trading market in the Company's common shares on the TSX will be sustained.

Shareholders' Rights Plan

The Company has adopted a shareholder rights plan (2013 Rights Plan) which among other things requires anyone who seeks to acquire 20% or more of the Company's outstanding common shares to make a bid complying with specific provisions contained in the plan. Failure

of the acquirer to comply with the provisions of the 2013 Rights Plan can trigger rights held by existing shareholders that may make the acquisition less attractive to the acquirer. See "Description of Capital Structure – Description of the Common Shares". The presence of this plan could prevent or delay a change of control and may deprive or limit strategic opportunities for shareholders to sell their shares.

Securities Industry Analyst Research Reports

The trading market for the Company's common stock is influenced by the research and reports that industry or securities analysts publish about the Company or any of its partners. If covered, a decision by an analyst to cease coverage of the Company or fail to regularly publish reports on the Company, could cause the Company to lose visibility in the financial markets, which in turn could cause the stock price or trading volume to decline. Moreover, if an analyst who covers the Company or any of its partners downgrades its, or its partner's stock or if operating results do not meet analysts' expectations, the stock price could decline. Currently, to the Company's knowledge, one analyst publishes research reports about the Company. The Company and its products have also been discussed in analyst research reports published about its partners and competitors.

Compliance with Laws and Regulations Affecting Public Companies

Any future changes to the laws and regulations affecting public companies, compliance with existing provisions of Multilateral Instrument 52-109 – Certification of Disclosure in Issuer's Annual and Interim Filings of the Canadian Securities Administrators and the other applicable Canadian securities laws and regulation and related rules and policies, may cause the Company to incur increased costs as it evaluates the implications of new rules and implements any new requirements. Delays or a failure to comply with the new laws, rules and regulations could result in enforcement actions, the assessment of other penalties and civil suits.

The new laws and regulations may make it more expensive for the Company to provide indemnities to the Company's officers and directors and may make it more difficult to obtain certain types of insurance, including liability insurance for directors and officers, as such, the Company may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for the Company to attract and retain qualified persons to serve on its Board of Directors or as executive officers. The Company may be required to hire additional personnel and utilize additional outside legal, accounting and advisory services, all of which could cause general and administrative costs to increase beyond what the Company currently has planned. The Company is continuously evaluating and monitoring developments with respect to these laws, rules and regulations and it cannot predict or estimate the amount of the additional costs it may incur or the timing of such costs.

The Company is required annually to review and report on the effectiveness of its internal control over financial reporting in accordance with Multilateral Instrument 52-109 – Certification of Disclosure in Issuer's Annual and Interim Filings of the Canadian Securities Administrators. The results of this review are reported in the Company's Annual Report and in its Management's Discussion and Analysis of Results of Operations and Financial Condition. The Company's Co-Chief Executive Officers and Chief Financial Officer are required to report on the effectiveness of the Company's internal control over financial reporting.

Management's review is designed to provide reasonable assurance, not absolute assurance, that all material weaknesses existing within the Company's internal controls are

identified. Material weaknesses represent deficiencies existing in the Company's internal controls that may not prevent or detect a misstatement occurring which could have a material adverse effect on the quarterly or annual financial statements of the Company. In addition, management cannot provide assurance that the remedial actions being taken by the Company to address any material weaknesses identified will be successful, nor can management provide assurance that no further material weaknesses will be identified within its internal controls over financial reporting in future years.

If the Company fails to maintain effective internal controls over its financial reporting, there is the possibility of errors or omissions occurring or misrepresentations in the Company's disclosures which could have a material adverse effect on the Company's business, its financial statements and the value of the Company's common shares.

Public Company Requirements May Strain Resources

As a public company, the Company is subject to the reporting requirements of the *Securities Act* (Ontario), as amended, the regulations and rules thereto, including the national and multilateral instruments adopted as rules, decisions, rulings and orders promulgated under the Act and the published policy statements issued by the Ontario Securities Commission (OSC) and the listing requirements of the TSX. The ever increasing obligations of operating as a public company will require significant expenditures and will place additional demands on management as the Company complies with the reporting requirements of a public company. The Company may need to hire additional accounting, financial and legal staff with appropriate public company experience and technical accounting and regulatory knowledge.

In addition, actions that may be taken by significant stockholders may divert the time and attention of the Company’s Board of Directors and management from its business operations. Campaigns by significant investors to effect changes at publicly traded companies have increased in recent years. If a proxy contest were to be pursued by any of the Company’s stockholders, it could result in substantial expense to the Company and consume significant attention of management and the Board of Directors. In addition, there can be no assurance that any stockholder will not pursue actions to effect changes in the management and strategic direction of the Company, including through the solicitation of proxies from the Company's stockholders.

Management of Growth

The Company’s future growth, if any, may cause a significant strain on management, operational, financial and other resources. The ability to effectively manage growth will require the Company to improve and/or expand its scientific, operational, financial and management information systems and to train, manage and motivate its employees. These demands may require the addition of new management personnel and the development of additional expertise by management. Any increase in resources devoted to research, product and business development without a corresponding increase in scientific, operational, financial and management information systems could have a material adverse effect on performance. The failure of the Company’s management team to effectively manage growth could have a material adverse effect on the Company’s business, financial condition and results of operations.

DIVIDENDS

Dividends are payable on the common shares if and when declared by Nuvo's Board of Directors. The Company has never paid dividends on the common shares and does not expect to do so in the near future.

DESCRIPTION OF CAPITAL STRUCTURE

The Company's authorized share capital consists of an unlimited number of common shares and an unlimited number of first and second preferred shares, issuable in series of which 10,774,757 common shares and no preferred shares were outstanding as of December 31, 2014.

The following is a description of the material characteristics of the Company's common shares and preferred shares including descriptions of other instruments that are convertible or exercisable into common shares.

Common Shares

Description of the Common Shares

The holders of common shares are entitled to receive notice of any meeting of the Company's shareholders and to attend and vote thereat, excepting those meetings at which only those holding another class of shares or a particular series are entitled to vote. Each common share entitles its holder to one vote. Subject to the rights of those holding preferred shares, the holders of common shares are entitled to receive on a pro rata basis such dividends as the Board of Directors of the Company may declare out of funds legally available. In the event of the dissolution, liquidation, winding-up or other distribution of the Company's assets, such holders are entitled to receive on a pro rata basis, all the Company's remaining assets after payment of all liabilities, subject to the rights of the holders of the preferred shares. The common shares carry no pre-emptive or conversion rights. The preceding was a summary of the principal characteristics of the common shares. A full description of the common shares can be found in the Company's Articles of Amalgamation dated January 1, 2007. The Articles of Amalgamation are available on SEDAR at www.sedar.com.

Shareholder Rights Plan

The Company instituted a shareholder rights plan in 1992 to provide the Board of Directors with sufficient time to consider and, if appropriate, to explore and develop alternatives for maximizing shareholder value if a takeover bid is made for the Company, and to provide every shareholder with an equal opportunity to participate in such a bid. Between 1992 and 2013, shareholders approved various amendments to, and restatements of, the shareholder rights plan, including, most recently, at the Company's 2013 Annual and Special Meeting of Shareholders (such amended and restated rights plan is referred to as the Rights Plan). The terms of the Rights Plan are set out in the shareholder rights plan agreement (the Rights Agreement) dated as of December 16, 1992 (amended and restated on June 18, 2013 and previously amended and restated on May 1, 2008, October 21, 2003 and September 28, 1998), between the Company and the CST Trust Company as rights agent (the Rights Agent).

The purpose of the Rights Plan is to provide some protection to shareholders of the Company from take-over strategies, including the acquisition of control of the Company by a bidder in a transaction or series of transactions, that do not treat all shareholders equally or fairly or afford all shareholders an equal opportunity to share in the premium paid upon an acquisition

of control. The Rights Plan is not intended to prevent all unsolicited take-over bids for the Company and will not do so, but rather, is designed to encourage potential bidders to make permitted bids or negotiate take-over proposals with the Board of Directors which they consider are in the best interest of the Company and to protect the Company's shareholders against being coerced into selling their shares at less than fair value.

Shareholder rights plans continue to be adopted by a large number of publicly held corporations in Canada and the U.S. The terms of the Company's Rights Plan are generally similar to those recently adopted by other major Canadian companies.

The following is a summary of the principal terms of the Rights Plan, which is qualified in its entirety by reference to the text of the Rights Agreement. Certain capitalized terms used in this section and not otherwise defined have the meanings given to such terms in the Rights Agreement.

Rights Prior to Separation Time

Rights (Rights) were issued on the commencement of the Rights Plan to all holders of common shares of the Company. Rights cannot be exercised prior to the Separation Time (defined below). Until the Separation Time, the Rights will be evidenced only by the register maintained by the Rights Agent and will be transferred with, and only with, the associated common shares. Until the Separation Time, or the earlier termination or expiration of the Rights, each new share certificate issued after the record date for the issuance or the Rights, upon transfer of existing common shares or the issuance of additional common shares, will display a legend incorporating the terms of the Rights Plan by reference.

Separation Time

The Rights will separate and trade apart from the common shares after the Separation Time, at which time separate certificates evidencing the Rights will be mailed to the holders of record of common shares. "Separation Time" means the close of business on the tenth business day after the earlier of (i) the first date of a public announcement of facts indicating that a person has become an Acquiring Person (defined below), (ii) the commencement of, or first public announcement of the intent of any person, other than the Company or any Company controlled by the Company, to commence a Take-over Bid (defined below) or (iii) the date upon which a Permitted Bid (defined below) ceases to be a Permitted Bid or, in any circumstances, such later date as may be determined by the Board, acting in good faith. After the Separation Time and prior to the occurrence of a Flip-in Event (defined below), each Right entitles the holder to acquire one common share upon payment of an Exercise Price of approximately $3,250 (which, prior to the Consolidation was $50).

Acquiring Person and Flip-in Event

An Acquiring Person is generally, a person who beneficially acquires 20% or more of the outstanding voting shares of the Company. The Rights Plan provides certain exceptions to that rule, including a person who acquires 20% or more of the outstanding common shares through a Permitted Bid, pursuant to certain other exempt acquisitions, or in its capacity as Investment Manager, Trust Company, Plan Trustee or Statutory Body, provided in these latter instances, that the person is not making or proposing to make a Take-over Bid. The term Acquiring Person does not include the Company or any corporation controlled by the Company. A Flip-in Event occurs when any person becomes an Acquiring Person, at which time each Right will convert into the right to purchase from the Company, upon exercise, a number of common shares having an

aggregate Market Price on the date of the Flip-in Event equal to twice the Exercise Price for an amount in cash equal to the Exercise Price.

Permitted Bid

A Flip-in Event does not occur if a take-over bid is a Permitted Bid. A Permitted Bid is a Take-over Bid, made by a means of a Take-over Bid circular, which among other things:

1) is made to all holders of record of common shares as registered on the books of the Company (other than the Offeror and the Offeror's Affiliates, Associates and persons acting jointly or in concert with any of them);

2) contains, and the take-up and payment for common shares tendered or deposited is subject to, an irrevocable and unqualified condition that no common shares will be taken up or paid for pursuant to the Take-over Bid prior to the close of business on a date which is not less than 120 days following the date of the Take-over Bid;

3) contains irrevocable and unqualified provisions that all common shares may be deposited pursuant to the Take-over Bid at any time prior to the close of business on the date of first take-up or payment for common shares under the bid and that all common shares deposited pursuant to the Take-over Bid may be withdrawn at any time prior to the close of business on such date;

4) contains an irrevocable and unqualified condition that the number of common shares deposited to the Take-over Bid and not withdrawn at the close of business on the date of first take-up or payment for common shares under the bid must constitute more than 50% of the then outstanding common shares held by shareholders independent of the Offeror; and

5) contains an irrevocable and unqualified provision that, should the condition referred to in clause 4 be met, the Take-over Bid will be extended on the same terms for a period of not less than 10 days from the date of first take-up or payment for common shares under the bid.

The Rights Plan also provides for a Competing Permitted Bid, which is a Take-over Bid, made during another Permitted Bid that satisfies all of the requirements of a Permitted Bid other than the requirements of clause 2. The competing Permitted Bid may not expire earlier than the date of the Permitted Bid.

Take-over Bid

A Take-over Bid is defined in the Rights Plan as an offer to acquire common shares or securities convertible into common shares, where the common shares subject to the offer to acquire, together with the common shares into which the securities subject to the offer to acquire are convertible, and the Offeror's securities, constitute in the aggregate 20% or more of the outstanding common shares at the date of the offer.

Redemption and Waiver

At any time prior to the occurrence of a Flip-in Event, the Board may, at its option, redeem all, but not part, of the outstanding Rights at a redemption price of $0.00065 per Right (which, prior to the Consolidation, was $0.00001), subject to appropriate adjustment in certain events.

The Board may, at its option, after the occurrence of a Flip-in Event, waive the application of the Flip-in Event provisions to a transaction that would otherwise be subject to those provisions.

Amendments

The Company may, from time-to-time, supplement or amend the Rights Plan in order to cure any ambiguity or to correct or supplement any provisions contained in the agreement which may be inconsistent with any other provision thereof or otherwise defective. The Company may also amend the agreement without the approval of any holders of Rights or common shares to make any changes which the Board may deem necessary or desirable and as shall not materially adversely affect the interests of the holders of Rights generally, provided that no such supplement or amendment shall be made to the provisions relating to the Rights Agent except with the concurrence of the Rights Agent.

Expiry of Rights

All Rights will expire unless continuance of the Rights Plan is approved by a majority vote of Independent Shareholders at the Annual and Special Meeting of Shareholders of the Company to be held in 2018.

Share Incentive Plan

Under the Company's Second Amended and Restated Share Incentive Plan (the Share Incentive Plan), there are three sub-plans: the Share Purchase Plan, the Share Option Plan and the Share Bonus Plan. The original plan was amended and restated effective September 21, 2005 when shareholders of the Company approved an amendment changing the maximum number of common shares that may be issued under the plan from a fixed maximum number to a fixed maximum percentage. The amendment changed the maximum number of common shares that may be issued under the Share Incentive Plan to a fixed maximum percentage of 15% of the Company's outstanding common shares (on a fully diluted basis other than stock options) from time-to-time. The common shares that may be issued under the plan are allocated to the three sub-plans as follows: Share Option Plan 10%, Share Purchase Plan 3% and Share Bonus Plan 2%. As the Share Incentive Plan is a "rolling plan", the TSX requires that it, along with any unallocated options, rights or other entitlements, receive shareholder approval at the Company's annual meeting every three years. At the Annual and Special Meeting of Shareholders of the Company held on June 11, 2014, the common shareholders approved an ordinary resolution affirming, ratifying and approving the Share Incentive Plan and approving all of the unallocated common shares issuable pursuant to the Share Incentive Plan.

Share Purchase Plan

Under the Share Purchase Plan, eligible officers, employees or consultants of the Company or its affiliates may contribute up to 10% of their annual base salary to the plan to purchase common shares. The Company matches each participant's contribution by issuing common shares having a value equal to the aggregate amount contributed by each participating employee. As at December 31, 2014, the number of common shares available for issuance under the Share Purchase Plan was 294.

Share Option Plan

Under the Share Option Plan, the Company may grant options to purchase common shares to officers, directors, employees or consultants of the Company or its affiliates. Options

issued under the Share Option Plan are granted for a term not exceeding ten years from the date of grant. Under the provisions of the Share Incentive Plan, the exercise price of all common share options shall not be less than the closing price of the common shares on the last trading date immediately preceding the grant date of the option. As at December 31, 2014, 886,742 common share options were issued and outstanding and the number of unoptioned common shares available to be reserved was 122,620. Any unexercised common share options that are surrendered, terminate or expire without being exercised become unoptioned and are available for reissuance under the Share Option Plan. When common share options are exercised, each option becomes available for reissuance under the Share Option Plan.

Share Bonus Plan

Under the Share Bonus Plan, the Company can issue common shares to eligible directors, officers or employees of the Company or its affiliates as a discretionary bonus. In addition, consultants are also eligible to receive common shares in lieu of cash compensation. As at December 31, 2014, the number of common shares available for issuance under the Share Bonus Plan was 90,127

Preferred Shares

Description of the Preferred Shares

Preferred shares may be issued from time-to-time in one or more series, the number, designation, rights, privileges, restrictions and conditions of which are to be determined by the Board of Directors. The preferred shares are entitled to priority over the common shares with respect to the payment of dividends and distributions in the event of the dissolution, liquidation or winding-up of the Company. Except as required by law, the holders of first preferred shares as a class, and holders of second preferred shares as a class, are not entitled to receive notice of, attend or vote at any meeting of the Company's shareholders. The preceding was a summary of the principal characteristics of the preferred shares. A full description of the preferred shares can be found in the Company's Articles of Amalgamation dated January 1, 2007. The Articles of Amalgamation are available on SEDAR at www.sedar.com.

MARKET FOR SECURITIES

The common shares are listed and posted for trading on the TSX under the symbol NRI. The common shares are also traded on the Unofficial Regulated Markets of many German stock exchanges including the Frankfurt Stock Exchange, the Berlin Stock Exchange, the Munich Stock Exchange and the XETRA electronic trading system of the Deutsche Börse and in the U.S. on the over-the-counter market as NRIFF.

The following table provides information on the monthly price range and trading volume for the common shares on the TSX during the year ended December 31, 2014:

Month	**High**	**Low**	**Volume**
	$	$	**(000s)***
January 2014	5.73	2.10	1,076
February 2014	3.30	2.46	264
March 2014	2.85	2.40	129
April 2014	3.73	2.58	392
May 2014	3.44	2.50	212
June 2014	2.92	2.55	249
July 2014	3.00	2.61	220
August 2014	3.67	2.57	604
September 2014	5.36	3.50	1,078
October 2014	5.70	4.39	1,184
November 2014	8.33	4.85	1,880
December 2014	7.14	6.00	832

DIRECTORS AND OFFICERS

The following table sets forth the name, municipality of residence, position with the Company and principal occupation of each director and executive officer of the Company. Directors of the Company hold office until the next annual shareholders' meeting or until successors are duly elected or appointed.

Name and Residence	Principal Occupation	Director Since	Number of Common Shares Beneficially Owned
Daniel N. Chicoine[5] Ontario, Canada	Chairman of the Board of the Company and Co-Chief Executive Officer	September 21, 2004	167,783
David A. Copeland[4][7][8] Ontario, Canada	Private Investor and Business Consultant	September 21, 2004	20,379
Anthony E. Dobranowski [1][3][6] Ontario, Canada	Private Business Consultant	September 21, 2004	12,419
Dr. Henrich R.K. Guntermann Aachen, Germany	President, Europe and Immunology Group	September 21, 2004	15,017
Dr. Klaus von Lindeiner [1,3] Munich, Germany	Private Business Consultant	September 21, 2004	1,538
John C. London[8] Ontario, Canada	President and Co-Chief Executive Officer	September 21, 2004	87,786
Dr. Jacques Messier [2] Ontario, Canada	CEO The Toronto Humane Society	September 21, 2004	14
Dr. Theodore H. Stanley [1] Utah, USA	Professor, University of Utah and Private Investor	May 26, 2011	99,877
Katina K. Loucaides Ontario, Canada	Vice President, Secretary and General Counsel	N/A	11,786
Stephen L. Lemieux Ontario, Canada	Vice President and Chief Financial Officer	N/A	14,917

Notes:

(1) Member of the Compensation and Corporate Governance Committee.
(2) Chairman of the Compensation and Corporate Governance Committee.
(3) Member of the Audit Committee.
(4) Chairman of the Audit Committee.
(5) Dan Chicoine was a director of NRI Industries Inc. (NRI), a company primarily involved in the manufacture of rubber and plastic components for automotive and industrial applications, until August 23, 2006, when he resigned. This company filed for protection pursuant to the Companies' Creditors Arrangement Act on September 5, 2006. On April 27, 2007,

subsequent to the sale of substantially all of the assets of NRI, the CCAA proceedings were terminated and NRI filed its assignment into bankruptcy and in July 2008 the government cancelled the Corporation for cause.

(6) Anthony Dobranowski was a trustee of Heating Oil Partners Income Fund. Subsequent to certain of its subsidiaries filing for creditor protection in the U.S. and Canada, the units of the fund were delisted from the TSX on November 7, 2005. In March 2006, the OSC issued an issuer cease trade order in respect of the units of the fund and it remains in default with the OSC. The debtor's joint plan of reorganization was approved by the U.S. bankruptcy court on June 26, 2006 and Heating Oil Partners Income Fund relinquished all equity interests in the reorganized subsidiaries under the approved plan of reorganization.

(7) David Copeland was Chairman of the Board of Triton Electronik, a group of Canadian companies primarily involved in electronic contract design and manufacturing service, until January 2009, when he resigned. This group of companies filed for protection pursuant to the Companies' Creditors Arrangement Act on January 28, 2009.

(8) John London and David Copeland were directors of MTB Industries Inc. (MTB) until May 1, 2009 when they both resigned. MTB filed for court appointed receivership on May 5, 2009.

Each of the directors of the Company has been engaged for more than five years in his present principal occupation or in other capacities with the corporation or organization (or predecessor thereof) in which he currently holds his principal occupation, with the exception of the following: Dr. Jacques Messier who from 2008 to 2011 was Director of the Veterinary Teaching Hospital at the University of Saskatchewan and since 2011 is the CEO of The Toronto Humane Society.

As at December 31, 2014, the directors and executive officers of Nuvo, as a group, beneficially owned, directly or indirectly, or exercised control or direction of 431,517 or 4.0% of the Company's common shares assuming all potentially dilutive instruments were exercised or converted.

LEGAL PROCEEDINGS AND REGULATORY ACTIONS

See "Narrative Description of the Business – Litigation".

TRANSFER AGENT

The transfer agent and registrar for the common shares is CST Transfer Company, P.O. Box 700, Station B, Montreal, QC, H3B 3K3.

AUDIT COMMITTEE

Charter of the Audit Committee

The Audit Committee of the Company's Board of Directors has developed its Charter, the text of which is set forth in Appendix I to this AIF.

Composition of the Audit Committee

The Audit Committee is comprised of three members, David A. Copeland, Anthony E. Dobranowski and Dr. Klaus von Lindeiner. Each member is independent and financially literate as defined in Multilateral Instrument 52-110 - Audit Committees.

Relevant Education and Experience of Audit Committee Members

In addition to each member's general business experience, the education and experience relevant to the performance of Audit Committee responsibilities are set forth below.

David A Copeland

Mr. Copeland is a Chartered Professional Accountant and a Chartered Accountant. He holds a Bachelor of Mathematics degree and has been the Chief Financial Officer of a major public Canadian company.

Anthony E. Dobranowski

Mr. Dobranowski is a Chartered Professional Accountant and a Chartered Accountant. He holds a Bachelor of Science Degree, a Masters of Business Administration Degree and has been the Chief Financial Officer and President of a major public Canadian company.

Dr. Klaus von Lindeiner

Dr. von Lindeiner holds a law degree from the University of Geneva and has been the Chief Financial Officer of two multinational European-based companies and was the Chairman of the Audit Committee for Bayerische Landesbank in Munich, Germany up to September 30, 2014.

Audit Fees

The following table outlines the fees paid to Ernst & Young LLP the Company's auditors for the years ended December 31, 2014 and December 31, 2013.

Fees	Year ended December 31, 2014	Year ended December 31, 2013
Audit Fees [(1)]	203,000	155,000
Audit – Related Fees[(2)]	57,000	57,000
Tax Fees[(3)]	23,000	-
All other Fees[(4)]	84,000	5,000
TOTAL	367,000	217,000

(1) Accrued for December 2014 Audit
(2) The fees related to quarterly reviews.
(3) The tax fees include assistance in preparing tax returns for certain foreign subsidiaries and other general tax matters.
(4) Other fees relate to assistance provided in planning work related to the Company's obligations under IFRS, the U.S. Listing process, the Private Placement, the CPAB fee and additional procedures regarding the royalty audit of Mallinckrodt.".

MATERIAL CONTRACTS

The only material contracts entered into by the Company during the recently completed financial year or prior to the most recently completed financial year (but after January 1, 2002) that are still in effect, other than in the ordinary course of business, are as follows:

- the Asset Purchase Agreement dated October 17, 2014 between the Company and Horizon Pharma plc (HZNP Limited) described under "General Development of the Business – Recent Financings and Corporate Transactions";

- the Agreement and Plan of Merger dated April 15, 2011 between the Company and Nuvo Research Delaware Inc. and ZARS Pharma, Inc.; and

- the 2013 Rights Plan Agreement dated as of December 16, 1992 as amended and restated on June 18, 2013, between the Company and CIBC Mellon Trust Company of Canada, described under “Description of Capital Structure – Description of the Common Shares – Shareholder Rights Plan”.

EXPERTS

The Company’s auditor is Ernst & Young LLP, Chartered Professional Accountants, Licensed Public Accountants, 222 Bay Street, Toronto, Ontario M5K 1J7. Ernst & Young LLP has confirmed that it is independent with respect to the Company within the meaning of the Rules of Professional Conduct of CPA Ontario. Ernst & Young LLP provides tax, financial advisory and other non-audit services to the Company and its subsidiaries. The Company’s Audit Committee has concluded that the provision of these non-audit services by Ernst & Young LLP is compatible with Ernst & Young LLP maintaining its independence.

ADDITIONAL INFORMATION

Additional information regarding the Company can be found at www.sedar.com. Additional information on Nuvo, including directors’ and officers’ remuneration and indebtedness, principal holders of the Company’s securities, options to purchase securities and interests of insiders in material transactions is contained in the Company’s Management Information Circular dated April 30, 2014. Additional financial information is provided in the Company’s Consolidated Financial Statements and Notes to the Consolidated Financial Statements and Management’s Discussion and Analysis for the year ended December 31, 2014.

Copies of the Company’s Report to Shareholders, including its Consolidated Financial Statements and Notes to the Consolidated Financial Statements and Management’s Discussion and Analysis for the year ended December 31, 2014, Management Information Circular and this AIF may be obtained upon request from the Company’s Investor Relations Department or on the Company’s website: www.nuvoresearch.com.

GLOSSARY

Abbreviated New Drug Application	An Abbreviated New Drug Application (ANDA) contains data that, when submitted to the FDA provides for the review and ultimate approval of a generic drug product. Generic drug applications are called "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, a generic applicant must scientifically demonstrate that its product is bioequivalent (i.e. performs in the same manner as the innovator drug).
Active Pharmaceutical Ingredient	An Active Pharmaceutical Ingredient (API) is any substance or mixture of substances intended to be used in the manufacture of a drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
Chemistry, Manufacturing and Controls	Chemistry, Manufacturing and Controls (CMC) constitutes that part of pharmaceutical development that deals with the nature of the drug substance (API) and drug product, the manner in which both are made, and the manner by which the manufacturing process is shown to be in control. CMC considerations include formulation development, manufacturing process and equipment, container-closure system (packaging), stability evaluation and shelf life (storage condition) and specifications for raw materials/components and the finished drug product.
Clinical Trials	The regulated process by which new drugs proceed after discovery through to acceptance for marketing to patients. The term most correctly refers to the period during which new compounds are tested in human subjects and encompasses the several phases as outlined under “Narrative Description of Business – Regulatory Environment and Drug Development Process”.
Complete Response Letter	The FDA issues complete response letters when communicating a decision to a drug company that its new drug application (NDA) or ANDA to market a new or generic drug will not be approved in its present form. The letter will describe specific deficiencies and, when possible, will outline recommended actions the applicant might take to get the application ready for approval.
Contract Manufacturing Organization	A Contract Manufacturing Organization (CMO) manufactures products under contract for other companies.
Contract Research Organization	A Contract Research Organization (CRO) is a company that conducts research on behalf of a pharmaceutical or biotechnology company.
Controlled Heat-Assisted Drug Delivery	A Controlled Heat-Assisted Drug Delivery (CHADD) unit contains a heat-generating powder that consists of a proprietary mixture of several non-toxic ingredients which produce heat when exposed to air.
Federal Institute for Drugs and Medical Devices	Germany’s Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) (BfArM) is the German regulatory authority that oversees all clinical trials conducted in Germany.
Development Bank of Saxony	Development Bank of Saxony (SAB) has the meaning ascribed thereto under “Narrative Description of the Business – Immunology Group – Funding”.
Diclofenac sodium	An NSAID that is the active pharmaceutical ingredient in Pennsaid and Pennsaid 2%.
Dimethyl sulfoxide	Dimethyl sulfoxide (DMSO) is the molecular penetration enhancer used in Pennsaid and Pennsaid 2%.
Drug Master File	A Drug Master File (DMF) is a submission to the FDA that may be used to provide confidential, detailed information about facilities, processes or articles employed in the manufacturing, processing, packaging, and storing of one or more human drugs. Neither law nor FDA regulations require the submission of a DMF. A DMF is submitted solely at the discretion of the

	holder. The DMF holder provides the written authorization to the FDA that allows the review of the Master File to support other regulatory applications. The information contained in a DMF may be used to support an Investigational New Drug Application (IND), a New Drug Application (NDA), an Abbreviated New Drug Application, another DMF, an Export Application or amendments to any of these. DMF's are generally created to allow a party other than the holder of the DMF to reference material without disclosing to that party the contents of the file.
DuraPeel	DuraPeel described under “Narrative Description of the Business – Topical Products and Technology Group - Technology”..
Efficacy	Capacity for producing a desired result or effect.
European Medicines Agency	The European Medicines Agency (EMA) regulates the research, development, manufacture and marketing of pharmaceutical products
Good Clinical Practices and Good Laboratory Practices	Good Clinical Practices (GCP) and Good Laboratory Practices (GLP) are standards for the conduct of clinical trials (including laboratory studies) the data from which are expected to be submitted to a regulatory agency such as the FDA. In the case of GLP these practices are defined by regulation. GCP have arisen from general accepted clinical practices within the industry.
Good Manufacturing Practices	Good Manufacturing Practices (GMP), i.e. guidelines established by the governments of various countries, including Canada and the U.S., to be used as a standard in accordance with the World Health Organization's Certification Scheme on the quality of pharmaceutical products.
Immune system	The totality of organs involved in the body’s immunologic response to foreign antigens.
Investigational New Drug Application	An investigational New Drug application (IND) which must be filed and accepted by the FDA before human clinical trials may begin.
In vitro	A test that is performed in vitro is one that is done in glass or plastic vessels in the laboratory.
In vivo	In the living body or organism. A test performed on a living organism.
Lidocaine	A common local anesthetic drug, when used topically, relieves pain by blocking signals at the nerve endings in skin and underlying tissues.
Marketing Authorization Application	A Marketing Authorization Application (MAA) is a document submitted to drug regulatory authorities in Europe providing data that a drug has quality, efficacy and safety properties suitable for the intended indication.
Macrophage	A type of white blood cell that coordinates aspects of the immune system.
Multiplexed molecular penetration enhancers	Multiplexed molecular penetration enhancers (MMPEs) are cocktails or combinations of MPEs that modify the permeability of the stratum corneum.
Molecular penetration enhancers	Molecular penetration enhancers (MPEs) are molecules that interact with the molecules comprising the stratum corneum so as to modify its permeability.
New Drug Application	New Drug Application (NDA), a document containing preclinical, clinical and chemistry, manufacturing and control data collected on a drug. An NDA is submitted to the FDA in order to obtain approval to market a prescription drug in the U.S.
Neuropathic pain	Neuropathic pain is a type of pain caused by injury to the nervous system. The injury can be to the central nervous system (brain and spinal cord) or the peripheral nervous system (nerves outside the brain and spinal cord). Neuropathic pain can occur after trauma or be associated with many diseases such as diabetes, shingles and cancer. Examples include post herpetic neuralgia, reflex sympathetic dystrophy/causalgia (nerve trauma), components of cancer pain, phantom limb pain, entrapment neuropathy (e.g., carpal tunnel syndrome), and peripheral neuropathy (widespread nerve damage).

Osteoarthritis	Osteoarthritis (OA) is a type of arthritis that is caused by the breakdown and eventual loss of the cartilage of one or more joints. Cartilage is a connective tissue that serves as a "cushion" between the bones of the joints.
Onychomycosis	Onychomycosis is a fungal infection of the finger or toe nails.
p-value	A statistics term. A measure of probability that a difference in outcome between groups during an experiment happened by chance. For example, a p-value of .01 (p = .01) means there is a 1 in 100 chance the result occurred by chance. The lower the p-value, the more likely it is that the difference between groups was caused by treatment.
Pharmacokinetics	The action of drugs in the body over a period of time, including the processes of absorption, distribution, metabolism and excretion.
Placebo	An inactive substance administered to a group of patients in a clinical study in order to form a control group against which the results obtained from patients receiving an active substance can be measured.
Preclinical studies	Those studies generally completed prior to human clinical trials.
Risk Evaluation and Mitigation Strategy	A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage a known or potential serious risk associated with a drug. A REMS may be required by the FDA and can include a Medication Guide, Patient Package Insert, a communication plan, an education plan, and even restricted marketing, to assure safe use of the drug.
Supplemental New Drug Application	Supplemental New Drug Application (sNDA) allows a company to make changes in a product that already has an approved new drug application (NDA). The Center for Drug Evaluation and Research (CDER) must approve all important NDA changes (in packaging or ingredients, for instance) to ensure the conditions originally set for the product are still met.
Tetracaine	A local anesthetic drug that can be administered by local injection or by topical application to conjunctiva, mucosae and skin. When used topically, relieves pain by blocking signals at the nerve endings in skin and underlying tissues.
Total Nasal Symptom Score	The Total Nasal Symptom Score (TNSS) is used to assess nasal symptoms associated with allergic rhinitis. The nasal symptoms include rhinorrhea (runny nose), itchy nose, sneezing and nasal congestion.
Toxicology	Toxicology (also called Safety Pharmacology) is the study of a chemical compound to determine the levels at which death occurs.
Therapeutic Products Directorate	The Therapeutic Products Directorate (TPD) is the division within Health Canada that reviews New Drug Submissions.
Topical and Transdermal Drug Delivery	Topical and Transdermal Drug Delivery (TTDD) described under “Narrative Description of the Business – Topical Products and Technology Group”.
United States Food and Drug Administration	The U.S. Food and Drug Administration (FDA), an agency within the Department of Health and Human Services, the U.S. government’s principal agency for protecting the health of all Americans, which is among other responsibilities charged with regulating pharmaceutical products in the U.S.

APPENDIX I – AUDIT COMMITTEE CHARTER

AUDIT COMMITTEE CHARTER FOR NUVO RESEARCH INC. (the "Company")

I. PURPOSE

The purpose of the Audit Committee (the "**Committee**") is to assist the Board of Directors of Nuvo Research Inc. (the "**Board**") in fulfilling its responsibilities of oversight and supervision of the accounting and financial reporting practices and procedures, the adequacy of internal accounting controls and procedures and the quality and integrity of the consolidated financial statements of Nuvo Research Inc. (the "Company") and its affiliates. The Committee is also responsible for the audit process.

More specifically the purpose of the Committee is to satisfy itself that:

A. The Company's annual financial statements are fairly presented in accordance with Canadian generally accepted accounting principles and to recommend to the Board whether the annual financial statements should be approved.
B. The information contained in the Company's quarterly financial statements, annual report and other financial publications, such as management's discussion and analysis, is complete and accurate in all material respects and to recommend to the Board whether these materials should be approved.
C. The Company has appropriate systems of internal control over the safeguarding of assets and financial reporting to ensure compliance with legal and regulatory requirements.
D. The external audit functions have been effectively carried out and that any matter which the independent auditors wish to bring to the attention of the Board has been addressed. The Committee will also recommend to the Board the re-appointment or appointment of auditors and their remuneration.

II. COMPOSITION AND TERMS OF OFFICE

A. Following each annual meeting of the Company, the Board shall appoint three or more directors to serve on the Committee. Such appointees shall not be officers or employees of either the Company or its affiliates. Each member of the Committee must be "Independent" as defined by Multilateral Instrument 52-110 and "Unrelated" according to the rules of the Toronto Stock Exchange (the "TSX") from time to time, and free of any relationship that could, or could reasonably be perceived to, in the opinion of the Board, interfere with the exercise of independent judgment as a member of the Committee. All members of the Committee must be financially literate and be able to read and understand fundamental financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the Company's financial statements including the Company's balance sheet, income statement and cash flow statement, or develop that capability within a reasonable time after appointment.
B. The chair of Committee shall be appointed by the Board and shall not be an officer or employee of the Company or its affiliates. The chair of the Committee

shall be a “financial expert” having an understanding of GAAP and financial statements, internal controls and procedures for financial reporting and, if possible, shall have served as the principal financial officer for another business entity.

C. Any member of the Committee may be removed or replaced at any time by the Board and shall cease to be a member upon ceasing to be a director of the Company. Each member of the Committee shall hold office until the close of the next annual meeting of the Company or until the member resigns or is replaced, whichever first occurs.
D. The Committee will meet at least four times per year. The meetings will be scheduled to permit timely review of the interim and annual financial statements of the Company and its affiliates. Additional meetings may be held as deemed necessary by the chair of the Committee or as requested by any member of the Committee or by the external auditors.
E. If all members consent, and proper notice has been given or waived, a member or members of the Committee may participate in a meeting of the Committee by means of such telephonic, electronic or other communication facilities as permit all persons participating in the meeting to communicate adequately with each other, and a member participating in such a meeting by any such means is deemed to be present at that meeting.
F. A quorum for the transaction of business at all meetings of the Committee shall be a majority of the members of the Committee. Questions arising at any meeting shall be determined by a majority of votes of the members of the Committee present, and in case of an equality of votes the Chair of Committee shall have a second casting vote.
G. The Committee may invite such directors, officers and employees of as it may see fit from time to time to attend meetings of the Committee and assist in the discussion and consideration of the business of the Committee, but without voting rights.
H. The Committee shall keep regular minutes of proceedings and shall cause them to be recorded in books kept for that purpose, and shall report the same to the Board at such times as the Board may, from time to time, require.
I. Supporting schedules and information reviewed by the Committee will be available for examination by any director upon request to the Secretary of the Committee.
J. The Committee shall choose as its secretary such person as it deems appropriate.
K. The external auditors shall be given notice of, and have the right to appear before and to be heard at, every meetings of the Committee, and shall appear before the Committee when requested to do so by the Committee.

III. DUTIES AND RESPONSIBILITIES

Subject to the powers and duties of the Board, the Board hereby delegates to the Committee the following powers and duties to be performed by the Committee on behalf of and for the Board:

A. **Financial Reporting Control**

The Committee shall:

(i) review reports from senior officers of the Company, outlining any significant changes in financial risks facing the Company;
(ii) review the management letter of the external auditors and responses to suggestions made;
(iii) annually review the Audit Committee Charter and the performance of the Committee itself;
(iv) review any new appointments to senior positions of the Company or its affiliates, with financial reporting responsibilities; and,
(v) obtain assurance the external auditors regarding the overall control environment and the adequacy of accounting system controls.

B. **Interim Financial Statements**

The Committee shall:

(i) review interim financial statements with officers of the Company prior to their release and recommend their approval to the Board. This will include a detailed review of quarterly and year-to-date results; and
(ii) review the Company's MD&A and press releases accompanying interim financial statements.

C. **Annual Financial Statements and Other Financial Information**

The Committee shall:

(i) review any changes in accounting policies or financial reporting requirements that may affect the current year's financial statements;
(ii) obtain summaries of significant transactions and other potentially difficult matters whose treatment in the annual financial statements merits advance consideration;
(iii) obtain draft annual financial statements in advance of the Committee meeting and assess, on a preliminary basis, the reasonableness of the financial statements in light of the analyses provided by officers of the Company;
(iv) review a summary provided by the Company's general counsel of the status of any material pending or threatened litigation, claims and assessments;
(v) discuss the annual financial statements and the auditors' report thereon in detail with officers of the Company and its auditors;
(vi) review the annual report and other annual financial reporting documents including management's discussion and analysis; (vii) provide to the Board a recommendation as to whether the annual financial statements should be approved;

(vii) review insurance coverage including directors' and officers' liability coverage ; and
(viii) review the Company's Annual Information Form ("AIF") and ensure compliance with FORM 52-110F1, audit committee information required in an AIF.

D. **External Audit Terms of Reference, Reports, Planning and Appointment**

The Committee shall:

(i) ensure that the external auditor explicitly acknowledges that they are ultimately and directly accountable to the Board and the Committee as representatives of the shareholders;
(ii) review the audit plan with the external auditors;
(iii) specify its expectations of the external auditors, including the expected relationship between the external auditors and the Committee;
(iv) discuss in private with the external auditors matters affecting the conduct of their audit and other corporate matters, including:

- the quality (not only acceptability) of Canadian GAAP accounting principles;
- the quality of internal controls;
- the appropriateness of financial statement disclosures; and
- any other matters the external auditors may wish to bring to the attention of the Committee.

(v) recommend to the Board each year the retention or replacement of the external auditors. This process shall include establishment of criteria for and an ongoing assessment of the continued independence of the external auditor. If there is a plan to change auditors, review all issues related to the change and the steps planned for an orderly transition; and

(vi) annually review and recommend for approval to the Board the terms of engagement and the remuneration of the external auditors.

E. **Other Matters**

The Committee shall:

(i) pre-approve all non-audit services to be provided to the Company or its subsidiary entities by the issuer's external auditor.
(ii) establish procedures for the receipt, retention and treatment of complaints received by the issuer regarding accounting, internal accounting controls, or auditing matters; and
(iii) establish procedures for the confidential, anonymous submission by employees of the issuer of concerns regarding questionable accounting or auditing matters.

IV. ACCOUNTABILITY

A. The Committee shall report to the Board at its next regular meeting all such action it has taken since the previous report.
B. The Committee is empowered to investigate any activity of the Company and all employees are to cooperate as requested by the Committee. The Committee may retain persons having special expertise to assist it in fulfilling its responsibilities.
C. The Committee is authorized to request the presence at any meeting, but without voting rights, of a representative from the external auditors, senior management, legal counsel or anyone else who could contribute substantively to the subject of the meeting and assist in the discussion and consideration of the business of the Committee, including directors, officers and employees of the Company.