NUVO PHARMACEUTICALS™ INC.

ANNUAL INFORMATION FORM

March 1, 2017

Table of Contents

CERTAIN REFERENCES

Unless otherwise noted, the information contained in this Annual Information Form (AIF) is provided as at December 31, 2016 or for the period ended December 31, 2016 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 Pharmaceuticals Inc.", "Nuvo", the "Company", "our" and "we" refers to Nuvo Pharmaceuticals Inc. and its subsidiaries, unless the context requires otherwise.

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

On December 14, 2015, the Company, 2487002 Ontario Limited and 2487001 Ontario Limited entered into an arrangement agreement (the Arrangement Agreement) in respect of a reorganization of the Company into two separate publicly traded companies (the Reorganization), Nuvo Pharmaceuticals Inc. and Crescita Therapeutics Inc. (Crescita), would each be owned 100% by Nuvo's shareholders. The Reorganization was approved by the shareholders of the Company at a special shareholders meeting on February 18, 2016 and by the Ontario Superior Court of Justice on February 24, 2016. The Reorganization was completed on March 1, 2016. In general, this AIF does not include historic information that is relevant only to Crescita, its subsidiaries, and their respective businesses.

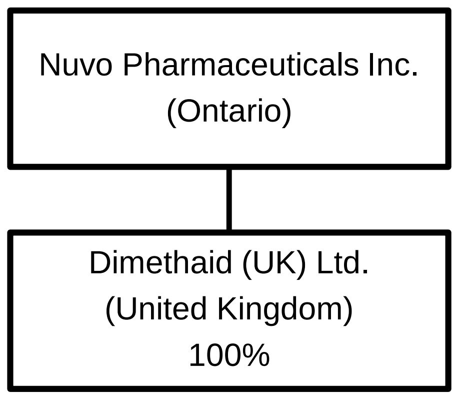
FORWARD-LOOKING INFORMATION

Certain statements in this AIF constitute forward-looking statements and/or forward-looking information (collectively, "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", "Narrative Description 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 "Risk 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. Additional factors that could affect the operation of Nuvo as a result of the completion of the Reorganization are described in the Reorganization Circular (defined below) under the heading "Risk Factors". 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 statements contained in this AIF are based upon what management believes are reasonable assumptions, there can be no assurance that actual results will be consistent with these forward-looking statements. 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 PHARMACEUTICALS INC. STRUCTURE

Organizational Chart

The following chart illustrates Nuvo's relationship to its subsidiary, its respective jurisdictions of incorporation, as well as the percentage ownership as at December 31, 2016.



Corporate Structure

Nuvo Pharmaceuticals 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 March 1, 2016, the articles were amended to change the name of the Company from Nuvo Research Inc. to Nuvo Pharmaceuticals Inc.

The Company's registered office and principal place of business is located at 7560 Airport Road, Unit 10, Mississauga, Ontario L4T 4H4.

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 Pharmaceuticals Inc.

Reorganization

On December 14, 2015, the Company, 2487002 Ontario Limited and 2487001 Ontario Limited entered into the Arrangement Agreement in respect of the proposed Reorganization of the Company into two separate publicly traded companies. Nuvo would be a commercial healthcare company to be owned 100% by Nuvo's shareholders. The second company, Crescita, would be a drug development company also initially owned 100% by Nuvo's shareholders. The Reorganization was approved by the shareholders of Nuvo at a special shareholders meeting on February 18, 2016 and by the Ontario Superior Court of Justice on February 24, 2016. The Reorganization was completed on March 1, 2016.

Detailed information regarding the Reorganization and its effects including a description of certain risks and uncertainties in respect of the Reorganization and the operation of Nuvo and Crescita as separate publicly traded companies are included in the Management Information Circular dated December 31, 2015 (Reorganization Circular) that is available under Nuvo's profile at www.sedar.com.

GENERAL DEVELOPMENT OF THE BUSINESS

Nuvo is a publicly traded, Canadian, commercial healthcare company with a portfolio of commercial products and pharmaceutical manufacturing capabilities. Nuvo has three commercial products that are available in a number of countries: Pennsaid 2%, Pennsaid and the heated lidocaine/tetracaine patch (HLT Patch). Pennsaid 2% is sold in the U.S. by Horizon Pharma plc (Horizon) and is available for partnering in certain other territories around the world. Nuvo manufactures Pennsaid for the global market and Pennsaid 2% for the U.S. market at its U.S. Food and Drug Administration (FDA), Health Canada and E.U. approved manufacturing facility in Varennes, Québec. See "General Development of Business – Recent Financings and Corporate Transactions." Nuvo is focused on licensing the rights to Pennsaid 2% in those territories that are available, as well as looking for new strategic acquisitions to diversify its commercial product portfolio and utilize its manufacturing capacity and capabilities.

Pursuant to the Reorganization, Nuvo's drug development business that focused on pain and dermatology, including Pliaglis and its Multiplexed Molecular Penetration Enhancer (MMPE) technology, and its Immunology Group (defined below), including its WF10 assets and drug development program, were transferred to Crescita. See "Nuvo Pharmaceuticals Inc. Structure – Reorganization".

Nuvo's products that have received regulatory approval have been commercialized in a number of countries. The commercial products include:

Pennsaid 2%, a topical non-steroidal anti-inflammatory drug (NSAID) containing 2% diclofenac sodium compared to 1.5% for original Pennsaid (described below). 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 "Legal Proceedings and Regulatory Actions". Under the terms of the settlement agreement, Mallinckrodt paid US$10.0 million to settle the claims and returned the U.S. sales and marketing rights for Pennsaid and Pennsaid 2% to Nuvo. In October 2014, the Company sold the U.S. rights to Pennsaid 2% to 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, a topical NSAID containing 1.5% diclofenac sodium is used to treat the signs and symptoms of OA of the knee and is approved for sale and marketing in Canada where it is licensed to Paladin Labs Inc. (Paladin) and several European countries. 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.

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.

Three Year History

Important events which have occurred in the last three fiscal years and the period subsequent to December 31, 2016 up to the date of this 2016 AIF include the following:

Fiscal 2017 to AIF filing date

- As of February 27, 85% of the target number of patients had been enrolled in the 2016 Pennsaid 2% Trial (described below). Top-line results of the trial are expected to be available in the second quarter of 2017;

- In February, the Company received notification from NovaMedica LLC (NovaMedica), its Russian licensee for Pennsaid 2% that the marketing authorization for Pennsaid 2% had been granted by the Russian Ministry of Health. The marketing authorization is inclusive of the non-prescription, human use of Pennsaid 2% in treating back pain, joint pain, muscle pain, and inflammation and swelling in soft tissue and joints associated with trauma and rheumatic conditions. The Company and NovaMedica are in discussions respecting NovaMedica’s commercial strategy and launch plans; and

- In February, Horizon advised the Company that, it plans to draw down some of its existing inventory of commercial bottles of Pennsaid 2% and shift commercial bottle production from the second quarter to later in 2017. Horizon has asked that the Company pull forward into the second quarter some product sample orders planned for later in the year. These inventory adjustments are in response to the U.S. Federal Drug Supply Chain Act taking effect November 27, 2017 that requires all pharmaceutical drugs manufactured for the U.S. market to have individually serialized tracking and will have a negative impact on the Company’s second quarter sales and earnings. The Company expects that sales to Horizon will increase in the second half of the year as Horizon resumes its more typical ordering patterns. See “Narrative Description of the Business – Pennsaid 2% and “Risk Factors”.

Fiscal 2016

- In July, after reviewing the data from the 2015 Pennsaid 2% Trial (described below), the Company announced that it would conduct a new placebo-controlled, multi-centre Phase 3 trial in Germany to study Pennsaid 2% for the treatment of acute ankle sprains (the 2016 Pennsaid 2% Trial). The primary endpoint for the Trial will be reduction in pain on movement (POM) at day three with anticipated results in the second quarter of 2017. The 2016 Pennsaid 2% Trial is designed to support regulatory applications for marketing approval of Pennsaid 2% for the treatment of acute pain in the E.U., Canada and Australia;

- In March, the Company announced top-line results of its Phase 3, multi-centre, randomized, placebo-controlled, double-blind, parallel group trial in patients with grade I or II ankle sprains conducted in Germany (the 2015 Pennsaid 2% Trial). The 2015 Pennsaid 2% Trial did not meet its primary endpoint, which was POM at day five. For the full analysis set group, the difference vs. placebo was statistically significant on the secondary time point on day 3, but not at the primary time point on day five or the secondary time point on day eight. The 2015 Pennsaid 2% Trial was conducted to support regulatory applications for marketing approval of Pennsaid 2% for the treatment of acute pain in the E.U., Canada and Australia which are potential new markets for Pennsaid 2%;

- In March, the Reorganization was completed. See "Nuvo Pharmaceuticals Inc. Structure – Reorganization";

- In February, Nuvo shareholders approved the Reorganization of the Company into two separate publicly traded companies and obtained final Court approval from the Ontario Superior Court of Justice. See "Nuvo Pharmaceuticals Inc. Structure – Reorganization"; and

- In February, the Company extended the initial term of their manufacturing agreement for the production of Pennsaid 2% for the U.S. market to December 31, 2029 from the initial term which ended on December 31, 2022. The amended agreement also provides for tiered pricing based on volumes of product supplied. See "General Development of the Business – Recent Financings and Corporate Transactions – Pennsaid 2% U.S. Asset Sale".

Fiscal 2015

- In December, the Company reacquired the Pliaglis development and marketing rights from Galderma S.A. (Galderma) for the U.S., Canada and Mexico. Under the Reorganization, rights to Pliaglis were transferred to Crescita. See "Nuvo Pharmaceuticals Inc. Structure – Reorganization", "General Development of the Business – Recent Financings and Corporate Transactions – Pliaglis North American Rights Acquisition" and "Narrative Description of the Business – Crescita Therapeutics";

- In December, the Company announced top-line results of the 2015 WF10 Trial (described below). The top-line results showed that patients dosed with WF10 did not report a reduction in symptoms that was significantly better than patients dosed with a saline placebo at any of the endpoints being measured in the Trial. There was no significant difference in the performance of WF10 relative to placebo when patients were exposed to grass and ragweed pollen in the environmental exposure chamber (EEC) or when they were exposed to naturally occurring allergens during the field portion of the Trial. The

Company believed that the results were not sufficient to justify the further development of WF10 for the treatment of allergic rhinitis and discontinued all WF10 development and divest of the Immunology Group. See “Nuvo Pharmaceuticals Inc. Structure – Reorganization” and “Narrative Description of the Business – Crescita Therapeutics”;

- In December, the Company announced it would hold a special meeting of Nuvo’s shareholders on February 18, 2016 at which shareholders were asked to approve the previously announced Reorganization. See “Nuvo Pharmaceuticals Inc. Structure – Reorganization”;

- In November, the Company announced that the Toronto Stock Exchange (TSX) had conditionally approved the listing of the shares of Crescita, subject to compliance with normal listing requirements. See “Nuvo Pharmaceuticals Inc. Structure – Reorganization”;

- In November, NovaMedica, the Company’s marketing licensee for Russia, advised the Company that the 7-week Russian trial of 95 patients with OA of the knee met its required endpoints. NovaMedica advised the Company that late in 2015, it filed for regulatory approval of Pennsaid 2% in Russia;

- In September, the Company announced that it was pursuing the Reorganization. See “Nuvo Pharmaceuticals Inc. Structure – Reorganization”;

- In April, after reviewing the data from both the previous two WF10 studies and consulting external experts, the Company believed that the placebo group in the 2014 WF10 Trial (described below) may not have recorded as high of a Total Nasal Symptom Score (TNSS) compared to the previous WF10 trial in 2010 due to a longer enrollment period that started later in the allergy season, varying environmental conditions and other factors that resulted in some patients in the 2014 WF10 Trial not being exposed to a high enough concentration of the allergens that they were allergic to throughout the trial period. The Company decided to conduct a new randomized, double-blind, placebo-controlled, single-centre trial to assess the efficacy, safety and tolerability of a regimen of five WF10 infusions (2015 WF10 Trial). See “Nuvo Pharmaceuticals Inc. Structure – Reorganization” and “Narrative Description of the Business – Crescita Therapeutics”;

- In April, the Company announced that the Board of Directors had determined that it should work towards spinning out WF10-related assets into a separate research and development (R&D) focused entity and transition the Company from a biotechnology company concentrated mainly on drug development into a more diversified, profitable, cash flow positive business; and

- 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 (2014 WF10 Trial). The WF10 arm reduced allergy symptoms as evidenced by recorded patient TNSS. The placebo arm demonstrated an unexpected reduction in patient TNSS scores and the differences between the active and placebo arms were not statistically significant. See “Nuvo Pharmaceuticals Inc. Structure – Reorganization” and “Narrative Description of the Business – Crescita Therapeutics”.

Fiscal 2014

- In November, the Company reacquired the Pennsaid 2% marketing rights to South America, Central America, South Africa and Israel from Paladin. 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 November, the Company announced its plan to conduct a Phase 3 clinical trial in Germany for Pennsaid 2% for the treatment of acute pain to support regulatory approval applications for Pennsaid 2% in international jurisdictions (the 2015 Pennsaid 2% Trial);

- In October, the Company paid $3.7 million to Paladin in full satisfaction of amounts outstanding pursuant to a loan agreement dated May 24, 2012 between the Company and Paladin. As a result of the payment, all obligations of Nuvo under the loan agreement were satisfied and all security relating thereto was released and discharged. See "General Development of the Business – Recent Financings and Corporate Transactions – Paladin Loan";

- 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 – Pennsaid 2% U.S. Asset Sale". Horizon launched the sale and marketing of Pennsaid 2% in January 2015;

- 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 "Legal Proceedings and Regulatory Actions";

- 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. Under the Reorganization, Nuvo's Immunology Group, including its WF10 assets and drug development program, was transferred to Crescita. See "Nuvo Pharmaceuticals Inc. Structure – Reorganization" and "Narrative Description of the Business – Crescita Therapeutics";

- In April, the Company entered into a collaboration involving Ferndale Laboratories, Inc. and a leading Contract Research Organization (CRO) to develop two topical dermatology products based on Nuvo's patented MMPE technology. Under the Reorganization, rights to the MMPE technology and the collaboration program were transferred to Crescita. See "Nuvo Pharmaceuticals Inc. Structure – Reorganization", "General Development of the Business – Recent Financings and Corporate Transactions – Ferndale Collaboration" and "Narrative Description of the Business – Crescita Therapeutics";

- In March, Galderma launched the commercial sale and marketing of Pliaglis in Brazil. Under the Reorganization, rights to Pliaglis were transferred to Crescita. See "Nuvo Pharmaceuticals Inc. Structure – Reorganization" and "Narrative Description of the Business – Crescita Therapeutics";

- 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 (the 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 – Private Placement”; and

- In January, Mallinckrodt received FDA approval for the sale and marketing of Pennsaid 2% in the U.S. and launched the product in the U.S. in February. See “Legal Proceedings and Regulatory Actions”.

Recent Financings and Corporate Transactions

Financings

In the past three years, the Company has raised approximately $5.6 million from the issuance of equity. The Company has also received approximately $55.6 million in upfront payments from product licensing and sale agreements, $11.2 million from the settlement of the litigation with Mallinckrodt (discussed below) and $0.3 million from the sale of excess land at its Varennes, Québec manufacturing facility. The Company is continuing to explore further financing opportunities in order to support general corporate initiatives.

Reorganization

See “Nuvo Pharmaceuticals Inc. Structure – Reorganization”.

Pliaglis North American Rights Acquisition

In December 2015, the Company reacquired the development and marketing rights for Pliaglis in the U.S., Canada and Mexico. Under the terms of the agreement, the Company paid Galderma 125,000 Swiss Francs (approximately CDN$174,000) and will pay an additional 125,000 Swiss Francs (approximately CDN$174,000) upon the transfer of certain rights and documents. Beginning in 2021, the Company has the right to reacquire the rest of world (ROW) rights on a country-by-country basis without additional compensation if Galderma does not achieve minimum sales targets. Galderma will continue to market Pliaglis in the U.S. and Canada and pay a royalty on net sales during an agreed upon transition period. Nuvo will receive a fixed single digit royalty on net sales in the territories outside of North America that Galderma still owns. Under the Reorganization, rights to Pliaglis and the obligation for the second 125,000 Swiss Francs (approximately CDN$174,000) payment were transferred to Crescita. See “Nuvo Pharmaceuticals Inc. Structure – Reorganization” and “Narrative Description of the Business – Crescita Therapeutics”.

Pennsaid 2% U.S. Asset Sale

On October 17, 2014, the Company entered into an asset purchase agreement with Horizon. Under the terms of the 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% (Pennsaid 2% U.S. Sale Agreement) for cash consideration of US$45.0 million received on the closing date.

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 was to expire on December 31, 2022 and, unless terminated, automatically renew for successive two-year terms, thereafter. In February 2016, the supply agreement was amended (Amended Supply Agreement) to extend the term of the agreement to December 31, 2029 and to introduce volume tiered pricing. The transfer price is subject to semi-annual adjustments based on Nuvo's raw material costs and annual adjustments based upon changes in a national manufacturing cost index for pharmaceutical products. The supply agreement may be terminated earlier by either party for any uncured material breach or other customary conditions. Under the Amended Supply Agreement, Nuvo is obligated to supply Pennsaid 2% to Horizon and Horizon is obligated to obtain 90% of its requirements for Pennsaid 2% from Nuvo. 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.

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, one of which has advanced into clinical studies. 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. Under the Reorganization, the collaboration agreement was transferred to Crescita. See "Nuvo Pharmaceuticals Inc. Structure – Reorganization" and "Narrative Description of the Business – Crescita Therapeutics".

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 were subject to an acceleration feature where the Company, at its option, could force the exercise of the Private Placement Warrants if the ten-day volume weighted share price for the Company's common shares was equal to or exceeded $3.50 on the TSX at any time during the warrant term. If the acceleration feature was used, any Private Placement Warrants that were not exercised during this period expire. The Company exercised its acceleration feature on November 30, 2015 and accelerated the expiry date of the outstanding warrants to January 15, 2016.

The Private Placement Warrants entitled the holder to purchase one common share of the Company at a price of $3.00 for a 24-month period. During the year ended December 31, 2016, 49,044 of the Private Placement Warrants were exercised [December 31, 2015 – 239,672 and December 31, 2014 – 433,149].

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. During the year ended December 31, 2016, 4,200 of the Broker Warrants were exercised [December 31, 2015 – 42,733 and December 31, 2014 – 31,300] and 2,100 Private Placement Warrants were issued upon exercise of the Broker Warrants [December 31, 2015 – 21,367 and December 31, 2014 – 15,650].

During the year ended December 31, 2016, 12,252 Private Placement Warrants expired.

Paladin Loan

In October, the Company paid $3.7 million to Paladin in full satisfaction of amounts outstanding pursuant to a loan agreement dated May 24, 2012 between the Company and Paladin. As a result of the payment, all obligations of Nuvo under the loan agreement were satisfied and all security relating thereto was released and discharged.

NARRATIVE DESCRIPTION OF THE BUSINESS

Nuvo is a publicly traded, Canadian, commercial healthcare company with a portfolio of products and pharmaceutical manufacturing capabilities. Nuvo has three commercial products that are available in a number of countries, Pennsaid 2%, Pennsaid and the HLT Patch. Nuvo is focused on licensing the rights to Pennsaid 2% in those territories that are available, as well as looking for new strategic acquisitions to diversify its commercial product portfolio and utilize its manufacturing capacity and capabilities.

Prior to the Reorganization, Nuvo operated two distinct business units: Nuvo and Crescita. At the time of the Reorganization, Crescita was a drug development business that operated two sub-groups: The Topical Products and Technology (TPT) Group and the Immunology Group. Crescita is presented as a discontinued operation in Nuvo's audited consolidated financial statements for the year ended December 31, 2016 and comparative year, and is generally not discussed in this AIF.

Nuvo's commercial products include:

Pennsaid 2%

Pennsaid 2%, the follow-on product to original Pennsaid (described below). Pennsaid 2% is a topical 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. This provides Pennsaid 2% with advantages over Pennsaid and other competitor products, and with patent protection.

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 "Legal Proceedings and Regulatory Actions". Under the terms of the settlement agreement, Mallinckrodt returned the U.S. sales and marketing rights to Pennsaid 2% to Nuvo. In October 2014, Nuvo 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 – Pennsaid 2% U.S. Asset Sale". In January 2015, Horizon launched its commercial sale and marketing of Pennsaid 2% in the U.S.

Nuvo records revenue to Horizon when it ships Pennsaid 2% commercial bottles and product samples to Horizon for the U.S. market. The Company earns product revenue from Horizon pursuant to a long-term, exclusive supply agreement as well as contract service revenue. The timing of Nuvo shipments to Horizon does not necessarily align with when U.S. patients fill prescriptions written by their physicians.

Horizon's orders from Nuvo are influenced by demand in the U.S. market, Horizon inventory levels and their management strategies. On November 27, 2017, the Federal Drug Supply Chain Security Act (DSCSA) rules come into force that require all manufacturers of drug products sold in the U.S. to "serialize" each individual package to enhance drug traceability in the event of an adverse event and to prevent drug counterfeiting. In order to be in compliance with the DSCSA, also known as the Serialization Track and Trace Bill, the Company has purchased new packaging equipment and technology systems that will give it the ability to individually serialize all Pennsaid 2% packaging. In coordination with Horizon, the Company has planned to install this new equipment well before the November 27, 2017 implementation date of the FDA rule change. The FDA was expected to publish regulations that grandfather existing non-serialized inventory in the supply chain, but hasn't released these much anticipated regulations yet. Due to this uncertainty, Horizon has decided to draw down some of its existing Pennsaid 2% inventory of non-serialized product in advance of the November 27, 2017 implementation date. Horizon has therefore advised the Company's Varennes manufacturing plant to shift commercial bottle production planned for the second quarter to later in the year. Sample production is not affected by the serialization issue and Horizon has asked that the Company pull forward into the second quarter some sample orders planned for later in the year. These production changes will have a negative impact on the second quarter sales and earnings; however, the Company expects that sales to Horizon will increase in the second half of the year, as the serialization equipment comes on stream and Horizon resumes its more typical ordering patterns. See “Risk Factors”.

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, Nuvo 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 Commonwealth of Independent States (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 informed Nuvo that the clinical trial it required for approval in Russia was completed successfully and it had submitted an application to obtain regulatory approval for Pennsaid 2% in Russia.

In February 2017, the Company received notification from NovaMedica that the marketing authorization for Pennsaid 2% had been granted by the Russian Ministry of Health. The marketing authorization is inclusive of the non-prescription, human use of Pennsaid 2% in treating back pain, joint pain, muscle pain, and inflammation and swelling in soft tissue and joints associated with trauma and rheumatic conditions. The Company and NovaMedica are in discussions respecting NovaMedica’s commercial strategy and launch plans.

Nuvo is actively seeking out commercialization partners for Pennsaid 2% in all remaining global markets.

As of February 23, 2017, patents have been granted in 19 countries outside the U.S. that provide protection for the Pennsaid 2% formulation and its use.

Additional clinical and non-clinical studies may be required to support applications for the regulatory approval of Pennsaid 2% in other countries in which Nuvo, or other licensees and distributors, could potentially market the product. The Company was advised by regulatory authorities in Canada and the U.K. that the data from the Pennsaid 2% Phase 2 trial conducted by Mallinckrodt was insufficient to support approval of Pennsaid 2% in their respective countries and that additional clinical trials would be required.

In July 2015, the Company commenced the 2015 Pennsaid 2% Trial to support regulatory approval applications for Pennsaid 2% in certain international jurisdictions. The Pennsaid 2% Trial enrolled 126 patients (the full analysis set or FAS) of which 116 patients followed the protocol (the per protocol set or PP). The patients enrolled in the 2015 Pennsaid 2% Trial applied either Pennsaid 2% or a placebo consisting of a topical vehicle that included all of the constituent ingredients of Pennsaid 2%, except its active ingredient diclofenac sodium, to their injured ankle twice a day for eight days. Randomly assigned double-blind treatment was started after baseline evaluation within 12 hours after injury (Day 1); the patients returned to the investigational site for in-depth evaluation on days three, five and eight of treatment. Results were tabulated for both the FAS and PP groups. The primary endpoint for the 2015 Pennsaid 2% Trial was reduction in POM at day five in the FAS group. On average, patients treated with Pennsaid 2% had a larger reduction in POM scores over the course of the trial. For the FAS group, the difference vs. placebo was statistically significant on the secondary time point on day three (p=0.0119), but not at the primary time point on day five (p=0.2430) or the secondary time point on day eight (p=0.2603). In the PP group, which excluded those patients with a lower usage of medication than as set out in the 2015 Pennsaid 2% Trial protocol (nine patients excluded out of 126 for this reason), the Pennsaid 2% group showed a statistically significant improvement at both the primary time point (day five p=0.0416), as well as the secondary time points (day three p=0.0018 and day eight p=0.0490).

The 2015 Pennsaid 2% Trial also included the measure of a number of secondary endpoints. These data are supportive of Pennsaid 2% being effective to treat ankle sprain injuries and specifically showed the following outcomes:

Tenderness	Pennsaid 2% demonstrated a statistically significant reduction in tenderness compared to placebo in the FAS group at days three, five and eight with p-values of 0.0055, 0.0150 and 0.0104, respectively.
Ankle Function	Pennsaid 2% demonstrated a statistically significant increase in ankle function compared to placebo in the FAS group at days three and eight with p-values of 0.0115 and 0.0232, respectively, but not at day five with a p-value of 0.1549.
Ankle Swelling	Pennsaid 2% demonstrated a statistically significant decrease in ankle swelling compared to placebo in the FAS group at days three, five and eight with p-values of 0.0020, 0.0018 and 0.0142, respectively.
Overall Assessment of Benefit and Satisfaction	Patients treated with Pennsaid 2% reported a statistically significantly higher level of satisfaction with and benefit of their treatment compared to placebo in the FAS group with a p-value of 0.0001 for the treatment benefit and a p-value of <0.0001 for satisfaction.

In October 2016, after reviewing the results of the 2015 Pennsaid 2% Trial, Nuvo commenced a Phase 3 clinical trial of Pennsaid 2% for the treatment of acute sprains and strains to support regulatory approval applications for Pennsaid 2% in certain international jurisdictions (the 2016 Pennsaid 2% Trial). Top-line results of this trial are expected in the second quarter of 2017. 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 trials 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, 2016, the Company recorded $22.8 million in revenue related to Pennsaid 2% representing 84% of the Company's total revenue from continuing operations [December 31, 2015 - $15.3 million or 74%].

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, an 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 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

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 "Legal Proceedings and Regulatory Actions". 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 – Pennsaid 2% U.S. Asset Sale". Under the terms of the Pennsaid 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 upfront, non-refundable milestone payment of US$0.5 million. In a patent infringement complaint against this generic company, the Company, along with Mallinckrodt, entered into a settlement agreement; whereby, this generic company agreed to pay an upfront, non-refundable milestone of US$0.5 million upon the launch of its generic version of Pennsaid and agreed to pay royalties calculated at 50% of gross profits from subsequent product sales until such time as a third generic version of Pennsaid was launched in the U.S. and the royalty rate would then 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. During the second quarter of 2015, a third generic version of Pennsaid was launched in the U.S. and the royalty rate decreased to 10% of gross profits from product sales. The generic version of Pennsaid that the Company earns royalty revenue from is not currently available in the U.S. market due to a manufacturing issue.

Canada

Pennsaid is licensed to Paladin for the Canadian market. Paladin markets Pennsaid and an authorized generic version of Pennsaid. The Company earns revenue in the form of product sales to Paladin and a royalty on Canadian net sales of both products. In February 2014, Taro Pharmaceutical Industries, Ltd. received approval in Canada for a generic version of Pennsaid which they launched in March 2014. This generic impacted the net sales that Paladin earns from Pennsaid, thereby reducing the Company's royalty income. There are currently four generic versions of Pennsaid approved in Canada, including the authorized generic and three have launched.

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. However, the Company does earn revenue in the form of product sales to its partners in these territories.

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.

In February 2017, the Company received notification from NovaMedica that the marketing authorization for Pennsaid 2% had been granted by the Russian Ministry of Health. The marketing authorization is inclusive of the non-prescription, human use of Pennsaid 2% in treating back pain, joint pain, muscle pain, and inflammation and swelling in soft tissue and joints associated with trauma and rheumatic conditions. The Company and NovaMedica are in discussions respecting NovaMedica's commercial strategy and launch plans.

For the year ended December 31, 2016, the Company recorded $1.9 million in revenue related to Pennsaid representing 7% of the Company's total revenue from continuing operations [December 31, 2015 - $3.9 million or 19%].

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, Nuvo sold the rights to sell and market Synera in the U.S. to Galen for its current indication. Under the terms of the license agreement, Nuvo earns royalties on the net sales of Synera and is eligible to receive sales milestones. The HLT Patch has FDA Orange Book listed patent which expires in July 2020.

In most countries in the E.U., 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 three years of age and for use in cases of superficial surgical procedures on normal intact skin in adults. Nuvo 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, Nuvo earns royalties on the net sales of Rapydan and is eligible to receive sales milestones.

The HLT Patch is manufactured by a third party contract manufacturing organization (CMO) for Galen and Eurocept. Currently, Nuvo manufactures the bulk drug substance for both parties.

In May 2012, Nuvo 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, Nuvo 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.

Nuvo holds the sales and marketing rights for the HLT Patch in Mexico, South America, Australia, Africa and most regions in Asia. Nuvo is planning to look 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 Pharmacokinetic (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, 2016, the Company recorded $1.1 million in revenue related to the HLT Patch representing 4% of the Company's total revenue from continuing operations [December 31, 2015 - $0.6 million or 3%].

Manufacturing

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 2016, the plant passed two FDA inspections as part of the U.S. Pennsaid 2% NDA review. In February 2013, the plant passed an FDA inspection related to the U.S. Synera Supplemental New Drug Application (sNDA) review.

Crescita Therapeutics

Pursuant to the Reorganization, Nuvo's drug development business that focused on pain and dermatology, including Pliaglis, its MMPE technology, a development pipeline that consisted of Ibuprofen Foam for the treatment of acute pain, a topical treatment for onychomycosis and Flexicaine for the treatment of postherpetic neuralgia, and its Immunology Group, including its WF10 assets and drug development program, were transferred to Crescita. Detailed information regarding the Reorganization and its effects including a description of certain risks and uncertainties in respect of the Reorganization and the operation of Nuvo and Crescita as separate publicly traded companies are included in the Reorganization Circular that is available under Nuvo's profile at www.sedar.com.

Intellectual Property

The value of the Company's operations and commercial and drug development candidates, and their future prospects, depends heavily on establishing and protecting valid intellectual property rights. See "Risk Factors – Patents, Trademarks and Proprietary Technology".

Patents – Nuvo

Pennsaid 2%

The Company has filed patent applications to cover Pennsaid 2% and other related formulations in a number of jurisdictions worldwide. Outside of the U.S., there are issued patents covering Pennsaid 2% in Australia, Canada, Europe (Denmark, France, Great Britain, Germany, Greece, Ireland, Italy, Netherlands and Switzerland), Hong Kong, India, Israel, Japan, Mexico, Russia, South Africa and New Zealand that have an anticipated expiry date in 2027. In addition, there are applications pending in a number of countries, the latest having an anticipated expiry date in 2033. In the U.S., there are 19 issued patents that are listed in the FDA's Orange Book for Pennsaid 2%. 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.

HLT Patch

The Company owns or has licensed rights to patents covering the HLT Patch, methods of manufacture and methods of use. Territories covered by issued patents, include the U.S. and certain countries in Europe.

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

Patents – Crescita

Under the Reorganization, certain intellectual property including Patents related to the TPT Group and Immunology Group products and pipeline were transferred to Crescita.

Trademarks

The Company holds certain registered trademarks and trademark applications that will cover its pipeline and commercial products. Under the Reorganization, certain intellectual property including Trademarks related to the TPT Group and Immunology Group products and pipeline were transferred to Crescita.

Confidential Information and Trade Secrets

In addition to patent protection, the confidential nature of the Company's expertise and its trade secrets will provide 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 the necessary steps to protect the confidentiality of its commercially sensitive activities.

Employees

As at March 1, 2017, the Company had 42 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 identifying and evaluating acquisition or in-licensing opportunities and manufacturing semi-solid and liquid pharmaceutical-grade compounds at its GMP facility in Varennes, Québec.

The Company is experienced in drug development and navigating the regulatory pathway in Canada, the U.S. and Europe to out-license its products. 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 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 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 will 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 non-clinical 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* (Canada) and are enforced by the Therapeutic Products Directorate (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 GMPs 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 a company if the application is satisfactory by issuance of a No Objection Letter (NOL), after which a 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 (the IRB)/research ethics board (the 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, a company will be required to 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 the *Food and Drugs Act* (Canada) 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 Code of Federal Regulations 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 GMPs. 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 a company if the application is unsatisfactory. If the application is not deemed unsatisfactory, then a 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., a 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 GMPs. 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 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 Reference Member State 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 are typically 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 Post-marketing Requirements (PMRs) 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. PMRs include studies and clinical trials that sponsors are required to conduct under one or more statutes or regulations. Post-marketing commitments 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.

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. Additional factors that could affect the operation of Nuvo as a result of the completion of the Reorganization are described in the Reorganization Circular under the heading "Risk Factors".

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 in which they are currently available. Decisions impacting sales and marketing efforts are made by the Company's partners for their respective territories. If one of the Company's partners is unable to successfully sell or stops selling its respective product, for any reason, 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 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 the Company's partners do not comply, this could have a material impact on the cash flows of the Company.

Dependency on Horizon

The Company currently derives the majority of its revenue from Pennsaid 2% U.S. product sales to Horizon. If Horizon was unable to successfully sell or stops selling its respective product, for any reason, it would have an adverse effect on the Company's product sales and cash resources.

In February, Horizon advised the Company that, it plans to draw down some of its existing inventory of commercial bottles of Pennsaid 2% and shift commercial bottle production from the second quarter to later in 2017. Horizon has asked that the Company pull forward into the second quarter some product sample orders planned for later in the year. These inventory adjustments are in response to the U.S. Federal Drug Supply Chain Act taking effect November 27, 2017 that requires all pharmaceutical drugs manufactured for the U.S. market to have individually serialized tracking and will have a negative impact on the Company's second quarter sales and earnings. While the Company expects that sales to Horizon will increase in the second half of the year as Horizon resumes its more typical ordering patterns, there can be no assurance that this will be the case. If sales to Horizon do not increase in the second half of the year, the negative impact on the Company's sales and earnings may be prolonged beyond the second quarter.

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.

The Company's partner in Canada has launched an authorized generic version of Pennsaid to compete with the generic version of Pennsaid and protect market share. The Company earns revenue in the form of product sales to Paladin and a royalty on Canadian net sales of the generic. In February 2014, Taro Pharmaceutical Industries, Ltd. received approval in Canada for a generic version of Pennsaid which they launched in March 2014. This generic impacted the net sales that Paladin earns from Pennsaid, thereby reducing the Company's royalty income. There are currently four generic versions of Pennsaid approved in Canada, including the authorized generic and three have launched.

In the U.S., under the Hatch-Waxman Act, the FDA can approve an Abbreviated New Drug Application (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 three-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 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 (Pennsaid 2% Orange Book Patents) 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. It is our understanding that patent litigation is currently pending in the United States District Court for the District of New Jersey against several companies intending to market a generic version of Pennsaid 2% prior to the expiration of certain Pennsaid 2% Orange Book Patents. These cases involve the following sets of defendants: (i) Actavis Laboratories UT, Inc., formerly known as Watson Laboratories, Inc., Actavis, Inc. and Actavis plc; and (ii) Lupin Limited and Lupin Pharmaceuticals, Inc. In Horizon Pharma Ireland Limited, et al v. Actavis Laboratories UT, Inc., C.A. No. 14-cv-7992-NLH-AMD, a bench trial is scheduled to begin on March 21, 2017. No trial date has been set in any other pending Pennsaid 2% cases. 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, import controls, tariffs and taxes or product marketing approvals. Such changes remain beyond the Company's control and have an unpredictable impact.

Risks Related to Unexpected Product Safety or Efficacy Concerns

Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales, as well as potential product liability, consumer fraud or other claims. Any of such occurrences could have a material adverse effect on the Company's business, financial condition and results of operations.

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.

If the relationships with 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.

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 United States Environmental Protection Agency, the Occupational Safety and Health

Administration, 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 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, the E.U. and the U.S. For some of the Company's other raw materials required to manufacture Pennsaid and the bulk substance for the HLT Patch, 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 manufacturing site of Pennsaid, Pennsaid 2% and the bulk drug product for the HLT Patch for all markets. The Company has never achieved capacity in this facility. 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 materially adversely affect the Company's business.

The Company may encounter manufacturing failures that could impede or delay commercial production of its products. Any failure in the Company's manufacturing operations could cause the Company to be unable to meet the demand for its products and lose potential revenue and harm its reputation. The Company's manufacturing operations may encounter difficulties involving, among other things, production yields, regulatory compliance, quality control and quality assurance and shortages of qualified personnel.

Impact of demand fluctuations outside our ability to control or influence

In general, the Company's marketing partners are required to provide 12 to 24-month rolling forecasts of their demand on a quarterly basis, and are also required to place firm purchase orders based on the near-term portion of those forecasts. If wholesaler or market demand for these products is lower than forecasted, the Company's marketing partners or their wholesaler customers may accumulate excess inventory. If such conditions persist, the Company's marketing partners may sharply reduce subsequent purchase orders for a sustained period of time until such excess inventory is consumed, if ever. Significant and unplanned reductions in our manufacturing orders have occurred in the past and the Company's results of operations were adversely affected. If such reductions occur again in the future, the Company's revenues will be negatively impacted, economies of scale will be lost, and revenues may be insufficient to fully absorb overhead costs, which could result in net losses. Conversely, if the Company's marketing partners promote significantly increased demand, the Company may not be able to manufacture such unplanned increases in a timely manner, especially following prolonged periods of reduced demand. As the Company has no control over these factors, purchase orders could fluctuate significantly from quarter-to-quarter, and the results of operations could fluctuate accordingly.

Impact of natural disasters or other events that disrupt our business operations

Nuvo's manufacturing facilities are located in Varennes, Québec, where natural disasters or similar events, like blizzards, fires or explosions or large-scale accidents or power outages, could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a disaster, power outage or other event occurred that prevented Nuvo from using all or a significant portion this facility, that damaged critical infrastructure or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for Nuvo to continue our business for a substantial period of time.

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.

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 results of its 2015 Pennsaid 2% Trial. 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 OTC 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 broaden its product portfolio. 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 Pfizer Inc. The second drug product, GSK's 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%. 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, there are four generic versions of Pennsaid approved in the market. The first generic was launched in 2014. In addition, our partner launched an authorized generic to protect market share. The launch of these generic versions of Pennsaid had an adverse impact on the Company's revenue from Canada. A topical diclofenac product, GSK's 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 GSK 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

The HLT Patch faces 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% or the HLT Patch will be successfully commercialized in current markets or that the additional regulatory approvals necessary to commercialize Pennsaid, Pennsaid 2% 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 a material 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.

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.

Security and Cyber Security Breaches

The Company has implemented security protocols and systems with the intent of maintaining the physical and electronic security of its operations and protecting its confidential information and information related to identifiable individuals against unauthorized access. Despite such efforts, Nuvo may be subject to security breaches, which could result in unauthorized access to its facilities or the information that the Company is trying to protect. Unauthorized physical access to one of the Company's facilities or electronic access to its information systems could result in, among other things, unfavorable publicity, litigation by affected parties, damage to sources of competitive advantage, disruptions to its operations, loss of proprietary information, customer information and customers, financial obligations for damages related to the theft or misuse of such information and costs to remediate such security vulnerabilities, any of which could have a substantial impact on the Company's results of operations, financial condition or cash flows.

Accumulated deficit

The Company had an accumulated deficit at December 31, 2016 of $176.5 million. Although the Company is currently profitable, it may not remain profitable. The Company's inability to 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.

Quarterly Fluctuations

The Company's quarterly and annual operating results are likely to fluctuate in the future. These fluctuations could cause the Company's 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 the Company's 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, manufacturing 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 the Company's 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 the Company's 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.

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 nature 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.

Taxes

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.

Prior to the Reorganization, the Company was 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.

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., 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.

The market price of the Company's common shares could fluctuate significantly for many other reasons, including for reasons unrelated to our specific performance, such as reports by industry analysts, investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance, as well as general economic and industry conditions. For example, to the extent that other companies within our industry experience declines in their stock price, the share price of the Company's common shares may decline as well. In addition, when the market price of a company's shares drops significantly, shareholders may institute securities class action lawsuits against the company. A lawsuit against the Company could result in substantial costs and could divert the time and attention of the Company's management and other resources.

Ability to Have Access to Additional Financing and Capital and Dilution

The Company may consider issuing debt or equity securities in the future to fund potential acquisitions or for general corporate purposes. 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. If the Company incurs debt, it may increase its leverage relative to its earnings or to its equity capitalization, requiring the Company to pay interest expenses. The Company may not be able to market such issuances on favourable terms, or at all, in which case, the Company may not be able to execute its business plan.

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 the Rights Plan (defined below) 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 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 – Shareholder Rights Plan". 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 failure 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, there are two analysts that publish 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.

Any 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. Accordingly, 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 Chief Executive Officer 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 11,546,397 common shares and no preferred shares were outstanding as of December 31, 2016.

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 terms of the 2013 Rights Plan require that it be ratified by shareholders at the 2018 Annual General Meeting.

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 of Directors, 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 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 of Directors 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 of Directors 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 of Directors 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.

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, which 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, 2016:

Month	High	Low	Volume
	$	$	(000s)
January 2016	6.45	5.18	376
February 2016	7.10	6.25	592
March 2016	6.71	5.27	407
April 2016	6.18	5.25	406
May 2016	7.00	6.08	430
June 2016	7.10	6.69	510
July 2016	7.30	6.93	168
August 2016	7.87	6.86	462
September 2016	8.12	7.05	426
October 2016	7.20	6.50	336
November 2016	6.41	5.50	582
December 2016	5.70	5.50	237

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[(1)] Ontario, Canada	Chairman of the Board of the Company Executive Chairman & Interim Chief Executive Officer, Crescita	September 21, 2004	235,784
David A. Copeland[(2)(3)(4)] Ontario, Canada	Private Investor and Business Consultant	September 21, 2004	57,692
Anthony E. Dobranowski[(2)(5)] Ontario, Canada	Private Business Consultant	September 21, 2004	47,085
John C. London[(4)] Ontario, Canada	Chief Executive Officer	September 21, 2004	155,786
Dr. Jacques Messier[(6)] Ontario, Canada	Chief Executive Officer, The Toronto Humane Society	September 21, 2004	34,523
Samira Sakhia[(5)(7)] Québec, Canada	President, Knight Therapeutics Inc.	October 29, 2015	13,778
Jesse F. Ledger Ontario, Canada	President	N/A	2,000
Mary-Jane E. Burkett Ontario, Canada	Vice President and Chief Financial Officer	N/A	5,000
Katina K. Loucaides Ontario, Canada	Vice President, Secretary and General Counsel	N/A	17,736

Notes:

(1) 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. NRI filed for protection pursuant to the *Companies' Creditors Arrangement Act* (CCAA) 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. In July 2008 the government cancelled NRI for cause.

(2) Member of the Audit Committee.

(3) 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 CCAA on January 28, 2009.

(4) 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.

(5) Member of the Corporate Governance, Compensation & Nominating Committee.

(6) Chairman of the Corporate Governance, Compensation & Nominating Committee.

(7) Chairman of the Audit Committee.

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: Ms. Samira Sakhia who was the Chief Financial Officer of Paladin Labs Inc. until 2015 and since 2016 is the President of Knight Therapeutics Inc.

As at December 31, 2016, the directors and executive officers of Nuvo, as a group, beneficially owned, directly or indirectly, or exercised control or direction of 1,526,927 or 11.9% of the Company's common shares assuming all potentially dilutive instruments were exercised or converted.

Conflicts of Interest

Certain directors and officers of Nuvo or its subsidiaries are, and may continue to be, directors, officers or shareholders of other companies whose operations may, from time-to-time, be in direct competition with those of Nuvo or with entities which may, from time-to-time, provide financing to, or make equity investments in competitors of the Nuvo. In accordance with the *Business Corporations Act* (Ontario), such directors and officers will be required to disclose all conflicts of interest as such conflicts arise. If a conflict of interest arises at a meeting of the Board of Directors, any director in a conflict will disclose his or her interest and abstain from voting on such matter.

LEGAL PROCEEDINGS AND REGULATORY ACTIONS

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 trials 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 trials 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.

INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Other than as set out below and elsewhere in this AIF, none of the following persons has any material interest, direct or indirect, in any transaction within the three most recently completed financial years or during the current financial year that has materially affected or will materially affect the Company:

(a) a director or executive officer of the Company;

(b) a person or company that is the direct or indirect beneficial owner of, or who exercises control or direction over, more than 10% of any class or series of the Company's outstanding voting securities; and

(c) an associate or affiliate of any of the persons or companies referred to in paragraphs (a) or (b).

TRANSFER AGENT

The transfer agent and registrar for the common shares is CST Trust Company at its office in Toronto, Ontario, Canada.

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: Samira Sakhia, David A. Copeland and Anthony E. Dobranowski. 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.

Samira Sakhia

Ms. Sakhia has been a Nuvo director and member of the Audit Committee and Corporate Governance, Compensation & Nominating Committee since October 2015. She has been the Chair of the Audit Committee since March 2016. Ms. Sakhia is currently the President and Director of Knight Therapeutics Inc. Prior to joining Knight, Ms. Sakhia served as the Chief Financial Officer at Paladin Labs Inc. (acquired by Endo International plc February 2014), a specialty pharmaceutical company from 2001 to 2015. At Paladin, Ms. Sakhia was responsible for the finance, operations, human resources and investor relations functions. During her employment with Paladin, Ms. Sakhia was instrumental in executing in-licensing and acquisition transactions of Canadian and international pharmaceutical products and businesses. In addition, Ms. Sakhia led several M&A and strategic lending transactions as well as equity rounds on the TSX and completed the sale of Paladin to Endo International for over $3 billion. Prior to joining Paladin, Ms. Sakhia held various senior finance positions with Discreet Logic, a digital video effects and editing software tools maker acquired by AutoDesk in 1999. Ms. Sakhia also serves on the board of directors and is Chair of Audit Committees for Antibe Therapeutics Inc. and Crescita Therapeutics Inc. Ms. Sakhia is a Chartered Professional Accountant and a Chartered Accountant and holds a Masters of Business Administration Degree and Bachelors of Commerce Degree from McGill University.

David A Copeland

Mr. Copeland has been Nuvo's Lead Director and member of the Audit Committee since 2004. He was the chair of Nuvo's Audit Committee until February 2016. Mr. Copeland was the former President and Chief Operating Officer of Triam Automotive Inc., an automobile parts supplier. From 1984 to 1992, Mr. Copeland held a number of senior management positions at Magna International Inc. including Chief Financial Officer of Magna and Chief Executive Officer of the Cosma Group of Magna. Mr. Copeland has been an advisor, investor and director in a number of private early stage companies since 1998. His background includes a focus on business valuation and mergers and acquisitions. Mr. Copeland is also a director and a member of the Audit Committee and the Corporate Governance, Compensation & Nominating Committee of Crescita Therapeutics Inc. since March 2016. Mr. Copeland is a Chartered Professional Accountant and a Chartered Accountant and holds a Bachelor of Mathematics.

Anthony E. Dobranowski

Mr. Dobranowski has been a Nuvo director and member of the Audit Committee and the Corporate Governance, Compensation & Nominating Committee since 2004. Mr. Dobranowski retired from Magna International Inc., a global automotive parts supplier in 2007. During his employment with Magna, Mr. Dobranowski was most recently a Vice President of Magna, and prior to that held various executive positions (Vice Chairman, President and CFO) at Tesma International Inc., a publicly traded Magna subsidiary. He was instrumental in the initial public offering of Tesma in 1995, and was involved in all aspects of Tesma's growth, with particular emphasis on financing, investor relations and M&A activity. Previous to that, Mr. Dobranowski held various senior management positions with other Magna companies. Mr. Dobranowski is also the Lead Director, the Chair of the Corporate Governance, Compensation & Nominating Committee and a member of the Audit Committee of Crescita Therapeutics Inc. since March 2016. Mr. Dobranowski is a Chartered Professional Accountant and a Chartered Accountant and holds Bachelor of Science and Masters of Business Administration degrees from the University of Toronto.

Audit Fees

The following table outlines the fees paid to Ernst & Young LLP, the Company's auditors, for the years ended December 31, 2016 and December 31, 2015.

Fees	Year ended December 31, 2016	Year ended December 31, 2015
Audit Fees (1)	190,000	220,000
Audit – Related Fees(2)	140,000	79,000
Tax Fees(3)	22,000	67,000
All Other Fees(4)	206,000	1,023,000
TOTAL	558,000	1,389,000

(1) The years ended December 31, 2016 and December 31, 2015 includes accrued audit fees.
(2) The fees relate to quarterly reviews and fees related to the reorganization.
(3) The fees include assistance for general tax matters. In the comparative period, the fees include assistance preparing tax returns for certain foreign subsidiaries and other general tax matters.
(4) For the year ended December 31, 2016 fees include services provided to the Company for a proposed merger transaction the Company is no longer pursuing and the CPAB fee. In the comparative period, fees include services provided to the Company for the reorganization including the audit of the Combined Financial Statements of Crescita, and the CPAB fee.

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 Separation and Transition Agreement (the Separation Agreement) dated March 1, 2016 between the Company and Crescita providing for, among other things, the transfer of the Company's drug development business to Crescita and certain arrangements governing the separation of the drug development business and the specialty pharmaceutical business. The drug development business was transferred to Crescita on an “as-is”, “where-is” basis. The Separation Agreement provides for a full and complete mutual release and discharge of all liabilities existing or arising from all acts, events and conditions (including liabilities arising under contractual agreements or arrangements between or among such parties other than the Arrangement Agreement, the Separation Agreement and the Transitional Services Agreement (defined below)) occurring or existing before March 1, 2016 between the Company or any of its subsidiaries, on the one hand, and Crescita or any of its subsidiaries, on the other hand, except as expressly be set forth in the Separation Agreement. Under the Separation Agreement, Crescita agreed to indemnify Nuvo and its affiliates from and against any liabilities associated with, among other things, the drug development business, whether relating to the period, or arising, prior to or after the Reorganization. The Separation Agreement contains a reciprocal indemnity under which Nuvo generally agrees to indemnify Crescita and its affiliates from and against any liabilities relating to, among other things, the specialty pharmaceutical business. Nuvo and Crescita also indemnify each other with respect to non-performance of their respective obligations under the Separation Agreement. In addition, each of the parties has agree to cooperate with each other and use reasonable commercial efforts to take or to cause to be taken all actions, and to do, or to cause to be done, all things reasonably necessary under applicable law or contractual obligations to consummate and make effective the transactions contemplated by the Separation Agreement. Other matters governed by the Separation Agreement include responsibility for taxes, access to books and records, confidentiality, insurance and dispute resolution.

- The Transitional Services Agreement (the Transition Services Agreement) dated March 1, 2016 between the Company and Crescita pursuant to which Nuvo and Crescita have agreed to provide each other, on a transitional basis, certain services in order to facilitate the orderly transfer of the drug development business to Crescita and the operation of Nuvo as an independent public company. The transitional services include, among other things, information technology transition, use of facilities, sharing of human resources, accounting services and general consulting services. The transitional services will be provided, at negotiated rates, for a period of up to eighteen months after the Reorganization (unless extended by Nuvo and Crescita).

- The Arrangement Agreement dated December 14, 2015 between Nuvo, 2487002 Ontario Limited and 2487001 Ontario Limited, described under “Nuvo Pharmaceuticals Inc. Structure – Reorganization”.

- The Asset Purchase Agreement dated October 17, 2014 between the Company and Horizon, described under “General Development of the Business – Recent Financings and Corporate Transactions – Pennsaid 2% U.S. Asset Sale”.

- The Rights Plan 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 the Chartered Professional Accountants of Ontario (registered name of

The Institute of Chartered Accountant of 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 May 4, 2016. 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, 2016.

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, 2016, Management Information, Circular Reorganization Circular, and this AIF may be obtained upon request from the Company's Investor Relations Department or on the Company's website: www.nuvopharma.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".
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.
Clinical Trial Application	An application that must be submitted to Health Canada and deemed acceptable prior to the initiation of conducting a clinical trial using a new drug involving human subjects.
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.
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.
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.
Lidocaine	A common local anesthetic drug, when used topically, relieves pain by blocking signals at the nerve endings in skin and underlying tissues.
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.
New Drug Submission	An application submitted to Health Canada containing information on a drug's safety, effectiveness and quality in order to obtain approval to market the drug in Canada.
No Objection Letter	A notification, issued by Health Canada, indicating that an application for a clinical trial application is deemed acceptable.
Notice of Compliance	A notification, issued by Health Canada, indicating that a manufacturer has complied with relevant sections of the Food and Drug Regulations following the satisfactory review of a submission. This notification serves as the marketing authorization for a new drug in Canada.
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.
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.
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.
Therapeutic Products Directorate	The Therapeutic Products Directorate (TPD) is the division within Health Canada that reviews New Drug Submissions.
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 PHARMACEUTICALS INC. (the "Company")

I. PURPOSE

The purpose of the Audit Committee (the "**Committee**") is to assist the Board of Directors of Nuvo Pharmaceuticals 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 meeting 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 and press release;
(vii) provide to the Board a recommendation as to whether the annual financial statements should be approved;

(viii) review insurance coverage including directors' and officers' liability coverage ; and
(ix) 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.