

# Management's Discussion and Analysis (MD&A)

February 17, 2016 / The following information should be read in conjunction with the Nuvo Research<sup>®</sup> Inc. (Nuvo or the Company) Consolidated Financial Statements for the year ended December 31, 2015 which were prepared in accordance with International Financial Reporting Standards (IFRS) and filed on SEDAR on February 17, 2016. Additional information relating to the Company, including its Annual Information Form (AIF), can be found on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a>.

All amounts in the MD&A, Consolidated Financial Statements and related Notes are expressed in Canadian dollars, unless otherwise noted.

On December 14, 2015, Nuvo, 2487002 Ontario Limited and 2487001 Ontario Limited entered into an arrangement agreement (Arrangement Agreement) in respect of a reorganization of Nuvo into two separate publicly traded companies (Reorganization), Nuvo Pharmaceuticals Inc. (Nuvo Pharma) and Crescita Therapeutics Inc. (Crescita) that would each be owned 100% by Nuvo shareholders. References in this MD&A to Nuvo Pharmaceuticals or Nuvo Pharma are to Nuvo Research Inc.'s commercial healthcare business that would be operated by Nuvo Pharmaceuticals Inc. if the Reorganization is completed and references to Crescita Therapeutics or Crescita are to Nuvo Research Inc.'s drug development business as it is proposed to be transferred to Crescita Therapeutics Inc. if the Reorganization is completed. However, completion of the Reorganization remains subject to a number of conditions and Nuvo may decide in its discretion not to proceed with the Reorganization for any reason. Accordingly, there can be no assurance that the Reorganization will be completed as planned or at all. For further details, see Corporate Development – Proposed Reorganization of the Company.

# **Forward-looking Statements**

Certain statements in this MD&A constitute forward-looking information and/or forward-looking statements (collectively, "forward-looking statements") statements within the meaning of applicable securities laws. Forward-looking statements include, but are not limited to, statements made under the headings ["Overview", "Results of Continuing Operations, "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 also include statements regarding the proposed Reorganization of Nuvo into two separate publicly-traded companies. 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 MD&A under the heading "Risks Factors", the Company's AIF 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 proposed Reorganization and the operation of Nuvo Pharma and Crescita as separate publicly-traded companies are described in the Reorganization Circular (as 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 MD&A 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 MD&A are qualified by these cautionary statements. The forward-looking statements contained herein are made as of the date of this MD&A 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.

## **Corporate Development**

## **Proposed Reorganization of the Company**

On December 14, 2015, Nuvo, 2487002 Ontario Limited and 2487001 Ontario Limited entered into the Arrangement Agreement in respect of the proposed Reorganization of Nuvo into two separate publicly-traded companies. Nuvo Pharma would be a revenue and EBITDA generating 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. Crescita would have a diversified pipeline of product candidates and sufficient cash resources to execute its current business plan into 2017. The obligation of Nuvo to complete the Reorganization is subject to receipt of a number of approvals and fulfillment of a number of conditions, including the approval of the Ontario Superior Court of Justice, the final approval of the Toronto Stock Exchange and the approval of Nuvo's shareholders. If the Reorganization is approved by shareholders and all other conditions are satisfied, Nuvo expects the Reorganization to be completed in the first quarter of 2016. However, there can be no assurances regarding the ultimate timing of the Reorganization or that the Reorganization will be completed at all. Even if the Reorganization is approved by shareholders and all other conditions are satisfied, Nuvo's Board of Directors will have the authority to determine when to effect the Reorganization, as well as the authority to decide not to proceed with the Reorganization at all.

If the proposed Reorganization proceeds, there will be a significant and material effect on the operations and results of Nuvo. Detailed information regarding the proposed Reorganization and its effects including a description of certain risks and uncertainties in respect of the Reorganization and the operation of Nuvo Pharma and Crescita as separate publicly traded companies are included in the Reorganization Circular dated December 31, 2015 (Reorganization Circular) that is available under Nuvo's profile at <a href="https://www.sedar.com">www.sedar.com</a>.

## **Overview**

## **Background**

Nuvo is a publicly traded, Canadian life sciences company with revenues and a diverse portfolio of topical products and technologies. The Company operates two distinct business units: Nuvo Pharma and Crescita. Nuvo Pharma is a commercial healthcare business with three commercial products. Crescita is a drug development business that operates two sub-groups: the Topical Products and Technology (TPT) Group and the Immunology Group. The TPT Group has one commercial product, a pipeline of topical and transdermal products focusing on pain and dermatology and multiple drug delivery platforms that support the development of patented formulations that can deliver actives into or through the skin. The Immunology Group has two commercial products.

Subsequent to the year ended December 31, 2015 Nuvo's Board of Directors unanimously approved a proposal to initiate a divestiture or orderly wind down of the Company's Immunology Group. While the Company continues to explore a possible sale of the Immunology Group, if a divestiture transaction does not materialize, the wind down of the Immunology operations is expected to be completed by the end of 2016.

As of December 31, 2015, the Company and its subsidiaries employed a total of 74 full-time employees at its head office in Mississauga, Ontario, its manufacturing and research facility in Varennes, Québec, its manufacturing facility in Wanzleben, Germany and its research and development (R&D) facility in Leipzig, Germany.

#### **Nuvo Pharma**

Nuvo Pharma is a commercial healthcare business with a portfolio of products and pharmaceutical manufacturing capabilities. Nuvo Pharma has three commercial products that are available in a number of countries: Pennsaid 2%, Pennsaid and the HLT Patch.

#### Pennsaid 2%

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

The following table summarizes where the Company's partners have commercialized Pennsaid 2% or are working to obtain regulatory approval:

Brand	Therapeutic Area	Licensee or Distributor	Licensed Territories	Intellectual Property
Pennsaid 2%	Osteoarthritis of the knee	Horizon Pharma plc	United States	Twelve granted U.S. patents listed in the FDA's Orange Book with latest expiry in 2030.
		Paladin Labs Inc. 1	Canada <sup>1</sup>	One patent granted in Canada expiring in 2027.
		NovaMedica LLC	Russia <sup>1</sup> ; some Community of Independent States <sup>1</sup>	One patent granted in Russia expiring in 2027.

Partner is working to obtain regulatory approval in licensed territory.

The following table summarizes additional development the Company is undertaking to expand the therapeutic area of Pennsaid 2%:

Product	Therapeutic Area	Stage of Development	Intellectual Property <sup>1</sup>
Pennsaid 2%	Acute strains & sprains	Phase 3 clinical trials	Patents granted in AU, CA, CH, DE, DK, FR, GB, GR, IE, IL, IT, NL, HK, JP, MX, NZ, RU, ZA, expiring in 2027. Applications pending in 5 countries.
			Patent applications pending in AU, BR, CA, CL, CN, EP, IL, JP, MX and RU through 2033.

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

Pennsaid 2% was approved on January 16, 2014 in the U.S. for the treatment of the pain of osteoarthritis (OA) of the knee and is not currently approved for sale or marketing in any other jurisdiction. 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 Inc. (Mallinckrodt). In September 2014, the Company reached a settlement related to its litigation with Mallinckrodt (See Litigation - Mallinckrodt). Under the terms of the settlement agreement, Mallinckrodt returned the U.S. sales and marketing rights to Pennsaid 2% to Nuvo. In October 2014, the Company sold the U.S. rights to Pennsaid 2% to Horizon Pharma plc (Horizon) for US\$45.0 million. The Company earns revenue from product sales of Pennsaid 2% to Horizon (See Significant Transactions – 2014 – Pennsaid 2% U.S. Asset Sale). In January 2015, Horizon launched its commercial sale and marketing of Pennsaid 2% in the U.S.

Paladin Labs Inc. (Paladin) has the exclusive rights to market and sell Pennsaid 2% in Canada. In November 2014, the Company reacquired the Pennsaid 2% marketing rights from Paladin for South

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

Additional clinical and non-clinical trials may be required to support applications for the regulatory approval of Pennsaid 2% in other countries in which the Company, or other licensees and distributors, could potentially market the product. The Company was advised by regulatory authorities in Canada and the United Kingdom that the data from the 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 a Phase 3 clinical trial of Pennsaid 2% for the treatment of acute pain to support regulatory approval applications for Pennsaid 2% in certain international jurisdictions. The Company anticipates that results could be available in Q1 2016. In addition, NovaMedica LLC (NovaMedica) advised the Company that their Pennsaid 2% clinical trial was successful and that they had submitted their application to obtain regulatory approval in Russia. There can be no assurance that the current trials 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.

#### Pennsaid

Pennsaid, the Company's first commercial topical pain product, is used to treat the signs and symptoms of OA of the knee. Pennsaid combines the transdermal carrier (containing dimethyl sulfoxide, popularly known as DMSO), with diclofenac sodium, a leading NSAID and delivers the active drug through the skin at the site of pain. Pennsaid no longer has patent protection in the territories where it is currently marketed by our partners.

## Pennsaid Commercial Partners:

The following table summarizes where the Company's partners have commercialized Pennsaid or are working to obtain regulatory approval:

Brand	Therapeutic Area	Licensee or Distributor	Licensed Territories <sup>1</sup>
Pennsaid	Osteoarthritis of the knee	Paladin Labs Inc.	Canada
	G. 4.10 14.100	Vianex S.A.	Greece
		Italchimici S.p.A.	Italy
		Movianto UK Limited	U.K.
		NovaMedica LLC	Russia <sup>2</sup> ; some Community of Independent States <sup>2</sup>

- The Company's patents associated with Pennsaid have expired.
- <sup>2</sup> Partner is working to obtain regulatory approval in licensed territory.

#### **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 Litigation – Mallinckrodt). In October 2014, the Company sold the U.S. rights to Pennsaid 2% to Horizon (Pennsaid U.S Sale Agreement) (See Significant Transactions – 2014 – 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

In February 2014, Taro Pharmaceutical Industries, Ltd. received approval in Canada for a generic version of Pennsaid which was launched in March 2014. To compete with this generic version of Pennsaid, the Company's licensee in Canada launched an authorized generic version of Pennsaid in late 2014. The Company receives royalty revenue based on net sales and product sales from selling this product. Despite these efforts, the Company's royalty revenue from Canadian net sales of Pennsaid and product sales has been negatively impacted. Other generic versions of Pennsaid have been approved in Canada and one launched in Canada in late 2015.

#### Heated Lidocaine/Tetracaine Patch

The HLT Patch is a topical patch that combines lidocaine, tetracaine and heat, using proprietary Controlled Heat-Assisted Drug Delivery (CHADD™) technology. The CHADD unit generates gentle heating of the skin and in a well-controlled clinical trial 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 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.

#### HLT Patch Commercial Partners:

The following table summarizes where the Company's partners have commercialized the HLT Patch or are working to obtain regulatory approval:

Brand	Therapeutic Area	Licensee or Distributor	Licensed Territories	Intellectual Property
Synera <sup>2</sup>	Local Dermal Analgesia (Patch)	Galen US Incorporated	United States	One granted U.S. patent listed in the FDA's Orange Book expiring in 2020. Method of manufacturing patents that expire 2019 (U.S.).
Rapydan <sup>2</sup>		Eurocept B.V.	Europe, Russia <sup>1</sup> , Turkey <sup>1</sup> , Israel <sup>1</sup> and People's Republic of China <sup>1</sup>	Two granted European patent validated in 10 countries with latest expiry in 2016. Two patents granted worldwide <sup>2</sup> with latest expiry in 2016
Heated Lidocaine/ Tetracaine Patch		Paladin Labs Inc.	Canada <sup>1</sup>	Method of manufacturing patents that expire 2020 (Europe).

Partner is responsible for obtaining regulatory approval in licensed territory.

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

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

#### Crescita

Crescita is a drug development business that operates two sub-groups: the TPT Group and the Immunology Group.

#### **Topical Products and Technology Group**

The TPT Group has one commercial product, Pliaglis and products in development focusing on pain and dermatology, and multiple drug delivery platforms that support the development of patented formulations that can deliver actives into or through the skin.

## **Pliaglis**

Pliaglis is a topical local anaesthetic cream that provides safe and effective local dermal analgesia on intact skin prior to superficial dermatological procedures, such as dermal filler injection, pulsed dye laser

<sup>&</sup>lt;sup>2</sup> Rapydan is the brand name for the heated lidocaine/tetracaine patch (HLT Patch) in the respective jurisdiction.

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

Except as described below, Galderma Pharma S.A. (Galderma), a global pharmaceutical company specialized in dermatology, holds the worldwide sales and marketing rights for Pliaglis. Galderma is responsible for manufacturing Pliaglis. In December 2015, Nuvo reacquired the development and marketing rights for Pliaglis for the U.S., Canada and Mexico. Under the terms of the agreement, Nuvo paid Galderma 125,000 Swiss Francs (approximately \$174,000) and will pay an additional 125,000 Swiss Francs (approximately \$174,000) upon transfer of certain rights and documents. Beginning in 2021, Nuvo 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 a transition period. Nuvo will receive a fixed single-digit royalty on net sales in the territories outside of North America where Galderma still owns the development and marketing rights.

Pliaglis was launched in the U.S. market in March 2013 and in the E.U. in April 2013. In the E.U., the regulatory approval required a post-approval commitment trial, the cost of which will be shared equally by Galderma and Nuvo. In South America, Pliaglis is approved and marketed in Brazil, Argentina and Columbia. Pliaglis was launched in Brazil in March 2014. Pliaglis is also approved and marketed in Canada. Nuvo understands that Galderma is seeking approvals in additional countries. However, there can be no assurance that any such approvals will be obtained or the timing thereof.

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

## **Crescita Pipeline**

Crescita has a broad portfolio of development stage products and proprietary platform technologies, which include multiplexed molecular penetration enhancers (MMPE $^{\text{TM}}$ ) and DuraPeel $^{\text{TM}}$ . Crescita will not only develop products on its own, but will also actively seek co-development partners to help advance its pipeline products and fund some or all of their development.

# <u>Topical Products and Technology Product Candidate Development Pipeline:</u> The following table summarizes the Company's key product candidates:

Product	Therapeutic Area	Stage of Development	Intellectual Property <sup>1</sup>
Flexicaine (lidocaine 7%/ tetracaine 7% cream)	Postherpetic Neuralgia	Phase 2 clinical trial	Patents granted in AU, CN,HK, MX, RU and the U.S. with latest expiring in 2031. Applications allowed in CA and pending in 8 countries including EP. Latest anticipated expiry date is 2031.
Ibuprofen Foam (5% ibuprofen)	Acute Pain	Preclinical	Patent granted in the U.S. expiring in 2031.  Applications pending in EP and CA. Anticipated expiry date is 2031.
Terbinafine 10% solution	Onychomycosis	Preclinical	Patents granted in AU, JP and the U.S. with latest expiry date in 2031. Applications pending in 4 countries including EP. Latest anticipated expiry date is 2030.
Mical 1 <sup>2</sup>	Psoriasis	Preclinical	Patent granted in the U.S. expiring in 2027.
Mical 2 <sup>2</sup>	Dermatological skin treatment	Preclinical	Patent granted in the U.S. expiring in 2027.

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

Mical is a product being developed under the Ferndale Laboratories, Inc. collaboration (see Significant Transactions – 2014 - Ferndale Collaboration).

## **Technology**

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

## <u>DuraPeel</u>

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

#### **MMPE**

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

## **Immunology Group**

The Immunology Group has two commercial products: WF10 and Oxoferin™. WF10 is approved in Thailand under the brand name Immunokine as an adjunct in the treatment of cancer to relieve post radiation therapy syndromes and as an adjunct therapy for diabetic foot ulcers, but is not otherwise approved for sale and marketing in any other jurisdictions. Oxoferin, a topical wound healing agent, contains the active ingredient in WF10, but at a lower concentration. Oxoferin is marketed by Nuvo and its partners in parts of the E.U. and Asia as a topical wound healing agent under the trade names Oxoferin and Oxovasin™.

The Immunology Group, based in Leipzig, Germany, was focused on developing drug products that modulate chronic inflammation processes resulting in a therapeutic benefit. In December 2015, the Company announced topline results of a Phase 2 clinical trial to assess WF10<sup>™</sup> for the treatment of allergic rhinitis. The topline 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. Nuvo believes that the results are not sufficient to justify the further development of WF10 for the treatment of allergic rhinitis and has discontinued all WF10 development.

Subsequent to the year ended December 31, 2015 Nuvo's Board of Directors unanimously approved a proposal to initiate a divestiture or orderly wind down of the Company's Immunology Group. While the Company continues to explore a possible sale of the Immunology Group, if a divestiture transaction does not materialize, the wind down of the Immunology operations is expected to be completed by the end of 2016.

## WF10

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

WF10 Clinical Trials for the Treatment of Allergic Rhinitis

## Single-Centre Phase 2a Trial

In 2010, Nuvo conducted a Phase 2 proof-of-concept clinical trial to evaluate WF10 as a treatment for persistent allergic rhinitis (the 2010 WF10 Trial). The trial was a 60-subject, randomized, double-blind,

placebo-controlled, single-centre trial to assess the efficacy and safety of a regimen of five daily WF10 infusions. The trial met its primary endpoint as measured by the change in Total Nasal Symptom Scores (TNSS) from baseline to assessment after three weeks comparing the WF10 group with the placebo group. The trial also met its secondary endpoints as measured by the change in TNSS at six, nine and twelve weeks and in the Total Ocular Symptom Score (TOSS) from baseline to assessment after three, six, nine and twelve weeks. The TNSS and TOSS are validated scales to measure nasal and ocular symptoms associated with allergic rhinitis. The results were statistically significant as the p-value for all primary and secondary endpoints was less than 0.001 except for the change in TOSS after three weeks for which the p-value was less than 0.003. WF10 was very well tolerated with a favourable safety profile.

## Multi-Centre Phase 2b Trial (the 2014 WF10 Trial)

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

Each of the Active Arms was compared to a placebo arm in which patients received saline. The primary endpoint was change in TNSS from baseline to assessment after three weeks comparing the Active Arms with the placebo arm. The primary endpoint was not achieved as the Active Arms and the placebo arm all demonstrated a reduction in TNSS and the difference between the Active Arms and the placebo arm did not achieve statistical significance at measured time points over the course of the observation period.

## E.E. Chamber and Field Phase 2a Trial (the 2015 WF10 Trial)

After reviewing the data from both the 2010 WF10 Trial and 2014 WF10 Trial and consulting external experts, Nuvo believed that the placebo group in the 2014 WF10 Trial may not have recorded as high TNSS and TOSS scores compared to the 2010 WF10 Trial 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. Nuvo therefore made the decision to conduct a new Phase 2 clinical trial to assess WF10 for the treatment of allergic rhinitis. The 2015 WF10 Trial was a randomized, double-blind, placebo-controlled, single-centre trial to assess the efficacy, safety and tolerability of a regimen of five WF10 infusions. The trial enrolled patients who have a moderate to severe allergy to grass and ragweed pollen. Patients' symptoms were recorded prior to commencement of the grass allergy season in an ECC, in the field throughout the grass and ragweed allergy seasons and again in the EEC after completion of the ragweed season. In December 2015, Nuvo announced that the topline results of the 2015 WF10 Trial 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 EEC or when they were exposed to naturally occurring allergens during the field portion of the trial. Nuvo believes that the results are not sufficient to justify the further development of WF10 for the treatment of allergic rhinitis and has discontinued all WF10 development.

#### Intellectual Property

## WF10

The Company owns the following patents and patent applications covering WF10 and related formulations for the treatment of asthma, allergic rhinitis and atopic dermatitis.

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

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

In December 2014, the USPTO granted U.S. Patent No. 8,911,797, related to the use of formulations that include chlorite ions (such as WF10) to treat or inhibit allergy-like symptoms that include conjunctivitis in patients suffering from or at risk of developing allergic asthma, allergic rhinitis or atopic dermatitis.

The three U.S. patents will expire in 2028.

## **Manufacturing and Facilities**

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

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

# Litigation

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

#### 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 pharmacokinetic 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.

## **Capability to Deliver Results**

The Company will need to spend considerable resources to research, develop and manufacture its products and technologies. The Company may finance these activities through: existing cash, revenue generated by product sales to our licensees and partners, royalties and other milestones under existing agreements, licensing and co-development agreements for other new drug candidates or for its existing products in territories where they are not currently licensed or by raising funds in the capital markets or by acquiring debt.

The Company is or will be dependent on its commercial partners for the sale and marketing of its products and for obtaining regulatory approvals in the following territories, if necessary:

- Pennsaid Canada, Greece, Italy and Russia and the Community of Independent States (CIS);
- Pennsaid 2% U.S., Canada and Russia and the CIS;
- HLT Patch U.S., Europe, Russia and many of its former republics, Turkey, Israel and the People's Republic of China;
- Pliaglis throughout the world, except for U.S., Canada and Mexico (See Overview Crescita – Pliaglis); and
- Oxoferin several Asian countries.

The Company has broad in-house talent with the capability to develop its pipeline. To execute the current business plan, the Company may selectively add key personnel and in the future may need to hire more staff as activities expand. In addition, the Company has access to the commercial, regulatory and scientific expertise of its advisory boards to assist it through all aspects of the commercialization and drug development process.

# Liquidity

The Company has incurred substantial losses since its inception, as it has invested significantly in drug development activities. At December 31, 2015, the Company had an accumulated deficit of \$200.1 million, including a net loss of approximately \$7.1 million for the year ended December 31, 2015. At December 31, 2015, the Company had cash of \$48.7 million.

The Company expects that it will continue to incur losses as its revenue streams are not yet sufficient to fund: its operations, the infrastructure necessary to support a public company and the costs of selectively advancing its drug development pipeline. The Company's ability to continue as a going concern depends on:

- the commercial success of Pennsaid 2% in the U.S., as the Company earns revenue from product sales of Pennsaid 2% to Horizon;
- the commercial success of Pennsaid outside of the U.S., as the Company earns revenue from sales of Pennsaid to its licensees and distributors in all territories where Pennsaid is sold, as well as royalties on net sales in Canada;
- the success of the Company's clinical trials for Pennsaid 2% for the treatment of acute sprains and strains; and
- its ability to secure additional licensing fees, secure co-development agreements, obtain additional capital when required, gain regulatory approval for other drugs and ultimately achieve profitable operations.

As there can be no certainty as to the outcome of the above matters, there is material uncertainty that may cast significant doubt about the Company's ability to continue as a going concern.

The Company anticipates that its current cash together with the revenues it expects to generate from product sales to its licensees and distributors and royalty payments will be sufficient to execute its current business plan into 2017. Beyond that date, there can be no assurance that the Company will have sufficient capital to fund its ongoing operations or develop or commercialize any further products without future financings.

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

There can be no assurance that additional financing would be available on acceptable terms, or at all, when and if required. If adequate funds were not available when required, the Company may have to substantially reduce or eliminate planned expenditures, terminate or delay clinical trials for its product candidates, curtail product development programs designed to expand the product pipeline or discontinue certain operations. If the Company is unable to obtain additional financing when and if required, the Company may be unable to continue operations.

The Consolidated Financial Statements do not include adjustments to the amounts and classification of assets and liabilities that would be necessary should the Company be unable to continue as a going concern.

As part of the Nuvo Strategic Transaction (See Corporate Development – Proposed Reorganization of the Company), the Company plans to transfer \$35.0 million to Crescita as part of the reorganization. Completion of the reorganization is subject to a number of conditions including shareholder and court approval. If the proposed transaction is approved by shareholders and all other conditions are satisfied, Nuvo expects the transaction to be completed in Q1 2016.

## **Selected Financial Information**

in thousands (except per share)

	Year ended December 31, 2015	Year ended December 31, 2014
Operations		2000111201 01, 2011
Product sales	\$ 19,208	\$ 6,470
Royalties	1,390	5,458
Research and other contract revenue	754	505
Licensing fees	-	624
Total Revenue	21,352	13,057
Total operating expenses	29,425	27,080
Loss from operations	(8,073)	(14,023)
Other income	(960)	(52,632)
Income (loss) before income taxes	(7,113)	38,609
Income tax expense	7	19
Net income (loss)	(7,120)	38,590
Other comprehensive income (loss)	(65)	38
Total comprehensive income (loss)	(7,185)	38,628
Share Information		
Net income (loss) per share		
Basic	\$ (0.65)	\$ 3.85
Diluted	\$ (0.65)	\$ 3.71
Average number of common shares outstanding for the year		
Basic	10,942	10,031
Diluted	10,942	10,400
Financial Position		
Cash	\$ 48,680	\$ 48,275
Short-term investments	-	10,000
Total assets	59,132	65,140
Finance lease & other obligations, including current portion	235	328
Total liabilities	9,413	9,477
Total equity	49,719	55,663

## **Non-IFRS Financial Measure**

The Company discloses non-IFRS measures that do not have standardized meanings prescribed by IFRS, but are considered useful by management, investors and other financial stakeholders to assess the Company's performance and management from a financial and operational standpoint. Total operating expenses is defined as the sum of: cost of goods sold (COGS), R&D expenses, general and administrative (G&A) expenses, interest expense and interest income. Loss from operations is defined as total revenue, less total operating expenses, and the Company considers it a useful measure, as it provides investors with an indication of the operating performance by the Company before considering gains or losses from foreign exchange or items that are non-recurring transactions.

## **Fluctuations in Operating Results**

The Company's results of operations have fluctuated significantly from period-to-period in the past and are likely to do so in the future. The Company anticipates that its quarterly and annual results of operations will be impacted for the foreseeable future by several factors including: the level of Pennsaid and Pennsaid 2% product sales to the Company's licensees and distributors, the timing and amount of

royalties and other payments received pursuant to current and future collaborations and licensing arrangements and the progress and timing of expenditures related to R&D efforts. Due to these fluctuations, the Company believes that the period-to-period comparisons of its operating results are not necessarily a good indicator of future performance.

# **Significant Transactions**

## 2015

## Pliaglis North American Rights Reacquisition

In December 2015, the Company reacquired the development and marketing rights for Pliaglis for the U.S., Canada and Mexico. Under the terms of the agreement, Nuvo paid Galderma approximately \$174,000 (CHF125,000). The Company will pay an additional amount of CHF125,000 (approximately \$174,000) upon the transfer of certain rights and documents. Beginning in 2021, the Company has the right to reacquire the 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 the agreed upon transition period. The Company will receive a fixed single-digit royalty on net sales in the Galderma territories outside of North America where Galderma still owns the development and marketing rights.

#### 2014

#### Pennsaid 2% U.S. Asset Sale

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

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

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

In connection with the Pennsaid 2% U.S. Sale Agreement, the Company also entered into a long-term supply agreement with Horizon. Pursuant to the supply agreement, the Company agreed to supply Pennsaid 2% to Horizon from its Varennes, Québec manufacturing facility for commercialization in the U.S. The initial term of the supply agreement expires December 31, 2022 and, unless terminated, will automatically renew for successive two-year terms, thereafter. 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.

## **Litigation Settlement**

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

#### Ferndale Collaboration

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

#### Private Placement

On March 31, 2014, the Company completed a non-brokered private placement (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 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, 2015, 239,672 of the Private Placement Warrants were exercised [December 31, 2014 – 433,149].

In connection with the Private Placement, the Company issued 78,233 broker warrants at a price of \$2.54 per Unit (Broker Warrants). Each Broker Warrant unit entitled the holder to purchase one common share of the Company at a price of \$2.54 and included one half of one Private Placement Warrant. During the year ended December 31, 2015, 42,733 of the Broker Warrants were exercised [December 31, 2014 – 31,300] and 21,367 Private Placement Warrants were issued upon exercise of the Broker Warrants [December 31, 2014 – 15,650].

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 Toronto Stock Exchange (TSX) at any time during the warrant term. If the acceleration feature was used, any Private Placement Warrants that was not exercised during this period expired. The Company exercised its acceleration feature on November 30, 2015 and accelerated the expiry date of the outstanding warrants to January 15, 2016. Subsequent to the year ended December 31, 2015, 4,200 Broker Warrants and 49,044 Private Placement Warrants (inclusive of 2,100 Private Placement warrants that were issued on exercise of the Broker Warrants) were exercised for proceeds of \$0.2 million and 12,252 Private Placement Warrants expired.

## **Results of Operations**

#### **Product Sales**

in thousands

	Year ended December 31, 2015	Year ended December 31, 2014
	\$	\$
Pennsaid 2%	15,256	2,664
Pennsaid	3,147	3,091
Oxoferin and WF10	629	638
HLT bulk	176	77
Total product sales	19,208	6,470

Product sales which represent the Company's sales to our licensees and distributors increased significantly to \$19.2 million for the year ended December 31, 2015 compared to \$6.5 million for the year ended December 31, 2014.

#### Pennsaid 2%

Product sales of Pennsaid 2% were \$15.3 million for the year ended December 31, 2015 compared to \$2.7 million for the year ended December 31, 2014 and represent the Company's sales of the Pennsaid 2% commercial format and its physician sample format to its licensee in the U.S. market. The significant increase in the year ended December 31, 2015 related to Horizon's efforts to sell Pennsaid 2% in the U.S. market. Product sales for the year consisted of \$10.1 million of the commercial format and \$5.2 million of the physician sample format. In the comparative year, product sales consisted of \$2.3 million of the commercial format with the balance of the sales coming from the sample format. Under the terms of Pennsaid 2% U.S. Sale Agreement, the Company earns revenue from product sales of Pennsaid 2% to Horizon (See Significant Transactions – 2014 – Pennsaid 2% U.S. Asset Sale). All Pennsaid 2% product sales relate to the U.S. market as the product has not received regulatory approval in any other territory.

During the current year, the Company benefitted from a weaker Canadian dollar versus the US dollar, the currency in which it sells Pennsaid 2%. The \$12.6 million increase in Pennsaid 2% sales in the current year included a \$2.1 million foreign exchange gain.

According to IMS Health, approximately 320,000 Pennsaid 2% prescriptions were dispensed in the year ended December 31, 2015 compared to 59,000 prescriptions in the year ended December 31, 2014.

## Pennsaid

Product sales of Pennsaid were consistent at \$3.1 million for the years ended December 31, 2015 and December 31, 2014. An increase in product sales to the Company's partners in Europe was offset by the termination of sales of Pennsaid in the U.S. market and increased generic competition in Canada that negatively impacted sales of Pennsaid.

## **Geographic Pennsaid Product Sales**

in thousands

	Year ended December 31, 2015	Year ended December 31, 2014
	\$	\$
Europe	2,699	1,929
Canada	448	793
United States	-	369
Total Pennsaid Product Sales	3,147	3,091

Geographically for the year ended December 31, 2015, sales in the E.U. were 86% of Pennsaid product sales [December 31, 2014 - 62%] and sales in Canada were 14% of Pennsaid product sales [December

31, 2014 - 26%] and sales in the U.S. were nil% of total Pennsaid product sales [December 31, 2014 - 12%].

#### Oxoferin and WF10

Product sales of Oxoferin and WF10 were consistent at \$0.6 million for the years ended December 31, 2015 and December 31, 2014. In the current year, an increase in the Company's sales to partners in Morocco and Malaysia was offset by a decrease in the Company's sales to its partner in Pakistan.

## HLT Bulk

HLT Bulk sales were \$0.2 million for the year ended December 31, 2015 compared to sales of \$0.1 million for the year ended December 31, 2014. Sales related to the bulk drug substance that is used in the manufacturing of the HLT Patch for both the U.S. and E.U. markets. The bulk drug substance is shipped to a contract manufacturing organization in the U.S. that manufactures the HLT Patch.

#### Other Revenue

in thousands

	Year ended December 31, 2015	Year ended December 31, 2014
	\$	\$
Royalties	1,390	5,458
Research and other contract revenue	754	505
Licensing fees	<u>-</u>	624
	2,144	6,587

## Royalties

The Company receives royalty revenue from: Paladin, its Canadian licensee for Pennsaid and the authorized generic of Pennsaid, Galderma, its licensee for Pliaglis (See Significant Transactions – 2015 – Pliaglis North American Rights Reacquisition), Eurocept, its European licensee for Rapydan and Galen US Incorporated (Galen), its U.S. licensee for Synera. In addition, under the terms of a settlement agreement related to a patent infringement complaint filed by the Company and Mallinckrodt, its former U.S. licensee for Pennsaid and Pennsaid 2%, the Company started earning royalties in the fourth quarter of 2014 from a generic company calculated at 50% of gross profits from their sales of a generic version of Pennsaid in the U.S. Under the terms of the settlement agreement, the royalty declined to 10% when a third generic version of Pennsaid was launched in the second quarter of 2015. The settlement agreement was assigned to the Company under the terms of the litigation settlement with Mallinckrodt. During the second quarter of 2015, the Company was advised that the generic company had stopped production due to a manufacturing issue and has yet to restart production. Royalties from each licensee are determined using agreed upon formulas based on either a definition of the licensee's net sales or gross profits as defined in each agreement. The Company recognizes royalty revenue based on either the net sales or gross profits of each licensee.

In the comparative year, the Company also received royalties from Mallinckrodt, its former U.S. licensee for Pennsaid and Pennsaid 2%. 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 Litigation - Mallinckrodt). In October 2014, the Company sold the U.S. rights to Pennsaid 2% to Horizon (See Significant Transactions – 2014 – Pennsaid 2% U.S. Asset Sale). Under the terms of the Pennsaid U.S Sale Agreement, the Company no longer receives a royalty on Pennsaid 2% net sales in the U.S. as Horizon assumed sales and marketing responsibility on January 1, 2015.

Royalty revenue decreased to \$1.4 million for the year ended December 31, 2015 compared to \$5.5 million for the year ended December 31, 2014.

#### Pennsaid Royalties

Pennsaid royalties were \$0.7 million for the year ended December 31, 2015 compared to \$2.0 million for the year ended December 31, 2014. The significant decrease in royalty revenue for the year related to the termination of Pennsaid sales in the U.S., as well as lower net sales of Pennsaid in Canada due to the negative impact of generic versions of Pennsaid in the market. Partially offsetting this decrease, the

Company received royalty revenue of \$0.3 million from the generic sales of Pennsaid in the U.S. market for the first half of 2015. In the second half of the year, the Company did not earn royalty revenue as the company selling the generic version of Pennsaid in the U.S. ceased distribution due to a manufacturing issue.

## Pennsaid 2% Royalties

Royalty revenue related to sales of Pennsaid 2% in the U.S. was \$nil for the year ended December 31, 2015 compared to \$3.0 million for the year ended December 31, 2014. Under the terms of the Pennsaid U.S. Sale Agreement, the Company no longer receives a royalty on Pennsaid 2% net sales in the U.S. as Horizon assumed sales and marketing responsibility on January 1, 2015. In the comparative period, the Company earned royalties on U.S. sales of Pennsaid 2% from the Company's former U.S. partner, Mallinckrodt.

#### **HLT Patch Royalties**

Royalties related to the global net sales of the HLT Patch were \$0.4 million for the year ended December 31, 2015 compared to \$0.2 million year ended December 31, 2014. The Company's U.S. and European Partners recognized an increase in net sales.

## Pliaglis Royalties

Royalties related to the global net sales of Pliaglis were consistent at \$0.2 million for both years ended December 31, 2015 and December 31, 2014.

## **Research and Other Contract Revenue**

Research and other contract revenue for the year ended December 31, 2015 was \$0.8 million compared to \$0.5 million for the year ended December 31, 2014. These revenues were mainly derived from development services provided by the Company to its partners.

## Licensing Fee Revenue

The Company did not earn license fee revenues during the year ended December 31, 2015 compared to \$0.6 million for the year ended December 31, 2014. In 2014, the Company earned an upfront, non-refundable milestone of US\$0.5 million (\$0.6 million) related to the launch of the second generic version of Pennsaid in the U.S. market. In a patent infringement complaint against this generic company, the Company, along with Mallinckrodt, entered into a settlement agreement; whereby, this generic company would agree to pay an upfront, non-refundable milestone of US\$0.5 million upon the launch of its generic version of Pennsaid. License fees also included the recognition of a portion of the upfront fees received from Paladin in 2005 for the Canadian marketing rights for Pennsaid.

## **Significant Customers**

As the Company sells product and receives royalties in a limited number of markets through exclusive agreements, it receives most of its revenue from a limited number of customers. Revenue, derived from the Company's current four largest customers (excluding upfront payments and milestones from licensing arrangements), is illustrated in the following table:

	Year ended	Year ended
in thousands, except percentages	December 31, 2015	December 31, 2014
Four largest customers	\$18,538	\$10,558
% of total revenue	87%	81%
Largest customer as % of total revenue	71%	51%

## **Operating Expenses**

in thousands

	Year ended December 31, 2015	Year ended December 31, 2014
	\$	\$
Cost of goods sold	10,276	5,537
Research and development	10,329	8,051
General and administrative	9,295	12,978
Interest expense, net	(475)	514
Total operating expenses	29,425	27,080

Total operating expenses for the year ended December 31, 2015 were \$29.4 million, an increase from \$27.1 million for the year ended December 31, 2014. The increase for the current year was primarily due to the increase in COGS due to increased product sales and an increase in R&D expenses related to the 2015 WF10 Trial and the Pennsaid 2% phase 3 clinical trial which were slightly offset by the revaluation of cash-settled stock-based compensation (SBC) costs which are primarily included in G&A costs for both years.

#### **Cost of Goods Sold**

COGS for the year ended December 31, 2015 was \$10.3 million compared to \$5.5 million for the year ended December 31, 2014. The increase in COGS in the current year was associated with increased Pennsaid 2% product sales. The increase in product sales improved the gross margin on product sales to \$8.9 million or 47% for the year ended December 31, 2015 compared to a gross margin of \$0.9 million or 14% for the year ended December 31, 2014.

For Nuvo Pharma, gross margin on product sales was \$8.8 million or 47% for the year ended December 31, 2015 compared to a gross margin of \$0.6 million or 10% for the year ended December 31, 2014. During the current year, the Company benefitted from a weaker Canadian dollar versus the U.S. dollar, the currency in which it sources certain Pennsaid and Pennsaid 2% raw materials and sells Pennsaid 2%. In the current year, a 10% appreciation in the Canadian dollar versus the U.S. dollar would have reduced gross margin by approximately \$0.5 million and a 10% depreciation in the Canadian dollar versus the U.S. dollar would have increased gross margin by approximately \$0.5 million.

For Crescita, gross margin on product sales was \$0.1 million or 20% for the year ended December 31, 2015 compared to a gross margin of \$0.4 million or 56% for the year ended December 31, 2014. The decrease in gross margin primarily related to a \$0.1 million inventory write-down.

#### **Research and Development**

R&D expenses were \$10.3 million for the year ended December 31, 2015 compared to \$8.1 million for the year ended December 31, 2014.

For Nuvo Pharma, R&D expenses were \$1.2 million for the year ended December 31, 2015 compared to \$0.6 million for the year ended December 31, 2014 and related entirely to the Pennsaid franchise. The increase spending in the current year related to costs associated with the Pennsaid 2% Phase 3 trial for the treatment of acute pain to support regulatory approval applications for Pennsaid 2% in international jurisdictions. The trial is being conducted in Germany to assess the efficacy of Pennsaid 2% for the relief of pain associated with acute, localized muscle or joint injuries such as sprains, strains or sports injuries. The trial commenced in July 2015 and the Company expects topline results will be available in Q1 2016.

For Crescita, R&D expenses were \$9.1 million for the year ended December 31, 2015 compared to \$7.5 million for the year ended December 31, 2014.

In the Immunology Group, R&D expenses were \$7.6 million for the year ended December 31, 2015 compared to \$5.9 million for the year ended December 31, 2014. The costs in the current year related to the 2015 WF10 Trial to assess the efficacy, safety and tolerability of WF10 for the treatment of moderate to severe allergies to grass and ragweed pollens. The external costs for

this trial are approximately \$4.5 million of which the Company has paid \$3.1 million as of December 31, 2015. In December, the Company announced that the 2015 WF10 Trial was not successful and has discontinued all WF10 development.

• In the TPT Group, R&D expenses were \$1.5 million for the year ended December 31, 2015 compared to \$1.6 million for the year ended December 31, 2014. In the current and prior year, the Company incurred costs related to the advancement of the formulations for the Ferndale collaboration.

R&D expenditures vary depending on the stage of development of drug products and candidates in the Company's pipeline and management's allocation of the Company's resources to these activities in general and to each drug specifically.

#### **General and Administrative**

G&A expenses were \$9.3 million for the year ended December 31, 2015 compared to \$13.0 million for the year ended December 31, 2014. The decrease in the current year related to a \$5.2 million decrease in SBC primarily from the adjustment to market value for the outstanding Share Appreciation Rights (SARs) and Deferred Share Units (DSUs) at December 31, 2015, partially offset by a \$2.1 million increase in professional fees related to the proposed reorganization of the Company and a decrease in key management compensation expenses.

A change in the Company's share price can result in a significant charge or recovery of G&A expenses in a reporting period due to the revaluation of SARs and DSUs to fair market value at the end of each reporting period. Assuming all other valuation assumptions remain constant, a \$1.00 increase in the Company's share price at December 31, 2015 would have resulted in an additional \$0.9 million of G&A expenses in the year ended December 31, 2015. A \$1.00 decrease in the Company's share price at December 31, 2015 would have resulted in a decrease of \$0.9 million of G&A expenses in the year ended December 31, 2015.

#### Interest

Interest expense was \$40,000 for the year ended December 31, 2015 compared to \$0.7 million for the year ended December 31, 2014. Interest expense for the current and comparative periods included non-cash accretion charges on the five-year consulting agreement as part of the consideration paid for the 2011 acquisition of the non-controlling interest in Nuvo Research AG. In addition, in the comparative year, the Company incurred a 15% per annum interest cost related to the outstanding loan with Paladin which was repaid in full in the fourth quarter of 2014.

Interest income increased to \$0.5 million for the year ended December 31, 2015 compared to \$0.2 million for the year ended December 31, 2014. The increase in interest income related to the significantly higher balances in the interest bearing Canadian bank accounts, as well as the interest income the Company earned on the \$10.0 million invested in short-term investments that matured during the fourth quarter of 2014.

The aggregate result was net interest income of \$0.5 million for the year ended December 31, 2015 compared to net interest expense of \$0.5 million for the year ended December 31, 2014.

## **Loss from Operations**

Loss from operations was \$8.1 million for the year ended December 31, 2015 compared to \$14.0 million for the year ended December 31, 2014. The decreased loss from operations was attributable to an increased gross margin from higher Pennsaid 2% product sales, lower SBC costs from the revaluation of SARs and DSUs to market value and higher net interest income, partially offset by increased R&D expenditures related to the 2015 WF10 Trial and the Pennsaid 2% Phase 3 trial and lower royalty revenue.

#### Other Income

in thousands

	Year ended December 31, 2015	Year ended December 31, 2014
	\$	\$
Foreign currency gain	(960)	(1,657)
Litigation settlement	-	(52,343)
Impairment of intangible assets	-	1,664
Gain on disposal of property , plant and equipment	-	(296)
Total other income	(960)	(52,632)

## **Foreign Currency Gain**

The Company experienced a net foreign currency gain of \$1.0 million for the year ended December 31, 2015 compared to \$1.7 million for the year ended December 31, 2014. In the current year, the impact of the weaker Canadian dollar versus the U.S. dollar and euro increased the value of U.S. and euro denominated cash and receivables. In the comparative year, the foreign currency gain related to a foreign currency gain of \$1.1 million on the litigation settlement.

## **Litigation Settlement**

In September 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% (Pennsaid Rights) to Nuvo and paid US\$10.0 million.

The Pennsaid Rights were valued at US\$45.0 million, as this represented the fair market value as evidenced by the sale to Horizon in October 2014 (See Significant Transactions – 2014 – Pennsaid 2% U.S. Asset Sale). The total gain on litigation settlement for the year ended December 31, 2014 was \$52.3 million which included the net cash settlement payment of \$8.8 million and the non-cash portion of \$43.5 million, net of direct costs to sell.

## Impairment of Intangible Assets

The Company reviewed the carrying values of the intangible assets for potential impairment at December 31, 2014 as sales for the HLT Patch and Pliaglis were not meeting expectations. Commercial strategies for both products have produced revenues that were lower than expected. Indications for impairment did exist, and management determined that each asset was impaired, such that recoverable amounts were lower than the carrying amounts. The recoverable amount and value in use (being the present value of expected future cash flows) was calculated using historical results and management's estimate of potential cash flows over the remaining patent life, net of direct costs forecasted by management, discounted at an after-tax rate of 19% which approximated the Company's current weighted average cost of capital. At December 31, 2014, the Company recorded an impairment charge for the HLT Patch of \$0.5 million and an impairment charge for Pliaglis of \$1.2 million

## Gain on disposal of property, plant and equipment

The Company recognized a gain of \$0.3 million for the year ended December 31, 2014 related to the sale of a portion of unused land at its manufacturing site in Varennes, Québec.

## Net Income (Loss) and Total Comprehensive Income (Loss)

in thousands

	Year ended December 31, 2015	Year ended December 31, 2014
	\$	\$
Net income (loss) before income taxes	(7,113)	38,609
Income tax	7	19
Net income (loss)	(7,120)	38,590
Unrealized gains (losses) on translation of foreign operations	(65)	38
Total comprehensive income (loss)	(7,185)	38,628

## **Net Income (Loss)**

Net loss was \$7.1 million for the year ended December 31, 2015 compared to net income of \$38.6 million for the year ended December 31, 2014. The net income in the comparative year ended December 31, 2014 included a significant gain of \$52.3 million from the Company's litigation settlement.

## **Total Comprehensive Income (Loss)**

Total comprehensive loss was \$7.2 million for the year ended December 31, 2015 compared to a total comprehensive income of \$38.6 million for the year ended December 31, 2014. The current year included an unrealized loss of \$65,000 on the translation of foreign operations compared to an unrealized gain of \$38,000 in the comparative year.

## Net Income (Loss) Per Common Share

Net loss per common share was \$0.65 for the year ended December 31, 2015 versus net income per common share of \$3.85 for the year ended December 31, 2014. On a diluted basis, net loss per common share was \$0.65 for the year ended December 31, 2015 versus net income per common share of \$3.71 for the year ended December 31, 2014.

The weighted average number of common shares outstanding on a basic and diluted basis was 10.9 million for the year ended December 31, 2015. For the year ended December 31, 2014, the weighted average number of common shares outstanding on a basic and diluted basis was 10.0 million and 10.4 million.

#### **Segments**

IFRS 8 - Operating Segments, requires operating segments to be determined based on internal reports that are regularly reviewed by the chief operating decision maker for the purpose of allocating resources to the segment and to assessing its performance. Prior to September 30, 2015, the Company managed the business in the following operating segments: i) Topical Products and Technology Group and ii) Immunology Group. As discussed in Note 3(i) of the Consolidated Financial Statements for the year ended December 31, 2015, the Company realigned its operating segments as a result of proposed strategic changes to the organizational structure. Accordingly, the Company has presented the following operating segments that are independently and regularly reviewed and managed: i) Nuvo Pharma and ii) Crescita.

On a segmented basis, Nuvo Pharma incurred net income before income taxes of \$8.3 million for the year ended December 31, 2015 compared to \$53.3 million for the year ended December 31, 2014. In the current year, Nuvo Pharma experienced an increased gross margin due to increased Pennsaid 2% product sales and lower SBC costs from the revaluation of SARs and DSUs to market value, slightly offset by decreased royalty revenue. The comparative year included a net gain of \$52.3 million related to the litigation settlement with Mallinckrodt.

Crescita incurred net loss before income taxes of \$15.4 million for the year ended December 31, 2015 compared to \$14.7 million for the year ended December 31, 2014. In the current year, Crescita had an increase in costs related to the clinical trials for WF10 and Pennsaid 2%, as well as increased professional fees related to the Reorganization of the Company.

# **Liquidity and Capital Resources**

in thousands

	Year ended December 31, 2015	Year ended December 31, 2014
	\$	\$
Net income (loss)	(7,120)	38,590
Items not involving current cash flows	(171)	(41,463)
Cash used in operations	(7,291)	(2,873)
Net change in non-cash working capital	(3,341)	5,513
Cash provided by (used in) operating activities	(10,632)	2,640
Cash provided by investing activities	9,668	33,708
Cash provided by (used in) financing activities	827	(815)
	(137)	35,533
Effect of exchange rates on cash	542	121
Net change in cash during the year	405	35,654
Cash, beginning of year	48,275	12,621
Cash, end of year	48,680	48,275

#### Cash

Cash was \$48.7 million at December 31, 2015, an increase of \$0.4 million compared to \$48.3 million at December 31, 2014. The \$0.4 million increase in cash was primarily attributable to increased margins from higher product sales offset by costs associated with the clinical trials for WF10 and Pennsaid 2% and the costs related to the proposed Reorganization of the Company (See Corporate Development – Proposed Reorganization of the Company).

As part of the Nuvo Strategic Transaction (See Corporate Development – Proposed Reorganization of the Company), the Company plans to transfer \$35.0 million to Crescita as part of the reorganization. Completion of the reorganization is subject to a number of conditions including shareholder and court approval. If the proposed transaction is approved by shareholders and all other conditions are satisfied, Nuvo expects the transaction to be completed in Q1 2016.

## **Operating Activities**

Cash used in operations was \$7.3 million for the year ended December 31, 2015 compared to \$2.9 million for the year ended December 31, 2014. The increase in cash used in operations related to the decrease in net income that was mostly offset by the change in non-cash items. In the comparative year, net income included a \$52.3 million gain on the litigation settlement, of which \$43.5 million was a non-cash item.

Overall cash used in operating activities was \$10.6 million for the year ended December 31, 2015 compared to cash provided by operating activities of \$2.6 million for the year ended December 31, 2014. The increase in cash used in operating activities related to an increase in cash used in operations and a \$3.3 million investment in non-cash working capital compared to a \$5.5 million recovery of non-cash working capital in the prior year. The \$3.3 million investment in non-cash working capital in the current year was attributable to an increase in accounts receivable as a result of increased Pennsaid 2% product sales and the payment of a \$0.6 million deposit to the Canadian Revenue Agency related to fiscal 2014 that was refunded in full subsequent to the year ended December 31, 2015. The \$5.5 million recovery in working capital in the comparative period was primarily attributable to the collection of the milestone payment of US\$2.0 million (\$2.1 million) from Galderma related to the launch of Pliaglis in Brazil and an increase in accounts payable and accrued liabilities related to the cash-settled SBC liability, partially offset by the increase in inventory to support Horizon's launch of Pennsaid 2% in the U.S. market.

## **Investing Activities**

Net cash provided by investing activities totalled \$9.7 million for the year ended December 31, 2015 compared to net cash provided by investing activities of \$33.7 million for the year ended December 31, 2014. In the current period, the Company's \$10.0 million investment in short-term investments matured.

In the prior year, net cash provided by investing activities related primarily to net proceeds of \$43.6 million received from the Pennsaid 2% U.S. Asset Sale (See Significant Transactions – 2014 – Pennsaid 2% U.S. Asset Sale), partially offset by an investment of \$10.0 million in short-term investments. In both the current and comparative years, cash used in investing activities included the acquisition of property, plant and equipment for production and laboratory equipment acquired by the Company's manufacturing facility in Varennes, Québec.

## **Financing Activities**

Net cash provided by financing activities totalled \$0.8 million for the year ended December 31, 2015 compared to net cash used in financing activities of \$0.8 million for the year ended December 31, 2014. In the current year, the Company received \$0.9 million in cash from the exercise of warrants and \$0.1 million from the issuance of common stock that was slightly offset by payments towards the five-year consulting agreement recognized as part of the non-controlling interest in 2011. In the comparative year, the Company raised \$2.9 million net of financing fees through the Private Placement (See – Significant Transactions – 2014 – Private Placement) and received \$1.4 million from the exercise of warrants. This increase in cash was partially offset by payments towards the Company's loan and payments towards the five-year consulting agreement recognized as part of the non-controlling interest in 2011.

## **Selected Quarterly Information**

The following is selected quarterly financial information for the last eight quarterly reporting periods.

in thousands, except per share data

m thousands, except per share data	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
	\$	\$	\$	\$
Revenue	4,547	3,246	5,716	7,843
Net income (loss) before income taxes	(263)	(5,952)	(1,194)	296
Net income (loss) per common share				
Basic	(0.03)	(0.55)	(0.11)	0.03
Diluted	(0.03)	(0.55)	(0.11)	0.03
	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
	\$	\$	\$	\$

	2014	2014	2014	2014
	\$	\$	\$	\$
Revenue	2,757	3,863	3,010	3,427
Net income (loss) before income taxes	(2,722)	(2,279)	49,722 <sup>(2)</sup>	(6,112) <sup>(1)</sup>
Net income (loss) per common share				
Basic	(0.31)	(0.23)	4.84 <sup>(2)</sup>	(0.58) <sup>(1)</sup>
Diluted	(0.31)	(0.23)	4.71 <sup>(2)</sup>	(0.56) (1)

<sup>(1)</sup> The quarter ended December 31, 2014 included a \$1.7 million impairment charge on intangible assets related to Pliaglis and the HLT Patch.

<sup>(2)</sup> The quarter ended September 30, 2014 included a net gain of \$52.3 million related to the litigation settlement with Mallinckrodt (See Significant Transactions – 2014 – Mallinckrodt Litigation).

## **Fourth Quarter Results**

in thousands

	Three months ended December 31, 2015	Three months ended December 31, 2014
	\$	\$
Product sales	7,166	1,586
Royalties	345	1,226
License fees	-	567
Research and other contract revenue	332	48
Total Revenue	7,843	3,427
Cost of goods sold	3,235	1,601
Research and development	2,214	2,785
General and administrative expenses	2,513	4,255
Interest expense, net	(102)	56
Operating expenses	7,860	8,697
Other (income) expenses	(313)	842
Net income (loss) before income taxes	296	(6,112)
Income taxes	-	31
Net income (loss)	296	(6,143)
Other comprehensive income (loss)	(18)	39
Total comprehensive income (loss)	278	(6,104)

## **Key Developments**

During the guarter and prior to the release of the fourth guarter results:

## Proposed Reorganization of the Company

On December 14, 2015, Nuvo, 2487002 Ontario Limited and 2487001 Ontario Limited entered into the Arrangement Agreement in respect of the proposed Reorganization of Nuvo into two separate publicly-traded companies. Nuvo Pharma would be a revenue and EBITDA generating 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. See Corporate Development – Proposed Reorganization of the Company for more detail on this proposed transaction.

#### WF10

In December, the Company announced topline results of the 2015 WF10 Trial. 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. Management
believes that the results do not justify the further development of WF10 for the treatment of
allergic rhinitis and has discontinued all WF10 development.

## Pennsaid 2%

 NovaMedica advised the Company that their Pennsaid 2% clinical trial was successful and that they have submitted their application to obtain regulatory approval in their territory.

## Pliaglis

• In December, the Company reacquired Pliaglis development and marketing rights for the U.S., Canada and Mexico (See Significant Transactions – 2015 – Pliaglis North American Rights Reacquisition).

## **Operating Results**

Total revenue for the three months ended December 31, 2015 was \$7.8 million compared to \$3.4 million for the three months ended December 31, 2014. The increase in revenue primarily related to an increase in Pennsaid 2% product sales in the U.S., slightly offset by a decrease in royalty revenue from Pennsaid and Pennsaid 2% in the U.S. as the Company no longer earns a royalty on net sales in the U.S market.

Total operating expenses for the three months ended December 31, 2015 decreased to \$7.9 million compared to \$8.7 million for the three months ended December 31, 2014. The decrease in operating expenses was primarily due to a decrease in SBC expenses of \$3.9 million, partially offset by an increase in COGS and the costs related to the proposed Reorganization of the Company.

COGS for the three months ended December 31, 2015 was \$3.2 million compared to \$1.6 million for the three months ended December 31, 2014. The increase in COGS was primarily related to an increase in Pennsaid 2% product sales to Horizon. The increase in product sales improved the gross margin on product sales to \$3.9 million or 55% for the three months ended December 31, 2015 compared to a negative margin of \$15,000 for the three months ended December 31, 2014.

R&D expenses decreased to \$2.2 million for the three months ended December 31, 2015 compared to \$2.8 million for the three months ended December 31, 2014. The decrease in the quarter was primarily attributable to a \$0.3 million reduction in SBC expenses.

G&A expenses decreased to \$2.5 million for the three months ended December 31, 2015 compared to \$4.3 million for the three months ended December 31, 2014. The decrease in the quarter was primarily related to a \$3.6 million decrease in SBC expenses, slightly offset by \$1.7 million in professional fees associated with the proposed Reorganization of the Company.

Other income was \$0.3 million for the three months ended December 31, 2015 which was related to foreign exchange gain. In the comparative period, the Company recognized other expenses of \$0.8 million primarily related an impairment charge of \$1.7 million on intangible assets that was partially offset by a \$0.5 million foreign exchange gain and a gain related to the sale of unused land at the Company's manufacturing site in Varennes, Quebec.

Net income for the three months ended December 31, 2015 was \$0.3 million compared to a net loss of \$6.1 million for the three months ended December 31, 2014. The improvement in the quarter related to an increased gross margin on product sales and decreased SBC expense that was only slightly offset by costs associated with the proposed Reorganization of the Company.

Total comprehensive income was \$0.3 million for the three months ended December 31, 2015 compared to a total comprehensive loss of \$6.1 million for the three months ended December 31, 2014. Included in the comprehensive loss was an \$18,000 unrealized loss on the translation of foreign operations for the three months ended December 31, 2015 compared to a \$39,000 unrealized gain for the three months ended December 31, 2014.

# **Liquidity** in thousands

	Three months ended December 31, 2015	Three months ended December 31, 2014
	\$	\$
Net income (loss)	296	(6,143)
Items not involving current cash flows	(88)	2,564
Cash provided by (used in) operations	208	(3,579)
Net change in non-cash working capital	(2,993)	10,864
Cash provided by (used in) operating activities	(2,785)	7,285
Cash provided by investing activities	9,979	33,876
Cash provided by (used in) financing activities	419	(2,592)
	7,613	38,569
Effect of exchange rates on cash	218	24
Net change in cash	7,831	38,593
Cash, beginning of period	40,849	9,682
Cash, end of year	48,680	48,275

Cash was \$48.7 million at December 31, 2015, an increase of \$7.9 million compared to \$40.8 million at September 30, 2015. The increase in cash primarily related to the \$10.0 million invested in short-term investments that matured in the quarter.

Cash used in operating activities was \$2.8 million for the three months ended December 31, 2015 compared to cash provided by operating activities of \$7.3 million for the three months ended December 31, 2014. An increase in cash provided by operations was offset by a significant investment in non-cash working capital in the quarter primarily related to increased accounts receivable resulting from increased product sales and a decrease in accounts payable and accrued liabilities due to the revaluation of cash-settled share-based compensation. In the comparative period, the increase in cash used in operations was offset by a significant recovery of non-cash working capital due to the receipt of the US\$10 million litigation settlement proceeds.

Net cash provided by investing activities totalled \$10.0 million for the three months ended December 31, 2015 compared to net cash provided by investing activities of \$33.9 million for the three months ended December 31, 2014. In the current period, the Company's \$10.0 million short-term investments matured. In the comparative period, net cash provided by investing activities related primarily to net proceeds of \$43.6 million received from the Pennsaid 2% U.S. Asset Sale (See Significant Transactions – 2014 – Pennsaid 2% U.S. Asset Sale), slightly offset by the purchase of a \$10.0 million short-term investment.

Net cash provided by financing activities totalled \$0.4 million for the three months ended December 31, 2015 compared to net cash used of \$2.6 million for the three months ended December 31, 2014. In the fourth quarter of 2015, the Company received \$0.4 million in proceeds from the exercise of warrants. In the comparative period, the Company paid \$3.7 million to settle the Paladin loan which was slightly offset by \$0.9 million in proceeds from the exercise of warrants.

## Financial Instruments

IFRS 7 - Financial Instruments: Disclosures requires disclosure of a three-level hierarchy that reflects the significance of the inputs used in making fair value measurements. Fair values of assets and liabilities included in Level 1 are determined by reference to quoted prices in active markets for identical assets and liabilities. Assets and liabilities in Level 2 include those where valuations are determined using inputs other than quoted prices for which all significant outputs are observable, either directly or indirectly. Level 3 valuations are those based on inputs that are unobservable and significant to the overall fair value measurement.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification on a quarterly basis. Changes to the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy. The Company did not have any transfer of assets and liabilities between Level 1, Level 2 and Level 3 of the fair value hierarchy during the years ended December 31, 2015 and 2014.

The Company has determined the estimated fair values of its financial instruments based on appropriate valuation methodologies. However, considerable judgment is required to develop these estimates. Accordingly, these estimated values are not necessarily indicative of the amounts the Company could realize in a current market exchange. The estimated fair value amounts can be materially affected by the use of different assumptions or methodologies.

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis as at December 31, 2015:

	Total \$	Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Using Significant Other Unobservable Inputs (Level 2)	Using Significant Unobservable Inputs (Level 3)
Assets:	-		-	-
Total Assets	-	-	-	-
Liabilities:				
Deferred Share Units	2,231	2,231	-	-
Stock Appreciation Rights	1,328	-	1,328	-
Total Liabilities	3,559	2,231	1,328	-

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis as at December 31, 2014:

	Total	Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Using Significant Other Unobservable Inputs (Level 2)	Using Significant Unobservable Inputs (Level 3)
Assets:	Ф	<b>D</b>	<b>D</b>	<u> </u>
Short-term Investments	10,000	10,000	-	-
Total Assets	10,000	10,000	-	-
Liabilities:				
Deferred Share Units	2,770	2,770	-	-
Stock Appreciation Rights	2,876	-	2,876	-
Total Liabilities	5,646	2,770	2,876	-

Level 1 assets include guaranteed investment certificates or other securities held by the Company that are valued at quoted market prices. The Company accounted for its investment at fair value on a recurring basis at December 31, 2014. The Company has no level 1 assets at December 31, 2015.

Level 1 liabilities include obligations of the Company for the DSUs. One DSU has a cash value equal to the market price of one of the Company's common shares. The Company revalues the DSU liability each reporting period using the market value of the underlying shares.

Level 2 liabilities include obligations of the Company for the SARs Plan. The fair values of each tranche of SARs issued and outstanding are revalued at each reporting period using the Black-Scholes option pricing model.

The fair values of all other short-term financial assets and liabilities, presented in the Consolidated Statements of Financial Position approximate their carrying amounts due to the short period to maturity of these financial instruments.

Rates currently available to the Company for long-term obligations, with similar terms and remaining maturities, have been used to estimate the fair value of the finance lease and other obligations. These fair values approximate the carrying values for all instruments.

## FINANCIAL RISK MANAGEMENT

#### **Risk Factors**

The following is a discussion of liquidity, credit and market risks and related mitigation strategies that have been identified. This is not an exhaustive list of all risks nor will the mitigation strategies eliminate all risks listed.

## **Liquidity Risk**

While the Company had \$48.7 million in cash as at December 31, 2015, it continues to have an ongoing need for substantial capital resources to research, develop, commercialize and manufacture its products and technologies as the Company is not generating enough cash to fund its operations. The Company has limited participation in Pennsaid and Pennsaid 2% revenues in countries where it is currently marketed. In Canada, the Company receives royalties based on Canadian net sales of Pennsaid. In the first quarter of 2014, a generic version of Pennsaid was launched that has negatively impacted the Company's royalty revenue in Canada. In the U.S., the Company receives product revenues from the sale of Pennsaid 2% to Horizon pursuant to a long-term exclusive supply agreement.

The Company has contractual obligations related to accounts payable and accrued liabilities, purchase commitments and other obligations of \$10.8 million that are due in less than a year and \$0.1 million of contractual obligations that are payable from 2017 to 2020.

#### **Credit Risk**

The Company's cash balances subject the Company to a significant concentration of credit risk. As at December 31, 2015, the Company had \$48.2 million invested with two financial institutions, in various bank accounts as per its practice of protecting its capital rather than maximizing investment yield through additional risk. These financial institutions are major Canadian banks which the Company believes lessens the degree of credit risk. The remaining \$0.5 million of cash balances are held in bank accounts in various geographic regions outside of Canada.

The Company, in the normal course of business, is exposed to credit risk from its global customers, most of whom are in the pharmaceutical industry. The accounts receivable are subject to normal industry risks in each geographic region in which the Company operates. In addition, the Company is exposed to credit-related losses on sales to its customers outside North America and the E.U. due to potentially higher risks of enforceability and collectability. The Company attempts to manage these risks prior to the signing of distribution or licensing agreements by dealing with creditworthy customers; however, due to the limited number of potential customers in each market, this is not always possible. In addition, a customer's creditworthiness may change subsequent to becoming a licensee or distributor, and the terms and conditions in the agreement may prevent the Company from seeking new licensees or distributors in these territories during the term of the agreement. As at December 31, 2015, the Company's four largest customers located in North America and the E.U. represented 89% [December 31, 2014 - 60%] of total accounts receivable and accounts receivable from customers located outside of North America and the E.U. represented 2% [December 31, 2014 - 8%] of total accounts receivable.

Pursuant to their collective terms, accounts receivable were aged as follows:

	December 31, 2015	December 31, 2014
	\$	\$
Current	5,497	2,940
0-30 days past due	36	43
31-60 days past due	-	20
Over 90 days past due	-	2
	5,533	3,005

## **Interest Rate Risk**

All finance lease obligations are at fixed interest rates.

## **Currency Risk**

The Company operates globally, which gives rise to a risk that earnings and cash flows may be adversely affected by fluctuations in foreign currency exchange rates. The Company is primarily exposed to the U.S. dollar and euro, but also transacts in other foreign currencies. The Company currently does not use financial instruments to hedge these risks. The significant balances in foreign currencies were as follows:

	Euros		U.S. Dollars	
	December 31,	December 31,	December 31,	December 31,
	2015	2014	2015	2014
	€	€	\$	\$
Cash	885	1,266	4,783	665
Accounts receivable	782	242	3,010	2,205
Other current assets	2	159	-	-
Accounts payable and accrued liabilities	(959)	(943)	(520)	(601)
Finance lease and other long-term	` ,	, ,	` ,	, ,
obligations	-	-	(162)	(281)
	710	724	7,111	1,988

Based on the aforementioned net exposure as at December 31, 2015, and assuming that all other variables remain constant, a 10% appreciation or depreciation of the Canadian dollar against the U.S. dollar would have an effect of \$984 on total comprehensive income (loss) and a 10% appreciation or depreciation of the Canadian dollar against the euro would have an effect of \$107 on total comprehensive income (loss).

In terms of the euro, the Company has three significant exposures: its net investment and net cash flows in its European operations, its euro denominated cash held in its Canadian operations and sales of Pennsaid by the Canadian operations to European distributors. In terms of the U.S. dollar, the Company has four significant exposures: its net investment and net cash flows in its U.S. operations, its U.S. dollar denominated cash held in its Canadian operations, the cost of purchasing raw materials either priced in U.S. dollars or sourced from U.S. suppliers that are needed to produce Pennsaid, Pennsaid 2% or other products at the Canadian manufacturing facility and revenue generated in U.S. dollars from agreements with Horizon, Galderma, Galen and Eurocept.

The Company does not actively hedge any of its foreign currency exposures given the relative risk of currency versus other risks the Company faces and the cost of establishing the necessary credit facilities and purchasing financial instruments to mitigate or hedge these exposures. As a result, the Company does not attempt to hedge its net investments in foreign subsidiaries.

The Company does not currently hedge its euro cash flows. Sales to European distributors for Pennsaid are primarily contracted in euros. The Company receives payments from the distributors in its euro bank accounts and uses these funds to pay euro denominated expenditures and to fund the net outflows of the European operations as required. Periodically, the Company reviews the amount of euros held, and if they are excessive compared to the Company's projected future euro cash flows, they may be converted into U.S. or Canadian dollars. If the amount of euros held is insufficient, the Company may convert a portion of other currencies into euros.

The Company does not currently hedge its U.S. dollar cash flows. The Company's U.S. operations have net cash outflows, and currently these are funded using the Company's U.S. dollar denominated cash and payments received under the terms of the agreements with Horizon, Galderma and Galen. Periodically, the Company reviews its projected future U.S. dollar cash flows and if the U.S. dollars held are insufficient, the Company may convert a portion of its other currencies into U.S. dollars. If the amount of U.S. dollars held is excessive, they may be converted into Canadian dollars or other currencies, as needed for the Company's other operations.

## **Contractual Obligations**

The following table lists the Company's contractual obligations for the twelve-month periods ending December 31 as follows:

in thousands	Total	2016	2017	2018 and thereafter
	\$	\$	\$	\$
Finance lease obligations	15	3	3	9
Operating leases	287	239	47	1
Purchase obligations	1,124	1,124	-	-
Other obligations <sup>(1)</sup>	9,420	9,385	35	_
	10,846	10,751	85	10

<sup>(1)</sup> Other obligations include accounts payable, accrued liabilities and the long-term consulting contract with the former minority shareholder of Nuvo Research AG.

# **Off-Balance Sheet Arrangements**

The Company does not have any off-balance sheet arrangements.

# **Related Party Transactions**

For the year ended December 31, 2015, certain officers of the Company exercised 33,884 Private Placement Warrants (See – Significant Transactions – 2014 – Private Placement). Proceeds raised from the Company's officers totalled \$0.1 million.

For the year ended December 31, 2014, certain officers of the Company participated in the Private Placement (See – Significant Transactions – 2014 – Private Placement) and acquired 67,768 Private Placement Warrants on the same terms as the other purchasers. Proceeds raised from the Company's officers totalled \$0.2 million.

# **Outstanding Share Data**

The number of common shares outstanding as at December 31, 2015 was 11.1 million compared to 10.8 million at December 31, 2014. The increase was due to the issuance of approximately 0.3 million shares from the exercise of Private Placement Warrants and Broker Warrants issued with the Company's Private Placement (See – Significant Transactions – 2014 – Private Placement).

As at December 31, 2015, there were 750,021 options outstanding of which 560,847 have vested.

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of Consolidated Financial Statements in conformity with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the Consolidated Financial Statements and the reported amounts of revenue and expenses during the reporting periods. Management has identified the following

accounting estimates that it believes are most critical to understanding the Consolidated Financial Statements and those that require the application of management's most subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. The Company's actual results could differ from these estimates and such differences could be material. All significant accounting policies are disclosed in Note 3, "Summary of Significant Accounting Policies" of the Company's Consolidated Financial Statements for the year ended December 31, 2015.

## <u>Critical Accounting Estimates</u>

Key areas of estimation or use of managerial assumptions are as follows:

## (i) Change in Operating Segments

During 2015, the Board of Directors of Nuvo unanimously approved a proposed reorganization of Nuvo into two separate publicly traded companies. This organizational realignment gave rise to changes in how the Company presents information for financial reporting and management decision-making purposes and resulted in a change in the Company's reporting segments. The realignment resulted in two operating segments: i) Nuvo Pharma and ii) Crescita. Historically, the Company operated under two distinct business units: i) the TPT Group and ii) the Immunology Group. These business units will remain operating segments of Crescita. The Nuvo Pharma segment comprises the Company's manufacturing facility in Varennes, Quebec and includes the Company's Pennsaid, Pennsaid 2% and HLT Patch franchises. Corporate overhead costs are allocated to Nuvo Pharma and Crescita's TPT Group. All prior period segment disclosures have been restated to reflect the changes in the Company's operating segments. The change did not impact the results reported in the Consolidated Financial Statement.

## (ii) Share-based Payments:

The Company measures the cost of share-based payments, either equity or cash-settled, with employees by reference to the fair value of the equity instrument or underlying equity instrument at the date on which they are granted. In addition, cash-settled share-based payments are revalued to fair value at every reporting date.

Estimating fair value for share-based payments requires management to determine the most appropriate valuation model for a grant, which is dependent on the terms and conditions of each grant. In valuing certain types of stock-based payments, such as incentive stock options and stock appreciation rights, the Company uses the Black-Scholes option pricing model.

Several assumptions are used in the underlying calculation of fair values of the Company's stock options and stock appreciation rights using the Black-Scholes option pricing model, including the expected life of the option, stock price volatility and forfeiture rates.

## (iii) Revenue Recognition:

As is typical in the pharmaceutical industry, the Company's royalty streams are subject to a variety of deductions that generally are estimated and recorded in the same period that the revenues are recognized and primarily represent rebates, discounts and incentives and product returns. These deductions represent estimates of the related obligations. Amounts recorded for sales deductions can result from a complex series of judgments about future events and uncertainties and can rely on estimates and assumptions.

#### (iv) Intangible Assets:

The Company determines fair values based on discounted cash flows, market information, independent valuations and management's estimates. The values calculated for intangible assets involve significant estimates and assumptions, including those with respect to future cash flows, discount rates and asset lives. These significant estimates and judgments could impact the Company's future results if the current estimates of future performance and fair values change and could affect the amount of amortization expense on intangible assets in future periods.

#### (v) Cash-generating Units:

The identification of cash-generating units (CGUs) within the Company requires considerable judgment. Under IFRS, management must determine the smallest group of assets that generate independent cash

inflows. Management first considers the Company's commercialized products and then determines the operations that contribute to each product's revenue base and net cash inflows. Management has identified three CGUs: the U.S. operations dedicated to generating cash inflows for Synera and Pliaglis, the manufacturing facility in Québec that generates cash inflows for Pennsaid and Pennsaid 2% and the Immunology Group that generates cash inflows for WF10.

## (vi) Impairment of Non-financial Assets:

The Company reviews the carrying value of non-financial assets for potential impairment when events or changes in circumstances indicate that the carrying amount may not be recoverable. The impairment test on CGUs is carried out by comparing the carrying amount of the CGU and its recoverable amount. The recoverable amount of a CGU is the higher of fair value, less costs to sell, and its value in use. This complex valuation process entails the use of methods, such as the discounted cash flow method, which requires numerous assumptions to estimate future cash flows. The recoverable amount is impacted significantly by the discount rate selected to be used in the discounted cash flow model, as well as the quantum and timing of expected future cash flows and the growth rate used for the extrapolation.

# **Recent Accounting Pronouncements**

Certain new standards, interpretations, amendments and improvements to existing standards were issued by the IASB or IFRS Interpretations Committee (IFRIC) that are not yet effective and have not yet been early adopted by the Company. The standards impacted that may be applicable to the Company are as follows:

## IFRS 9 – Financial Instruments

In October 2010, the IASB issued IFRS 9, which replaces IAS - 39 Financial Instruments: Recognition and Measurement. IFRS 9 establishes principles for the financial reporting of financial assets and financial liabilities that will present relevant and useful information to users of financial statements for their assessment of the amounts, timing and uncertainty of an entity's future cash flows. This new standard is effective for the Company's interim and annual financial statements commencing January 1, 2018. The Company is in the process of reviewing the standard to determine the impact on the Consolidated Financial Statements.

## IFRS 15 – Revenue from Contracts with Customers

In May 2014, the IASB issued IFRS 15 - Revenue from Contracts with Customers, which covers principles for reporting about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. IFRS 15 is effective for annual periods beginning on or after January 1, 2018, with earlier adoption permitted. Entities will transition following either a full or modified retrospective approach. The Company is in the process of reviewing the standard to determine the impact on the Consolidated Financial Statements.

#### IFRS 16 - Leases

In January 2016, the IASB has issued IFRS 16 - *Leases*, its new leases standard that requires lessees to recognize assets and liabilities for most leases on their balance sheets. Lessees applying IFRS 16 will have a single accounting model for all leases, with certain exemptions. Lessor accounting is substantially unchanged. The new standard will be effective from January 1, 2019 with limited early application permitted. The Company is in the process of reviewing the standard to determine the impact on the Consolidated Financial Statements.

Other accounting standards or amendments to existing accounting standards that have been issued, but have future effective dates, are either not applicable or are not expected to have a significant impact on the Company's Consolidated Financial Statements.

The Company assesses the impact of adoption of future standards on its Consolidated Financial Statements, but does not anticipate significant changes in 2016.

# Management's Responsibility for Financial Reporting

#### **Disclosure Controls**

Disclosure controls and procedures (DCP) are designed to provide reasonable assurance that information required to be disclosed by the Company in its filings under Canadian securities legislation is recorded, processed, summarized and reported in a timely manner. The system of DCP includes, among other things, the Company's Corporate Disclosure and Code of Conduct and Business Ethics policies, the review and approval procedures of the Corporate Disclosure Committee and continuous review and monitoring procedures by senior management.

At December 31, 2015, the system of DCP was evaluated, under the supervision of the Company's Chairman and Co-Chief Executive Officer, President and Co-Chief Executive Officer and Vice President and Chief Financial Officer. Based on this evaluation, the Company's management has concluded that the DCP are effective and provide reasonable assurance that all material information relating to the Company would be made known to them. While the Co-Chief Executive Officers and the Chief Financial Officer believe that the Company's DCP provide reasonable assurance, they are also aware that any control system can only provide reasonable, not absolute, assurance of achieving its control objectives.

## **Internal Controls Over Financial Reporting**

Management is also responsible for the design of internal controls over financial reporting (ICFR) within the Company, in order to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS. Due to its inherent limitations, ICFR may not prevent or detect misstatements. In addition, the design of any system of control is based upon certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all future events, no matter how remote or that the degree of compliance with the policies or procedures may not deteriorate. Accordingly, even effective ICFR can only provide reasonable, not absolute, assurance of achieving the control objectives for financial reporting.

The design and operating effectiveness of the Company's ICFR were evaluated, under the supervision of the Company's Chairman and Co-Chief Executive Officer, President and Co-Chief Executive Officer and Vice President and Chief Financial Officer, in accordance with criteria established in the 2013 Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and Multilateral Instrument 52-109 as at December 31, 2015. Based on this evaluation, the Company's management has concluded that ICFR are effective and provided reasonable assurance that its financial reporting is reliable.

## **Changes to Internal Controls Over Financial Reporting**

There were no changes to ICFR that occurred during the year ended December 31, 2015 that has materially affected the Company's ICFR.

## Risk Factors

Prospects for companies in the biotechnology and pharmaceutical industry generally may be regarded as uncertain given the nature of the industry and, accordingly, investments in biotechnology and pharmaceutical companies should be regarded as speculative. R&D involves a high and significant degree of risk. An investor should carefully consider the risks and uncertainties described below, as well as other information contained in this MD&A, as well as broader risk factors discussed in the Company's AIF. The risks and uncertainties described below are not an exhaustive list. Additional risks and uncertainties not presently known to the Company or that the Company believes to be immaterial may also adversely affect the Company's business. If any one or more of the following risks occur, the Company's business, financial condition and results of operations could be seriously harmed. Further, if the Company fails to meet the expectations of the public market in any given period, the market price of the Company's common shares could decline. Before making an investment decision, each prospective investor should carefully consider the risk factors set out below and those included in the AIF and other public documents.

There are also certain risks relating to the Reorganization and if the Reorganization is completed, the business of Nuvo Pharma and Crescita following the completion of the Reorganization. For a complete discussion of these risks factors, please refer to the Reorganization Circular that was filed on SEDAR on January 22, 2016.

## **Need for Additional Financing**

The Company has an ongoing need for substantial capital resources to research, develop, commercialize and manufacture its products and technologies as the Company is not generating enough cash to fund its operations. The Company has limited participation in revenues from the commercial products that the Company has out-licensed and these revenues are not sufficient to cover the costs of operating the business. The Company earns revenue from product sales of Pennsaid 2%, Pennsaid, WF10 and Oxoferin, but is dependent on its partners to sell these products in their respective licensed territories. The Company also earns revenue from royalties on the net sales of Pennsaid in Canada, on the net sales of Pliaglis in the Galderma territory and net sales of the HLT Patch - branded as Synera in the U.S. and Rapydan in Europe.

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

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

## **Economic Environment**

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

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

## **Dependence on Sales and Marketing Partnerships**

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

payments that the Company or its partners believe are due under such distribution or marketing arrangements, a partner or distributor may develop or distribute products that compete with the Company's products or they may terminate the relationship.

The Company has no influence in sales and marketing activities for Pennsaid and Pennsaid 2% in the markets it is currently available in. Decisions impacting sales and marketing efforts are made by the Company's partners for their respective territories. If one of the Company's partners (especially Paladin in Canada for Pennsaid and Horizon in the U.S. for Pennsaid 2%) was unable to 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 has minimal influence in the worldwide sales and marketing activities for Pliaglis, as these decisions are made by Galderma, except for North America. In December 2015, the Company reacquired the North American rights to Pliaglis. (See Significant Transactions – 2015 – Pliaglis North American Rights Reacquisition). Although the Company has three seats on the Joint Steering Committee that was established to monitor the development and commercial activities related to Pliaglis in the Galderma territory, the Company has no direct control over the technical, regulatory and commercial activities for the product. In addition, Galderma is responsible for the commercialization of Pliaglis outside of North America and, as such, the Company will rely on Galderma to successfully execute a worldwide commercialization program. Delays in obtaining the appropriate regulatory approvals for Pliaglis in territories or an unsuccessful launch in any major territory may have an adverse effect on the Company's royalty income and cash flows.

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.

#### **Generic Drug Manufacturers**

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

In 2014, a generic version of Pennsaid was launched in Canada. The Company's partner in Canada has launched an authorized generic to compete with the generic version of Pennsaid and protect market share. The Company's revenues from royalties and product sales in Canada were negatively impacted as a result of the launch of these generic versions. In addition, another generic version of Pennsaid was launched in late 2015.

In the U.S., under the "Hatch-Waxman Act", the FDA can approve an ANDA for a generic version of a branded drug or a variation of an existing branded drug, without undertaking the clinical testing necessary to obtain approval to market a new drug. This is referred to as the "ANDA process". In place of such clinical studies, an ANDA applicant usually needs to submit data and information demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product, in addition to, for example, any data necessary to establish that any difference in inactive ingredients does not result in different safety or efficacy profiles, as compared to the reference drug. The "Hatch-Waxman Act", in addition to providing brand-name drug manufacturers with periods of marketing exclusivity, such as 3-year "new clinical investigation" exclusivity, requires an applicant for a drug that relies, at least in part, on

the FDA's findings of safety or effectiveness for a branded drug, to notify the sponsor of the branded drug of their application and potential infringement of any patents timely listed in the FDA Orange Book. Upon receipt of this notice, the sponsor of the branded drug has 45 days to bring a patent infringement suit in federal district court against the applicant seeking approval of a product covered by the patent. If such a suit is commenced and the ANDA was filed after the patent had been listed in the FDA Orange Book. then the FDA is generally prohibited from granting approval of the ANDA or Section 505(b)(2) NDA, a type of NDA that relies on information for which the applicant does not have a right of reference, until the earliest of 30 months from the date the FDA accepted the application for filing (the 30-Month Stay), or the conclusion of patent infringement litigation in the generic's favour or expiration of the patent. If an ANDA was filed before the patent had been listed in the FDA Orange Book, the 30-Month Stay does not apply and it is possible that the ANDA holder may launch its generic product "at risk" of patent infringement proceedings initiated by the innovator drug company. If the litigation is resolved in favour of the applicant or the challenged patent expires during the 30-month stay period, the stay is terminated and the FDA may thereafter approve the application based on the standards for approval of ANDAs and Section 505(b)(2) NDAs. Frequently, the unpredictable nature and significant costs of patent litigation leads the parties to settle out of court. Settlement agreements between branded companies and generic applicants may allow, among other things, a generic product to enter the market prior to the expiration of any or all of the applicable patents covering the branded product, either through the introduction of an authorized generic or by providing a license to the patents in suit.

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

# **Obtaining Government and Regulatory Approvals**

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

The process of completing a drug development program and obtaining regulatory approval for a drug can be long and may involve significant delays despite the Company's best efforts and can require substantial cash resources. Even after initial approval has been obtained, further research, including post-marketing studies, may be required to expand indications covered under the product approvals and labelling. Also, regulatory agencies require post-marketing surveillance programs to monitor side effects. Results of post-marketing programs may limit or expand additional marketing of the drug. Moreover, regulations are rigorous, time consuming and costly and the Company cannot predict the extent to which it may be affected by changes in regulatory developments and its ability to meet such regulations. There is also a risk that the Company's products may be withdrawn from the market and the required approvals suspended as a result of non-compliance with regulatory requirements.

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

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

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

# **United States Regulation**

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

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

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

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

In addition, the FDA has the authority to regulate the claims the Company's partners make in marketing its prescription drug products to ensure that such claims are true, not misleading, supported by scientific evidence and consistent with the product's approved labelling. Failure to comply with FDA requirements in this regard could result in, among other things, suspensions or withdrawal of approvals, product seizures and injunctions against the manufacture, holding, distribution, marketing and sale of a product, civil and criminal sanctions.

# Canada Regulation

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

# Additional Regulatory Considerations

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

# **Manufacturing and Supply Risks**

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

In the case of Pennsaid and Pennsaid 2%, the Company has a supply agreement with a single supplier based in the U.S. to purchase all of the Company's requirements for pharmaceutical grade DMSO (one of the key ingredients in Pennsaid and Pennsaid 2%) until December 31, 2022 using the supplier's patented process. It may be difficult to find another manufacturer if the supplier is unable to supply the Company with a sufficient amount of DMSO or if the Company is forced for any other reason to find another supplier. It could take another supplier a significant period of time to develop and certify the necessary processes to manufacture the product on terms acceptable to the Company or the related regulatory authority. There may not be suppliers who are able to meet the Company's volume or quality requirements at a price that is as favourable as the current supplier. Any operating, production or quality problems experienced by these suppliers that result in a reduction or interruption in supply could significantly delay the manufacture and sale of the Company's products.

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

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

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

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

In addition, the FDA and other regulatory agencies require that raw material manufacturers comply with all applicable regulations and standards pertaining to the manufacture, control, testing and use of the raw materials as appropriate. For the Active API or critical raw materials depending on the drug product, this means compliance to current GMPs for APIs and submission of all data related to the manufacture,

control and testing of the API for quality, purity, identity and stability, as well as a complete description of the process, equipment, controls and standards used for the production of the API. This is usually submitted to the FDA in the form of a Drug Master File (DMF) by the manufacturer and referenced by the sponsor of the NDA. The DMF information and data is reviewed by the FDA as a critical component of the approvability of the NDA.

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

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

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

- The Company may encounter difficulties in achieving volume production, quality control
  and quality assurance, as well as relating to shortages of qualified personnel.
  Accordingly, the Company might not be able to manufacture sufficient quantities to meet
  its clinical trial needs or to commercialize its products;
- The Company's manufacturing facilities are required to undergo satisfactory current GMP inspections prior to regulatory approval and are obliged to operate in accordance with FDA, E.U. and other nationally mandated GMP, which govern manufacturing processes, stability testing, record keeping and quality standards. Failure to establish and follow GMPs and to document adherence to such practices, may lead to significant delays in the availability of material for clinical studies and may delay or prevent filing or approval of marketing applications for the Company's products; and
- Changing manufacturing locations would be difficult and the number of potential
  manufacturers is limited. Changing manufacturers generally requires re-validation of the
  manufacturing processes and procedures in accordance with FDA, E.U. and other
  nationally mandated GMPs. Such re-validation may be costly and would be time
  consuming. It would be difficult or impossible to quickly find replacement manufacturers
  on acceptable terms, if at all.

The Company's manufacturing facilities are subject to ongoing periodic unannounced inspection by the FDA and corresponding agencies, including E.U. and Canadian agencies, and may be subject to inspection by local, state, provincial and federal authorities from various jurisdictions to ensure strict compliance with GMPs and other government regulations. Failure by the Company to comply with applicable regulations could result in sanctions being imposed on it, including fines, injunctions, civil penalties, failure of the government to grant review of submissions or market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions, facility closures and criminal prosecutions, any of which could 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 vields, 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, our marketing partners are required to provide the Company with 12 to 24-month rolling forecasts of their demand on a quarterly basis, and are also required to place firm purchase orders with us based on the near-term portion of those forecasts. If wholesaler or market demand for these products is lower than forecasted, our marketing partners or their wholesaler customers may accumulate excess inventory. If such conditions persist, our 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 our results of operations were adversely affected. If such reductions occur again in the future, our revenues will be negatively impacted, we will lose our economies of scale, and our revenues may be insufficient to fully absorb our overhead costs, which could result in net losses. Conversely, if our marketing partners promote significantly increased demand, we may not be able to manufacture such unplanned increases in a timely manner, especially following prolonged periods of reduced demand. As we have no control over these factors, our purchase orders could fluctuate significantly from quarter-to-quarter, and the results of our 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 and Wanzleben, Germany, 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 us 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 us 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

# Inability to Achieve Drug Development Goals within Expected Time Frames

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

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

#### **Uncertainty of Drug Research and Development**

There can be no assurance that any of the Company's product candidates will be successfully developed in a timely manner or that they will prove to be more effective than products based on existing or new technologies or that a sufficient number of medical professionals will recommend their use. The risk that a product candidate may fail clinical trials, the Company may be unable to successfully complete development or a decision for financial or other reasons to halt development of any product candidate, particularly in instances where significant capital expenditures have already been made, could have a material adverse effect on the Company.

In December 2015, Nuvo announced that it failed to meet the primary endpoint in the 2015 WF10 Study. (See Overview – Crescita – Immunology Group). The Company will have product candidates that are at an early stage in the drug development process and have not progressed to the clinical trial phase of development. There can be no assurance that preclinical or clinical testing of the Company's product candidates will yield sufficiently positive results to enable progress toward commercialization and any such trials will take significant time to complete. Unsatisfactory results may prompt the Company to reduce or abandon future testing or commercialization of particular product candidates and this may have a material adverse effect on the Company.

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

may be unable to reasonably predict the total R&D costs to develop a particular product.

#### **Risk Related to Clinical Trials**

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

A number of companies in the biotechnology and pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials and preclinical studies. The Company suffered a similar setback with the recent results of its 2015 WF10 Study and the 2014 WF10 Study. (See Overview – Crescita – Immunology Group). In many cases where clinical results were not favourable, were perceived negatively or otherwise did not meet expectations, the share prices of these companies declined significantly. Failure to complete clinical trials successfully and to obtain successful results on a timely basis could have an adverse effect on the Company's future business and its common share price.

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

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

#### 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.

# Competition

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

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

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

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

# Competition for Pennsaid and Pennsaid 2%

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

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

In Canada, there are two generic versions of Pennsaid selling 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, Novartis' Voltaren Emulgel (1.16% w/w diclofenac diethylamine) has been available in Canada as an OTC since October 2008. In August 2014, Voltaren Emulgel Extra Strength (2.32% w/w diclofenac diethylamine) was approved in Canada as an OTC product and was launched by Novartis in October 2014. In the E.U., several major pharmaceutical companies market oral and topical NSAIDs that compete against Pennsaid in countries where it is marketed.

In addition to recently approved products, there may be other companies that are developing topical NSAID products for the U.S. and other markets that may present additional competition in the future.

Like Pennsaid and Pennsaid 2%, these drugs may be efficacious yet reduce the incidence of some of the side effects associated with oral NSAIDs.

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

# **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.

# **Reimbursement and Product Pricing**

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

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

Furthermore, even after approval for reimbursement for the Company's products is obtained from private health coverage insurers or government health authorities, it may be removed at any time. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products and there can be no assurance that third-party coverage will be sufficient to give the Company an appropriate return on its investment in developing existing or new products. Increasingly, government and other third-party payers are attempting to contain expenditures for new therapeutic products by limiting or refusing coverage, limiting reimbursement levels, imposing high co-pays, requiring prior authorizations and

implementing other measures. Inadequate coverage or reimbursement could adversely affect market acceptance of the Company's products. Third-party payers increasingly challenge the pricing of pharmaceutical products. Moreover, the trend toward managed healthcare in the U.S., the growth of organizations such as health maintenance organizations and reforms to healthcare and government insurance programs, could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for the Company's products.

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

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

#### **Potential Product Liability**

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

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

There can be no assurance that a product liability claim or series of claims brought against the Company would not have 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.

# 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.

# **International Operations**

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

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

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

#### **Taxes**

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

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

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

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

#### **Volatility of Share Price**

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

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 often 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.

# **Dilution from Further Equity Financing and Declining Share Price**

If the Company raises additional funding or completes an acquisition or merger by issuing additional equity securities, such issuance may substantially dilute the interests of shareholders of the Company and reduce the value of their investment. The market price of the Company's common shares could decline as a result of issuances of new shares or sales by existing shareholders of common shares in the

market or the perception that such sales could occur. Sales by shareholders might also make it more difficult for the Company itself to sell equity securities at a time and price that it deems appropriate.

# **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.

# **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 Co-Chief Executive Officers and Chief Financial Officer are required to report on the effectiveness of the Company's internal control over financial reporting.

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

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

### **Additional Risks**

Additional risks that could materially adversely affect the Company's business or an investment in its common shares include, but are not limited to:

- Changes in government regulation
- Ability to protect know how and trade secrets

- Rapid technological change could make products or drug delivery technology obsolete
- Prolonged development time
- Competition for the HLT Patch and Pliaglis
- Publications of negative study or clinical trial results
- Hazardous materials and environmental
- Operating losses
- Quarterly fluctuations
- Personnel
- Information technology infrastructure
- Issuance of preferred shares
- Absence of dividends
- Shareholders' rights plan
- Securities industry analyst research reports
- Public company requirements may strain resources
- Management of growth

# **Additional Information**

Additional information relating to the Company, including the Company's most recently filed AIF and Management Information Circular, can be found on SEDAR at www.sedar.com.

# **Management's Report**

The accompanying Consolidated Financial Statements have been prepared by management and approved by the Board of Directors of the Company. Management is responsible for the information and representations contained in these financial statements and the accompanying Management's Discussion and Analysis. The financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS). The significant accounting policies followed by the Company are set out in Note 3 to the Consolidated Financial Statements.

To assist management in discharging these responsibilities, the Company maintains a system of procedures and internal controls which are designed to provide reasonable assurance that its assets are safeguarded, that transactions are executed in accordance with management's authorization, and that the financial records form a reliable base for the preparation of accurate and timely financial information.

The Company's external auditors are appointed by the shareholders. They independently perform the necessary tests of accounting records and procedures to enable them to report their opinion as to the fairness of the consolidated financial statements and their conformity with IFRS.

The Board of Directors ensures that management fulfills its responsibilities for financial reporting and internal control. The Board of Directors exercises this responsibility through an Audit Committee composed of three Directors, all of whom are not involved in the day-to-day operations of the Company. The Audit Committee meets quarterly with management, and with external auditors to review audit recommendations and any matters that the auditors believe should be brought to the attention of the Board of Directors. The Audit Committee reviews the Consolidated Financial Statements and Management's Discussion and Analysis and recommends their approval to the Board of Directors.

Chairman and Co-Chief Executive Officer February 17, 2016

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President and Co-Chief Executive Officer February 17, 2016 Vice President and Chief Financial Officer February 17, 2016

#### INDEPENDENT AUDITORS' REPORT

#### To the Shareholders of Nuvo Research Inc.

We have audited the accompanying consolidated financial statements of **Nuvo Research Inc.** (the "Company"), which comprise the consolidated statements of financial position as at December 31, 2015 and 2014 and the consolidated statements of income (loss) and comprehensive income (loss), changes in equity and cash flows for the years ended December 31, 2015 and 2014, and a summary of significant accounting policies and other explanatory information.

#### Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with International Financial Reporting Standards, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditors' Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with Canadian generally accepted auditing standards. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditors considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained in our audits is sufficient and appropriate to provide a basis for our audit opinion.

#### Opinion

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Nuvo Research Inc. as at December 31, 2015 and 2014, and their financial performance and cash flows for the years ended December 31, 2015 and 2014 in accordance with International Financial Reporting Standards.

#### Emphasis of Matter

Without qualifying our opinion, we draw attention to Note 1 in the consolidated financial statements which indicates that the Company incurred a net loss of \$7,120,000 during the year ended December 31, 2015 and, as of that date the Company had an accumulated deficit of \$200,059,000. These conditions, along with other matters as set forth in Note 1, indicate the existence of a material uncertainty that may cast significant doubt about the Company's ability to continue as a going concern.

February 17, 2016 Toronto, Canada Crost + Young LLP
|| Chartered Professional Accountants |
| Licensed Public Accountants

# NUVO RESEARCH INC. CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

		As at December 31, 2015	As at December 31, 2014
(Canadian dollars in thousands)	Notes	\$	\$
ASSETS			
CURRENT			
Cash		48,680	48,275
Short-term investments	17	-	10,000
Accounts receivable	17	5,533	3,005
Inventories	4	2,402	1,929
Other current assets	5	1,337	770
TOTAL CURRENT ASSETS		57,952	63,979
NON-CURRENT			
Property, plant and equipment	6	1,180	1,161
TOTAL ASSETS		59,132	65,140
LIABILITIES AND EQUITY CURRENT			
Accounts payable and accrued liabilities	10	9,178	9,149
Current portion of other obligations	8	192	140
TOTAL CURRENT LIABILITIES	Ţ.	9,370	9,289
Other obligations	8	43	188
TOTAL LIABILITIES		9,413	9,477
EQUITY			
Common shares	9	234,763	233,568
Contributed surplus	9, 10	13,956	13,910
Accumulated other comprehensive income (AOCI)		1,059	1,124
Deficit		(200,059)	(192,939)
TOTAL EQUITY		49,719	55,663
TOTAL LIABILITIES AND EQUITY		59,132	65,140

Commitments (Note 16) See accompanying Notes.

On behalf of the Board of Directors

Anthony E. Dobranowski, Director

Dr. Klaus von Lindeiner, Director

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# NUVO RESEARCH INC. CONSOLIDATED STATEMENTS OF INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS)

		Year ended December 31, 2015	Year ended December 31, 2014
(Canadian dollars in thousands, except per share and share figures)	Notes	\$	\$
REVENUE			
Product sales		19,208	6,470
Royalties		1,390	5,458
Research and other contract revenue		754	505
Licensing fees	11	-	624
Total revenue		21,352	13,057
OPERATING EXPENSES			
Cost of goods sold	4, 10, 13	10,276	5,537
Research and development expenses	10, 13	10,329	8,051
General and administrative expenses	10, 13	9,295	12,978
Interest expense		40	713
Interest income		(515)	(199)
Total operating expenses		29,425	27,080
OTHER EXPENSES (INCOME)			
Litigation settlement, net	21	-	(52,343)
mpairment of intangible assets	7	-	1,664
Gain on disposal of property, plant and equipment	6	-	(296)
Foreign currency gain		(960)	(1,657)
Other income		(960)	(52,632)
Net income (loss) before income taxes		(7,113)	38,609
ncome tax expense		7	19
NET INCOME (LOSS)		(7,120)	38,590
Other comprehensive income (loss) to be reclassified to net income (loss) in subsequent periods		•	
Unrealized gains (losses) on translation of foreign operations		(65)	38
TOTAL COMPREHENSIVE INCOME (LOSS)		(7,185)	38,628
Net income (loss) per common share –			
- basic		\$(0.65)	\$3.85
- diluted		\$(0.65)	\$3.71
Average number of common shares outstanding (in thousands)			
- basic		10,942	10,031
- diluted		10,942	10,400

See accompanying Notes.

# NUVO RESEARCH INC. CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Common	Shares	Contributed Surplus	AOCI	Deficit	Total
(Canadian dollars in thousands, except for number of shares)	(000s)	\$	\$	\$	\$	\$
Notes	9, 10	9, 10	9, 10			
Balance, December 31, 2013	8,850	229,068	13,573	1,086	(231,529)	12,198
Shares issued, net of issue costs	1,390	2,582	-	-		2,582
Warrants issued, net of issuance costs	-	-	281	-	-	281
Warrants exercised Unrealized gains on translation of foreign	464	1,553	(174)	-	-	1,379
operations	-	-	-	38	-	38
Stock option compensation expense Performance stock unit compensation	-	-	274	-	-	274
expense	-	-	23	-	-	23
Shares issued under Share Bonus Plan Employee contributions to Share	10	57	(57)	-	-	-
Purchase Plan Employer's portion of Share Purchase	23	135	-	-	-	135
Plan	23	135	-	-	-	135
Stock options exercised	15	38	(10)	-	-	28
Net income	-	-	-	-	38,590	38,590
Balance, December 31, 2014	10,775	233,568	13,910	1,124	(192,939)	55,663
Warrants exercised Unrealized losses on translation of foreign	332	1,035	(116)	-	-	919
operations	-	-	-	(65)	-	(65)
Stock option compensation expense	-	-	177	-	-	177
Stock options exercised Employee contributions to Share	24	62	(15)	-	-	47
Purchase Plan Employer's portion of Share Purchase	7	49	-	-	-	49
Plan	7	49	-	-	-	49
Net loss		-		-	(7,120)	(7,120)
Balance, December 31, 2015	11,145	234,763	13,956	1,059	(200,059)	49,719

See accompanying Notes.

# NUVO RESEARCH INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

		Year ended December 31, 2015	Year ended December 31, 2014
(Canadian dollars in thousands)	Notes	\$	\$
OPERATING ACTIVITIES			
Net income (loss)		(7,120)	38,590
Items not involving current cash flows:			
Non-cash portion of litigation settlement	21	-	(43,554)
Impairment of intangible assets	7	-	1,664
Depreciation and amortization	6,13	313	715
Deferred license revenue recognized		-	(57)
Equity-settled stock-based compensation	10	226	432
Unrealized foreign exchange gain		(919)	(652)
Gain on disposal of property, plant and equipment	6	-	(296)
Inventory write-down	4	138	192
Interest and accretion of long-term other obligations		40	77
Other		31	16
		(7,291)	(2,873)
Net change in non-cash working capital	14	(3,341)	5,513
CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES		(10,632)	2,640
INVESTING ACTIVITIES			
Disposal (acquisition) of short-term investments	17	10,000	(10,000)
Acquisition of property, plant and equipment	6	(332)	(224)
Proceeds from sale of property, plant and equipment	6	-	378
Proceeds from disposal of asset held for sale, net	21	-	43,554
CASH PROVIDED BY INVESTING ACTIVITIES		9,668	33,708
FINANCING ACTIVITIES			
Issuance of common shares	9	96	3,026
Exercise of warrants	9	919	1,379
Repayment of other obligations	8	(188)	(5,220)
CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES		827	(815)
Effect of exchange rate changes on cash		542	121
Net change in cash during the year		405	35,654
Cash, beginning of year		48,275	12,621
CASH, END OF YEAR		48,680	48,275
Internat maid			700
Interest paid <sup>1</sup> Interest received <sup>1</sup>		- 542	700 149
Income taxes paid <sup>1</sup>		7	55

Amounts paid and received for interest and paid for income taxes were reflected as operating cash flows in the Consolidated Statements of Cash Flows.

See accompanying Notes.

# NUVO RESEARCH® INC. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Unless noted otherwise, all amounts shown are in thousands of Canadian dollars

# 1. NATURE OF BUSINESS AND GOING CONCERN ASSUMPTION

Nuvo Research Inc. (Nuvo or the Company) is a publicly traded, Canadian life sciences company with revenues and a diverse portfolio of topical products and technologies. The Company operates two distinct business units: Nuvo Pharmaceuticals (Nuvo Pharma) and Crescita Therapeutics (Crescita). Nuvo Pharma is a commercial healthcare business with three commercial products. Crescita is a drug development business that operates two sub-groups: the Topical Products and Technology (TPT) Group and the Immunology Group. The TPT Group has one commercial product, a pipeline of topical and transdermal products focusing on pain and dermatology and multiple drug delivery platforms that support the development of patented formulations that can deliver actives into or through the skin. The Immunology Group has two commercial products. The Company's registered office and principal place of business is located at 7560 Airport Road, Unit 10, Mississauga, Ontario, L4T 4H4.

# **Proposed Reorganization**

On December 14, 2015, Nuvo, 2487002 Ontario Limited and 2487001 Ontario Limited entered into the Arrangement Agreement in respect of the proposed reorganization of Nuvo into two separate publicly-traded companies, Nuvo Pharma and Crescita. The obligation of Nuvo to complete this reorganization is subject to receipt of a number of approvals and fulfillment of a number of conditions, including the approval of the Ontario Superior Court of Justice, the final approval of the Toronto Stock Exchange and the approval of Nuvo's shareholders. If the reorganization is approved by shareholders and all other conditions are satisfied, Nuvo expects the reorganization to be completed in the first quarter of 2016. However, there can be no assurances regarding the ultimate timing of the reorganization or that the reorganization will be completed at all. Even if the reorganization is approved by shareholders and all other conditions are satisfied, Nuvo's Board of Directors will have the authority to determine when to effect the reorganization, as well as the authority to decide not to proceed with the reorganization at all.

If the proposed reorganization proceeds, there will be a significant and material effect on the operations and results of Nuvo. Detailed information regarding the proposed reorganization and its effects including a description of certain risks and uncertainties in respect of the reorganization and the operation of Nuvo Pharma and Crescita as separate publicly traded companies are included in the information circular dated December 31, 2015 that is available under Nuvo's profile at <a href="https://www.sedar.com">www.sedar.com</a>.

# **Nuvo Pharma**

Nuvo Pharma is a commercial healthcare business with a portfolio of products and pharmaceutical manufacturing capabilities. Nuvo Pharma 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%

Pennsaid 2% is the follow-on product to original Pennsaid (described below). Pennsaid 2% is a topical non-steroidal anti-inflammatory drug (NSAID) containing 2% diclofenac sodium compared to 1.5% for original Pennsaid. Pennsaid 2% 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. Under the terms of the settlement agreement, Mallinckrodt paid US\$10.0 million to settle the claims and returned the sales and marketing rights for Pennsaid 2% to Nuvo (see Note 21, *Litigation Settlement*). In October 2014, the Company sold the U.S. rights to Pennsaid 2% to Horizon Pharma plc (Horizon) for US\$45.0 million (see Note 22, *Pennsaid 2% U.S. Asset Sale*). In January 2015, Horizon launched its commercial sale and marketing of Pennsaid 2% in the U.S. Pennsaid 2% is currently manufactured by the Company for sale to Horizon. Pennsaid 2% is not approved in any country outside of the U.S.

#### Pennsaid

Pennsaid is a topical NSAID containing 1.5% diclofenac sodium and is used to treat the signs and symptoms of OA of the knee. It is approved for sale and marketing in several countries including Canada, where it is licensed to Paladin Labs Inc. (Paladin). As a result of the litigation settlement with Mallinckrodt, the U.S. sales and marketing 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.

# **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 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 European-based licensee, Eurocept International B.V. (Eurocept), under the brand name Rapydan.

#### Crescita

Crescita is a drug development business that operates two sub-groups: the TPT Group and the Immunology Group.

# **Topical Products and Technology Group**

The TPT Group has one commercial product: Pliaglis. Pliaglis is a topical local anaesthetic cream that provides safe and effective local dermal anaesthesia on intact skin prior to superficial dermatological procedures, such as dermal filler injections, pulsed-dye laser therapy, facial laser resurfacing and laser-assisted tattoo removal. Except as described below, Galderma S.A. (Galderma) holds the worldwide marketing rights to Pliaglis. Pliaglis is approved for sale and marketing in the U.S., several Western European countries, Argentina, Brazil and Canada. Galderma launched the commercial sale and marketing of Pliaglis in the U.S., Canada and multiple countries in the European Union and South America. In December, the Company reacquired the Pliaglis development and marketing rights from Galderma for the U.S., Canada and Mexico (see Note 11, License Fees). The TPT Group is developing drugs for a variety of therapeutic areas with a focus on dermatology and pain.

# **Immunology Group**

The Immunology Group has two commercial products: WF10™ and Oxoferin™. WF10 is approved in Thailand under the brand name Immunokine as an adjunct in the treatment of cancer to relieve post radiation therapy syndromes and as an adjunct therapy for diabetic foot ulcers, but is not otherwise approved for sale and marketing in any other jurisdictions. Oxoferin, a topical wound healing agent, contains the active ingredient in WF10, but at a lower concentration. Oxoferin is marketed by Nuvo and its partners in parts of the E.U. and Asia as a topical wound healing agent under the trade names Oxoferin and Oxovasin™.

The Immunology Group was focused on developing drug products that modulate chronic inflammation processes resulting in a therapeutic benefit including the development of WF10 for the treatment of allergic rhinitis. In December 2015, the Company announced topline results of a Phase 2 clinical trial to assess WF10 for the treatment of allergic rhinitis. The topline 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 study. 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 study. Nuvo believes that the results do not justify the further development of WF10 for the treatment of allergic rhinitis and has discontinued all WF10 development.

Subsequent to the year ended December 31, 2015 Nuvo's Board of Directors unanimously approved a proposal to initiate a divestiture or orderly wind down of the Company's Immunology Group. While the Company continues to explore a possible sale of the Immunology Group, if a divestiture transaction does not materialize, the wind down of the Immunology operations is expected to be completed by the end of 2016 (see Note 24, *Subsequent Event – Disposal of Immunology Group*).

# **Going Concern**

These Consolidated Financial Statements have been prepared on a going-concern basis, which presumes that the Company will be able to realize its assets and discharge its liabilities in the normal course of operations for the

foreseeable future. As at December 31, 2015, the Company had an accumulated deficit of \$200,059 including a net loss of \$7,120 in 2015. The Company's ability to continue as a going concern depends on:

- the commercial success of Pennsaid 2% in the U.S., as the Company earns revenue from product sales
  of Pennsaid 2% to Horizon;
- the commercial success of Pennsaid outside of the U.S., as the Company earns revenue from sales of Pennsaid to its licensees and distributors in all territories where Pennsaid is sold, as well as royalties on net sales in Canada;
- the success of the Company's clinical trial for Pennsaid 2% for the treatment of acute sprains and strains;
- its ability to secure additional licensing fees, secure co-development agreements, obtain additional capital when required, gain regulatory approval for other drugs and ultimately achieve profitable operations.

As there can be no certainty as to the outcome of the above matters, there is material uncertainty that may cast significant doubt about the Company's ability to continue as a going concern.

The Company anticipates that its current cash, together with the revenues it expects to generate from product sales and royalties, will be sufficient to execute its current business plan into 2017. Beyond that date, there can be no assurance that the Company will have sufficient capital to fund its ongoing operations or develop or commercialize any further products without future financings.

There can be no assurance that additional financing would be available on acceptable terms or at all, when and if required. If adequate funds are not available when required, the Company may have to substantially reduce or eliminate planned expenditures, terminate or delay clinical trials for its product candidates, curtail product development programs designed to expand the product pipeline or discontinue certain operations. If the Company is unable to obtain additional financing when and if required, the Company may be unable to continue operations.

These Consolidated Financial Statements do not include any adjustments to the amounts and classification of assets and liabilities that would be necessary should the Company be unable to continue as a going concern.

# 2. BASIS OF PREPARATION

# **Statement of Compliance**

These Consolidated Financial Statements have been prepared by management in accordance with International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board (IASB).

The policies applied to these Consolidated Financial Statements are based on IFRS, which have been applied consistently to all periods presented. These Consolidated Financial Statements were issued and effective as at February 17, 2016, the date the Board of Directors approved the Consolidated Financial Statements.

# 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### **Basis of Measurement**

These Consolidated Financial Statements have been prepared under the historical cost convention, except for the revaluation of certain financial assets and financial liabilities to fair value. Items included in the financial statements of each consolidated entity in the Company are measured using the currency of the primary economic environment in which the entity operates (the functional currency). These Consolidated Financial Statements are presented in Canadian dollars, which is the Company's functional currency.

# **Use of Estimates and Judgments**

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the Consolidated Financial Statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from estimates, and such differences could be material.

Key areas of estimation or use of managerial assumptions are as follows:

# (i) Change in Operating Segments

During 2015, the Board of Directors of Nuvo unanimously approved a proposed reorganization of Nuvo into two separate publicly traded companies. This organizational realignment gave rise to changes in how the Company presents information for financial reporting and management decision-making purposes and resulted in a change in the Company's reporting segments. The realignment resulted in two operating segments: i) Nuvo Pharma and ii) Crescita. Historically, the Company operated under two distinct business units: i) the TPT Group and ii) the Immunology Group. These business units will remain operating segments of Crescita. The Nuvo Pharma segment comprises the Company's manufacturing facility in Varennes, Quebec and includes the Company's Pennsaid, Pennsaid 2% and HLT Patch franchises. Corporate overhead costs are allocated to Nuvo Pharma and Crescita's TPT Group. All prior period segment disclosures have been restated to reflect the changes in the Company's operating segments. The change did not impact the Consolidated Financial Statement results. See Note 19, Segmented Information, for further discussion.

# (ii) Share-based Payments:

The Company measures the cost of share-based payments, either equity or cash-settled, with employees by reference to the fair value of the equity instrument or underlying equity instrument at the date on which they are granted. In addition, cash-settled share-based payments are revalued to fair value at every reporting date.

Estimating fair value for share-based payments requires management to determine the most appropriate valuation model for a grant, which is dependent on the terms and conditions of each grant. In valuing certain types of stock-based payments, such as incentive stock options and stock appreciation rights, the Company uses the Black-Scholes option pricing model.

Several assumptions are used in the underlying calculation of fair values of the Company's stock options and stock appreciation rights using the Black-Scholes option pricing model, including the expected life of the option, stock price volatility and forfeiture rates.

### (iii) Revenue Recognition:

As is typical in the pharmaceutical industry, the Company's royalty streams are subject to a variety of deductions that are generally estimates and recorded in the same period that the revenues are recognized and primarily represent rebates, discounts and incentives and product returns. These deductions represent estimates of the related obligations. Amounts recorded for sales deductions can result from a complex series of judgments about future events and uncertainties and can rely on estimates and assumptions.

# (iv) Intangible Assets:

The Company determines fair values based on discounted cash flows, market information, independent valuations and management's estimates. The values calculated for intangible assets involve significant estimates and assumptions, including those with respect to future cash flows, discount rates and asset lives. These significant estimates and judgments could impact the Company's future results if the current estimates of future performance and fair values change and could affect the amount of amortization expense on intangible assets in future periods.

# (v) Cash-generating Units:

The identification of cash-generating units (CGUs) within the Company requires considerable judgment. Under IFRS, management must determine the smallest group of assets that generate independent cash inflows. Management first considers the Company's commercialized products, and then determines the operations that contribute to each product's revenue base and net cash inflows. Management has identified three CGUs: the U.S. operations dedicated to generating cash inflows for Synera and Pliaglis, the manufacturing facility in Québec that generates cash inflows for Pennsaid and Pennsaid 2% and the Immunology Group that generates cash inflows for WF10.

# (vi) Impairment of Non-financial Assets:

The Company reviews the carrying value of non-financial assets for potential impairment when events or changes in circumstances indicate that the carrying amount may not be recoverable. The impairment test on CGUs is carried out by comparing the carrying amount of the CGU and its recoverable amount. The recoverable amount of a CGU is the higher of fair value, less costs to sell, and its value in use. This complex valuation process entails the use of methods, such as the discounted cash flow method, which requires numerous assumptions to estimate

future cash flows. The recoverable amount is impacted significantly by the discount rate selected to be used in the discounted cash flow model, as well as the quantum and timing of expected future cash flows and the growth rate used for the extrapolation.

#### **Basis of Consolidation**

These Consolidated Financial Statements include the accounts of the Company and all of its subsidiaries as follows:

	% Ownership	
	December 31, 2015	December 31, 2014
Nuvo Research America, Inc. and its subsidiaries: Nuvo Research US, Inc., ZARS Pharma, Inc., and ZARS (UK) Limited	100%	100%
Dimethaid (UK) Ltd.	100%	100%
Dimethaid Immunology Inc.	100%	100%
Nuvo Research AG and its subsidiaries:  Nuvo Manufacturing GmbH and Nuvo Research GmbH	100%	100%

The Company controls the subsidiaries above with the power to govern their financial and operating policies. All significant inter-company balances and transactions have been eliminated upon consolidation.

# **Foreign Currency Translation**

The Company and its subsidiary companies each determine their functional currency based on the currency of the primary economic environment in which they operate. The Company's functional currency is the Canadian dollar, while subsidiary companies' functional currencies are either the Canadian dollar, U.S. dollar or the euro.

# (i) Transactions

Transactions denominated in a currency other than the functional currency of an entity are translated at exchange rates prevailing at the time the transaction occurred. The resulting exchange gains and losses are included in each entity's net income (loss) in the period in which they arise.

### (ii) Translation into Presentation Currency

The Company's foreign operations are translated to the Company's presentation currency, which is the Canadian dollar, for inclusion in the Consolidated Financial Statements. Foreign denominated monetary and non-monetary assets and liabilities of foreign operations are translated at exchange rates in effect at the end of the reporting period, and revenue and expenses are translated at the average exchange rate for the period (as this is considered a reasonable approximation to actual rates). The resulting translation gains and losses are included in other comprehensive income (OCI) with the cumulative gain or loss reported in accumulated other comprehensive income (AOCI).

When the Company disposes of its entire interest in a foreign operation or loses control or influence over a foreign operation, the foreign currency gains or losses in AOCI related to the foreign operation are recognized in profit or loss. If the Company disposes of part of an interest in a foreign operation that remains a subsidiary, the proportionate amount of foreign currency gains or losses in AOCI related to the subsidiary are reallocated between controlling and non-controlling interests.

#### Cash

Cash includes cash on hand and current balances with banks and similar institutions. They are readily convertible into known amounts of cash and have an insignificant risk of changes in value. Cost approximates fair value.

# **Short-term Investments**

Short-term investments are held in highly liquid instruments such as guaranteed investment certificates or other securities, held primarily with Schedule 1 Canadian banks, with an original term to maturity of more than three months and remaining term to maturity of less than one year.

#### Inventories

Inventories include raw materials, work-in-process and finished goods. Raw materials are stated at the lower of cost and replacement cost with cost determined on a first-in, first-out basis. Manufactured inventory (finished goods and work-in-process) is valued at the lower of cost and net realizable value determined on a first-in, first-out basis. Manufactured inventory cost includes the cost of raw materials, direct labour, an allocation of overhead and the cost to acquire finished goods. The Company monitors the shelf life and expiry of finished goods to determine when inventory values are not recoverable and a write-down is necessary.

# Property, Plant and Equipment

Property, plant and equipment (PP&E) is recorded at cost. Assets acquired under finance leases are carried at cost, which is the present value of minimum lease payments after deduction of any executory costs.

The Company allocates the amount initially recognized in respect of an item of PP&E to its significant parts and amortizes separately each such part. Depreciation of PP&E is provided for over the estimated useful lives from the date the assets becomes available for use as follows:

Buildings	10 to 25 years	Straight line
Leasehold improvements	Term of lease	Straight line
Furniture and fixtures	5 years	Straight line
Computer equipment and software	1 to 3 years	Straight line
Production, laboratory and other equipment	3 to 5 years	Straight line

Residual values, method of depreciation and useful lives of the assets are reviewed annually and adjusted if appropriate.

### **Intangible Assets**

Intangible assets acquired in a business combination are recognized separately from goodwill at their fair value at the date of acquisition, which is considered to be cost. Intangible assets consist of the costs to acquire intellectual property under a business acquisition. Amortization commences when the intangible asset is available for use and for patented assets is computed on a straight-line basis over the intangible asset's estimated useful life, which cannot exceed the lesser of the remaining patent life and 20 years.

# **Impairment of Non-financial Assets**

The Company reviews the carrying value of non-financial assets for potential impairment when events or changes in circumstances indicate that the carrying amount may not be recoverable. For the purpose of measuring recoverable amounts, assets are grouped at the lowest levels for which there are separately identifiable cash flows (or CGUs). The recoverable amount is the higher of an asset's fair value less costs to sell and value in use (being the present value of the expected future cash flows of the relevant asset or CGU). An impairment loss is recognized for the amount by which the asset's carrying value exceeds its recoverable amount.

A previously recognized impairment loss is reversed only if there has been a change in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized. If this is the case, the carrying amount of the asset is increased to its recoverable amount but cannot exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset in prior years. An impairment reversal is recognized as other income.

#### Leases

Leases are classified as finance leases whenever the terms of the lease transfer substantially all the risks and rewards of ownership to the Company. All other leases are classified as operating leases. The capitalized finance lease obligation reflects the present value of future lease payments, discounted at the appropriate interest rate. Assets under finance leases are amortized over the term of the lease. All other leases are accounted for as operating leases with rental payments being expensed on a straight-line basis.

#### **Financial Instruments**

All financial instruments are classified into one of the following five categories: fair value through profit or loss (FVTPL), held-to-maturity investments, loans and receivables, available-for-sale assets or other financial liabilities. All financial instruments, including derivatives, are included on the Consolidated Statements of Financial Position and are measured at fair market value upon inception. Subsequent measurement and

recognition of changes in the fair value of financial instruments depends on their initial classification. FVTPL financial investments are measured at fair value, and all gains and losses are included in operations in the period in which they arise. Available-for-sale financial instruments are measured at fair value with revaluation gains and losses included in OCI until the asset is removed from the Consolidated Statements of Financial Position. Loans and receivables, instruments held to maturity and other financial liabilities are measured at amortized cost using the effective interest method. Gains and losses upon inception, impairment write-downs and foreign exchange translation adjustments are recognized immediately.

The Company classifies its financial instruments as follows:

- Cash and accounts receivable are classified as loans and receivables and are measured at amortized cost. Interest income is recorded in net income (loss), as applicable.
- Short-term investments are classified as held to maturity and are measured at amortized cost. Interest income is recorded in net income (loss), as applicable.
- Accounts payable, accruals, long-term obligations and finance lease obligations are classified as other financial liabilities and are measured at amortized cost using the effective interest method. Interest expense is recorded in net income (loss), as applicable.

Financing costs associated with the issuance of debt are netted against the related debt and are deferred and amortized over the term of the related debt using the effective interest method.

#### **Impairment of Financial Assets**

At each reporting date, the Company assesses whether there is objective evidence that a financial asset is impaired. If such evidence exists, the Company recognizes an impairment loss. For financial assets carried at amortized cost, the loss is the difference between the amortized cost of the loan or receivable and the present value of the estimated future cash flows, discounted using the instrument's original effective interest rate. The carrying value of the asset is reduced by this amount either directly or indirectly through the use of an allowance account.

# **Comprehensive Income (Loss)**

Comprehensive income (loss) is the change in equity from transactions and other events and circumstances from non-shareholder sources. Other comprehensive income (loss) refers to items recognized in comprehensive income (loss), but that are excluded from net income (loss) calculated in accordance with IFRS. The resulting changes from translating the financial statements of foreign operations to the Company's presentation currency of Canadian dollars are recognized in comprehensive income (loss) for the year.

### **Revenue Recognition**

The Company recognizes revenue from product sales, royalties, research and development (R&D) collaborations and licensing arrangements, which may include multiple elements. Revenue arrangements with multiple elements are reviewed in order to determine whether the multiple elements can be divided into separate units of accounting, if certain criteria are met. If separable, the consideration received is allocated amongst the separate units of accounting based on their respective fair values, and the applicable revenue recognition criteria is applied to each of the separate units. If not separable, the applicable revenue recognition criteria are applied to combined elements as a single unit of accounting.

#### **Product Sales**

Revenue from product sales is recognized upon shipment of the product to the customer, provided transfer of title to the customer occurs upon shipment and provided the Company has not retained any significant risks of ownership or future obligations with respect to the product shipped, the price is fixed and determinable and collection is reasonably assured. Where applicable, revenue from product sales is recognized net of reserves for estimated sales discounts and allowances, returns, rebates and chargebacks.

#### Royalties

Revenue arising from royalties is recognized when reasonable assurance exists regarding measurement and collectability. Royalties are typically calculated as a percentage of net sales realized by the Company's licensees of its products (including their sublicensees), as specifically defined in each agreement. The licensees' sales generally consist of revenues from product sales of the Company's pharmaceutical products, and net sales are determined by deducting the following: estimates for chargebacks, rebates, sales incentives and allowances, returns and losses and other customary deductions in each region where the Company has licensees. While the Company receives royalty payments quarterly, it can only recognize the amounts as revenue when reasonable

assurance exists regarding measurement and collectability. Royalty revenue from the launch of a product in a new territory, for which the Company or its licensee are unable to develop the requisite historical data on which to base estimates of returns, may be deferred until such time that a reasonable estimate can be made and once the product has achieved market acceptance. Any royalty payments received or receivable in advance of when they would be recognized as revenue are recorded in deferred revenue.

# Licensing and Collaboration Arrangements

The Company may enter into licensing and collaboration agreements for product development, licensing, supply and distribution for its commercial products and product pipeline. The terms of the agreements may include non-refundable signing and licensing fees, milestone payments and royalties on any product sales derived from collaborations. These multiple-element arrangements are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting. License fees are recognized as revenue when persuasive evidence of an arrangement exists, the fee is fixed or determinable, delivery or performance has substantially completed and collection is reasonably assured. If there are no substantive performance obligations over the life of the contract, the up-front non-refundable payment is recognized when the underlying performance obligation is satisfied. If substantive contractual obligations are satisfied over time or over the life of the contract, revenue may be deferred and recognized over the performance. The term over which upfront fees are recognized is revised if the period over which the Company maintains substantive contractual obligations changes.

Milestone payments are immediately recognized as licensing revenue when the condition is met, if the milestone is not a condition to future deliverables and collectability is reasonably assured. Otherwise, they are recognized over the remaining term of the agreement or the performance period.

# Research and Other Contract Revenue

Revenues from R&D collaborations are generally recognized as the contracted services are performed, and the related expenditures are incurred pursuant to the terms of the agreement and provided collectability is reasonably assured.

# **Research and Development**

Research costs, other than capital expenditures, are charged to operations as incurred. Expenditures on internally developed products are capitalized if it can be demonstrated that:

- it is technically feasible to develop the product for it to be sold:
- adequate resources are available to complete the development;
- there is an intention to complete and sell the product;
- the Company is able to sell the product:
- sale of the product will generate future economic benefits; and
- expenditure on the project can be measured reliably.

Development expenses are charged to operations as incurred unless such costs meet the criteria for deferral and amortization. No development costs have been deferred to-date.

# **Government Assistance**

Government assistance received under incentive programs, including investment tax credits for qualifying R&D activities, is accounted for using the cost reduction method; whereby, the assistance is netted against the related expense or capital expenditure to which it relates when there is reasonable assurance that the credits will be realized.

Government assistance received under reimbursement or funding programs are accounted for using the cost reduction method; whereby, a receivable is set up as the costs are incurred based on the terms of reimbursement or funding program and the expected recoveries are netted against the related expense.

# **Net Income or Loss Per Common Share**

Basic net income or loss per common share is calculated using the weighted average number of common shares outstanding during the year.

Diluted net income or loss per common share is calculated assuming the weighted average number of common shares outstanding during the year is increased to include the number of additional common shares that would have

been outstanding if the dilutive potential shares had been issued. The dilutive effect of warrants, stock options and performance share units is determined using the treasury-stock method. The treasury-stock method assumes that the proceeds from the exercise of warrants and options are used to purchase common shares at the volume weighted average market price during the year. The dilutive effect of convertible securities is determined using the "if-converted" method. The "if-converted" method assumes that the convertible securities are converted into common shares at the beginning of the period and all income charges related to the convertible securities are added back to income.

# **Income Taxes**

Income taxes on profit or loss include current and deferred taxes. Income taxes are recognized in profit or loss except to the extent that they relate to business combinations or items recognized directly in equity or in OCI. Current tax is the expected tax payable or receivable on the taxable income or loss for the period, using tax rates enacted or substantively enacted at the reporting date and any adjustment to tax payable in respect of previous years. The Company is subject to withholding taxes on certain forms of income earned under its in-licensing agreements from foreign jurisdictions.

Deferred tax is generally recognized in respect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax is measured at the tax rates that are expected to be applied to temporary differences when they reversed, based on the laws that have been enacted or substantively enacted in the relevant jurisdiction by the reporting date.

Deferred tax assets and liabilities are recognized where the carrying amount of an asset or liability in the Consolidated Statements of Financial Position differs from its tax base, except for differences arising on:

- the initial recognition of goodwill;
- the initial recognition of an asset or liability in a transaction that is not a business combination and at the time of the transaction affects neither accounting or taxable profit; and
- investments in subsidiaries, branches and associates, and interests in joint ventures where the Company is
  able to control the timing of the reversal of the difference and it is probable that the difference will not
  reverse in the foreseeable future.

A deferred tax asset is recognized for unused tax losses, tax credits and deductible temporary differences, to the extent probable that future taxable income will be available against which they can be utilized. Deferred tax assets are reviewed at each reporting date and are reduced to the extent it is no longer probable the related tax benefit will be realized.

# Stock-based Compensation and Other Stock-based Payments

The Company has six stock-based compensation plans: the Share Option Plan, the Share Purchase Plan and the Share Bonus Plan, each a component of the Company's Amended and Restated Share Incentive Plan, the Deferred Share Unit (DSU) Plan for non-employee directors, the Deferred Share Unit Plan for employees and the Stock Appreciation Rights (SARs) Plan. All are described in Note 10.

## Share Incentive Plan

The Company measures and recognizes compensation expense for the Share Incentive Plan based on the fair value of the common shares or options issued.

Under the Share Option Plan, the Company issues either fixed awards or performance-based options. Options vest either immediately upon grant or over a period of one to four years or upon the achievement of certain performance related measures or milestones. Each tranche in an award is considered a separate award with its own vesting period and grant date fair value. Fair value of each tranche is measured at the date of grant using the Black-Scholes option pricing model. Compensation expense is recognized over the tranche's vesting period based on the number of awards expected to vest, by increasing contributed surplus. When options are exercised, the proceeds received by the Company, together with the fair value amount in contributed surplus, are credited to common shares.

Under the Share Purchase Plan, consideration paid by employees on the purchase of common shares is credited to common shares when the shares are issued. The fair value of the Company's matching contribution, determined based upon the trading price of the common shares, is recorded as compensation expense. These expenses are included in stock-based compensation expense and credited to common shares.

Under the Share Bonus Plan, the fair value of the direct award of common shares, determined based upon the trading price of the common shares, is recorded as compensation expense. These expenses are included in stock-based compensation expense and credited to contributed surplus over the vesting period, until the common shares are issued and the value is transferred from contributed surplus to common shares.

# Deferred Share Unit Plan

The DSU Plan consists of two plans: one for non-employee directors and one for employees. Under the DSU Plan, the Company issues DSUs to non-employee directors based on value of services provided and to employees based on their elected portion of quarterly earnings they wish to receive in units of the DSU plan. DSUs are intended to be settled in cash and recorded as liabilities and included in accounts payable and accrued liabilities. Upon issuance, the fair value of the DSUs is recorded as compensation expense and a corresponding liability (the DSU Accrual) is established. At all subsequent reporting dates, the DSU Accrual is adjusted for movements in fair value, with the amount of the adjustment charged to compensation expense.

### Stock Appreciation Rights Plan

SARs are issued to directors, officers, employees or designated affiliates to provide incentive compensation based on the appreciation in value of the Company's common shares. Under the SARs Plan, participants receive, upon vesting, a cash amount equal to the difference between the SARs' fair market value and the grant price value, also known as the intrinsic value. Fair market value is determined by the closing price of the Company's common share on the Toronto Stock Exchange (TSX) on the day preceding the exercise date. SARs vest in tranches prescribed at grant date, and each tranche is considered a separate award with its own vesting period and fair value. Until SARs vest, compensation expense is measured based on the fair value of the SARs at the end of each reporting period, using a Black-Scholes option pricing model. The fair value of the liability is remeasured at the end of each reporting date and adjusted at the settlement date, when the intrinsic value is realized. The SARs accrual is included in accounts payable and accrued liabilities.

# **Issuance Costs of Equity Instruments**

The Company records issuance costs of equity instruments against the equity instrument that was issued.

# **Accounting Standards Adopted**

There were no new accounting standards adopted by the Company during 2015.

# **Significant Accounting Policies**

All significant accounting policies have been applied on a basis consistent with those followed in the most recent annual Consolidated Financial Statements. The policies applied in these Consolidated Financial Statements are based on IFRS issued and outstanding as at February 18, 2016, the date the Board of Directors approved these Consolidated Financial Statements.

# **Accounting Standards Issued But Not Yet Applied**

Certain new standards, interpretations, amendments and improvements to existing standards were issued by the IASB or IFRS Interpretations Committee (IFRIC) that are not yet effective and have not yet been early adopted by the Company. The standards impacted that may be applicable to the Company are as follows:

# IFRS 9 - Financial Instruments

In October 2010, the IASB issued IFRS 9, which replaces IAS - 39 *Financial Instruments: Recognition and Measurement.* IFRS 9 establishes principles for the financial reporting of financial assets and financial liabilities that will present relevant and useful information to users of financial statements for their assessment of the amounts, timing and uncertainty of an entity's future cash flows. This new standard is effective for the Company's interim and annual financial statements commencing January 1, 2018. The Company is in the process of reviewing the standard to determine the impact on the Consolidated Financial Statements.

# IFRS 15 - Revenue from Contracts with Customers

In May 2014, the IASB issued IFRS 15 - Revenue from Contracts with Customers, which covers principles for reporting about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. IFRS 15 is effective for annual periods beginning on or after January 1, 2018, with earlier adoption permitted. Entities will transition following either a full or modified retrospective approach. The Company is in the process of reviewing the standard to determine the impact on the Consolidated Financial Statements.

#### IFRS 16 - Leases

In January 2016, the IASB has issued IFRS 16 - *Leases*, its new leases standard that requires lessees to recognize assets and liabilities for most leases on their balance sheets. Lessees applying IFRS 16 will have a single accounting model for all leases, with certain exemptions. Lessor accounting is substantially unchanged. The new standard will be effective from January 1, 2019 with limited early application permitted. The Company is in the process of reviewing the standard to determine the impact on the Consolidated Financial Statements.

Other accounting standards or amendments to existing accounting standards that have been issued, but have future effective dates, are either not applicable or are not expected to have a significant impact on the Company's Consolidated Financial Statements.

#### 4. INVENTORIES

Inventories consist of the following as at:

	December 31, 2015	December 31, 2014
	\$	\$
Raw materials	1,205	515
Work-in-process	349	146
Finished goods	848	1,268
	2,402	1,929

During the year ended December 31, 2015, inventories in the amount of \$9.3 million were recognized as cost of goods sold [December 31, 2014 - \$4.5 million]. For the Nuvo Pharma Group, \$3 of raw materials were written down during the year ended December 31, 2015 [December 31, 2014 - \$138] and there were no reversals of prior write-downs during the years ended December 31, 2015 and 2014. In Crescita, during the year ended December 31, 2015, \$7 (€5) of raw materials and \$128 (€89) of finished goods were written down [December 31, 2014 - \$54 (€38) of finished goods] and no reversals of prior write-downs occurred during the years ended December 31, 2015 and 2014. All Crescita inventories relate to the Immunology Group.

# 5. OTHER CURRENT ASSETS

Other current assets consist of the following as at:

	December 31, 2015	December 31, 2014
	\$	\$
Deposits <sup>(i)</sup>	728	45
Other receivables <sup>(ii)</sup>	468	543
Prepaid expenses	141	182
	1,337	770

<sup>(</sup>Included \$588 [December 31, 2014 - \$nil] related to taxes owed to the Canada Revenue Agency (CRA) for fiscal 2014. As part of the Company's tax filings for the 2014 fiscal year, the Company amended its tax filings from fiscal 2009 to 2013 (Amended Returns) that resulted in additional non-capital losses. Subsequent to the year end, the Company received a full refund of this deposit from the CRA.

<sup>(</sup>ii) Included \$nil [December 31, 2014 - \$223] related to R&D expenditures for which the Company was eligible for reimbursement under funding agreements with the Development Bank of Saxony (SAB) that expired in October 2014 for the development of WF10 related projects.

# 6. PROPERTY, PLANT AND EQUIPMENT

PP&E consists of the following:

	Land <sup>(ii)</sup>	Buildings	Leasehold Improvements	Furniture & Fixtures	Computer Equipment	Production Laboratory & Other Equipment <sup>(i)</sup>	Total
Cost	\$	\$	\$	\$	\$	\$	\$
Balance, December 31, 2013	124	2,082	114	271	1,004	3,522	7,117
Foreign exchange movements	-	(38)	-	(1)	(2)	(9)	(50)
Additions	-	15	-	-	37	172	224
Disposals	(82)	-	-	-	-	-	(82)
Balance, December 31, 2014	42	2,059	114	270	1,039	3,685	7,209
Foreign exchange	-	61	-	4	4	23	92
Additions	-	242	-	-	22	68	332
Disposals	-	(28)	-	-	-	(4)	(32)
Balance, December 31, 2015	42	2,334	114	274	1,065	3,772	7,601
Accumulated depreciation							
Balance, December 31, 2013	-	1,570	114	268	958	2,796	5,706
Foreign exchange movements	-	(37)	-	(3)	(1)	(7)	(48)
Depreciation expense	-	58	-	2	30	300	390
Balance, December 31, 2014	-	1,591	114	267	987	3,089	6,048
Foreign exchange	-	59	-	4	3	21	87
Depreciation expense	-	62	-	1	25	225	313
Disposals	-	(27)	-	-	-	-	(27)
Balance, December 31, 2015	-	1,685	114	272	1,015	3,335	6,421
NBV as at December 31, 2014	42	468	-	3	52	596	1,161
NBV as at December 31, 2015	42	649	-	2	50	437	1,180

Production, laboratory and other equipment as at December 31, 2015 included a cost of \$35 [December 31, 2014 - \$56] and accumulated depreciation of \$25 [December 31, 2014 - \$55] for assets under finance leases. Depreciation of PP&E was \$1 for the year ended December 31, 2015 [December 31, 2014 - \$2] related to assets under finance leases.

In the year ended December 31, 2014, the Company sold a portion of unused land at its manufacturing site in Varennes, Québec for proceeds of \$0.4 million and recognized a gain on the sale of the land of \$0.3 million.

# 7. IMPAIRMENT OF INTANGIBLE ASSETS

The Company reviewed the carrying values of the intangible assets for potential impairment at December 31, 2014 as sales for the HLT Patch and Pliaglis were not meeting expectations. Commercial strategies for both products produced revenues that were lower than expected, and the costs to maintain the intellectual property and regulatory commitments exceeded royalties earned. Indications for impairment did exist, and management determined that each asset was impaired, such that recoverable amounts were lower than the carrying amounts. The recoverable amount and value in use (being the present value of expected future cash flows) was calculated using best estimates for future periods based on discussions with licensing partners, knowledge of historical results and expectations for the future, net of direct costs forecasted by management, assuming declining revenues, discounted at an after-tax rate of 19% which approximated the Company's current weighted average cost of capital. As at December 31, 2014, the Company recorded an impairment charge for the HLT Patch of \$462 and an impairment charge for Pliaglis of \$1,202 in impairment of intangible assets in the Consolidated Statements of Income (Loss) and Comprehensive Income (Loss). The remaining net carrying amount was \$nil for both the HLT Patch and Pliaglis. Amortization of intangible assets is included in general and administrative (G&A) expenses in the Consolidated Statements of Income (Loss) and Comprehensive Income (Loss).

# 8. OTHER OBLIGATIONS

Other obligations consist of the following as at:

	December 31, 2015	December 31, 2014
	\$	\$
Long-term consulting agreement from acquisition of non-controlling interest (i)	225	326
Finance lease obligations (ii)	10	2
	235	328
Less amounts due within one year	192	140
Long-term balance	43	188

# (i) Long-term Consulting Agreement from Acquisition of Non-controlling Interest

In December 2011, the Company increased its ownership in Nuvo Research AG to 100% by acquiring the 40% interest held by the minority owner. The consideration transferred to the non-controlling interest included a five-year, US\$150 per annum consulting agreement with the former minority shareholder, discounted at 15.5% and fair valued at US\$519 (\$528).

The future payments on the consulting obligation are as follows for the years ending December 31:

	<u> </u>
2016	207
_2017	35
Total payments	242
Less amount representing interest (approximately 15.5%)	17
Present value of obligation, including accretion	225
Less current portion	190
Long-term balance	35

# (ii) Finance Lease Obligations

The Company leases office equipment under a finance lease expiring in 2020. The minimum future lease payments are as follows for the years ending December 31:

	<b>\$</b> _
2016	3
2017	3
2018 and thereafter	9_
Total minimum lease payments	15
Less: amount representing interest (approximately 15%)	5_
Present value of minimum lease payments	10
Less: current portion	2
Long-term balance	8

For the year ended December 31, 2015, interest paid on finance lease obligations was under \$1 [2014 – under \$1].

# 9. CAPITAL STOCK

#### **Authorized**

- Unlimited first and second preferred shares, non-voting, non-participating, issuable in series, number, designation, rights, privileges, restrictions and conditions are determinable by the Company's Board of Directors.
- Unlimited common shares, voting, without par value.

# Shareholders' Rights Plan

The Company initially instituted a shareholders' rights plan (the Rights Plan) in 1992. Since that time, the Rights Plan has been amended, restated and continued from time-to-time. Most recently, in June 2013, the shareholders approved certain amendments to the Rights Plan, including the continuation of the Rights Plan until the annual meeting of shareholders in 2018. The Rights Plan is intended to provide some protection to shareholders of the Company from unfair take-over strategies, including the acquisition of control of the Company by a bidder in a transaction or series of transactions that does 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. One right is, or will be, issued in respect of each outstanding common share. The rights become exercisable only when an acquiring person acquires or announces its intention to acquire 20% or more of the Company's outstanding common shares without complying with the "permitted bid" provisions of the Rights Plan. Subject to the terms of the Rights Plan, each right will entitle the holder thereof, to purchase a common share of the Company at a 50% discount to the market price.

#### **Private Placement**

On March 31, 2014, the Company completed a non-brokered private placement (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).

A Private Placement Warrant 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, 2015, 239,672 of the Private Placement Warrants were exercised [December 31, 2014 - 433,149].

In connection with the Private Placement, the Company issued 78,233 broker warrants at a price of \$2.54 per Unit (Broker Warrants). Each Broker Warrant unit entitled the holder to purchase one common share of the Company at a price of \$2.54 and included one half of one Private Placement Warrant. During the year ended December 31, 2015, 42,733 of the Broker Warrants were exercised [December 31, 2014 - 31,300] and 21,367 Private Placement Warrants were issued upon exercise of the Broker Warrants [December 31, 2014 - 15,650].

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 expired. The Company exercised its acceleration feature on November 30, 2015 and accelerated the expiry date of the outstanding warrants to January 15, 2016. Subsequent to the year-end, 4,200 Broker Warrants and 49,044 Private Placement Warrants (inclusive of 2,100 Private Placement Warrants that were issued on exercise of the Broker Warrants) were exercised for proceeds of \$0.2 million and 12,252 Private Placement Warrants expired.

# **Paladin Warrants**

In May 2012, the Company signed a loan agreement with Paladin, its Canadian licensing partner for Pennsaid. Under this loan facility, the Company could borrow up to \$12.0 million from Paladin in three equal tranches of \$4.0 million each. The first tranche was advanced on closing of the May 2012 agreement, the second tranche was advanced on closing of the July 2013 amendment. Under the terms of the Loan Agreements, when the second tranche was drawn by Nuvo, Paladin was issued warrants to acquire 50,000 Nuvo common shares at \$1.82 per share which represented a 130% premium to the 5-day trailing value weighted average trading price (VWAP) of Nuvo common shares on the TSX. The Company settled the entire Paladin loan in October 2014.

During the year ended December 31, 2015, Paladin exercised all of its 50,000 warrants.

#### **Warrants**

The warrants outstanding by tranche are as follows:

			Number of Warrants	
		_	December 31,	December 31,
	Expiry Date	Exercise Price	2015	2014
Private Placement Warrants	March 31, 2016	\$3.00	59,196	277,501
Broker Warrants <sup>(i)</sup>	March 31, 2016	\$2.54	4,200	46,933
Paladin Warrants <sup>(ii)</sup>	July 10, 2016	\$1.82	-	50,000
			63,396	374,434

Entitles the holder to purchase a Unit consisting of one common share of the Company for \$2.54 and one-half of one common share purchase warrant of the Company.

All warrants are exercisable on issuance. Changes in the number of warrants outstanding were as follows:

	Number of Warrants	Weighted Average Exercise Price	
	\$	\$	
Balance, December 31, 2013	50,000	1.82	
Issued	788,883	2.95	
Exercised	(464,449)	2.97	
Balance, December 31, 2014	374,434	2.78	
Issued	21,367	3.00	
Exercised	(332,405)	2.95	
Balance, December 31, 2015	63,396	2.97	

### 10. STOCK-BASED COMPENSATION AND OTHER STOCK-BASED PAYMENTS

The Company has six stock-based compensation plans: the Share Option Plan, the Share Purchase Plan and the Share Bonus Plan, each a component of the Company's Share Incentive Plan, the DSU Plan for non-employee directors, the DSU Plan for employees and the SARs Plan.

# **Share Incentive Plan**

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

# (i) Share Option Plan

Under the Share Option Plan, the Company may grant options to purchase common shares to officers, directors, employees or consultants of the Company or its affiliates. Options issued under the Share Option Plan are granted for a term not exceeding ten years from the date of grant. All options issued to-date have a life of ten years. In general, options have vested either immediately upon grant or over a period of one to four years or upon the achievement of certain performance related measures or milestones. Under the provisions of the Share Option Plan, the exercise price of all stock options shall not be less than the closing price of the common shares

<sup>(</sup>ii) Warrants previously issued to Paladin under a loan facility. All warrants were exercised by Paladin during the year.

on the last trading date immediately preceding the grant date of the option.

As at December 31, 2015, the number of options available and reserved for issue was 289,206.

The following is a schedule of the options outstanding as at:

	Number of Options	Range of Exercise Price	Weighted Average Exercise Price
	000s	\$	\$
Balance, December 31, 2013	785	1.96 – 37.05	8.91
Granted	212	3.39	3.39
Exercised	(15)	1.96	1.96
Forfeiture	(32)	5.53 - 13.00	7.09
Expired	(63)	19.50 - 37.05	20.61
Balance, December 31, 2014	887	1.96 - 24.05	6.93
Exercised <sup>(i)</sup>	(24)	1.96	1.96
Expired	(112)	11.70 – 13.00	12.95
Balance, December 31, 2015	751	1.96 - 24.05	6.18

<sup>(</sup>i) The weighted average share price for the options exercised in 2015 was \$5.79.

The following table summarizes the outstanding and exercisable options held by directors, officers, employees and consultants as at December 31, 2015:

	Outstanding		<b>Exercisable</b>		
Exercise Price Range	Number of Options	Remaining Contractual Life	Weighted Average Exercise Price	Vested Options	Weighted Average Exercise Price
\$	000s	years	\$	000s	\$
1.96 - 5.53	360	7.8	3.40	205	3.37
6.50 - 8.78	334	3.7	7.72	299	7.87
11.70 - 24.05	57	4.0	14.73	57	14.73
	751	5.7	6.18	561	6.92

The fair value of each tranche is measured at the date of grant using the Black-Scholes option pricing model. There were no options granted during the year ended December 31, 2015.

# (ii) Share Purchase Plan

Under the Share Purchase Plan, eligible officers, employees or consultants of the Company or its affiliates may contribute up to 10% of their annual base salary to the plan to purchase Nuvo common shares. The Company matches each participant's contribution by issuing Nuvo common shares having a value equal to the aggregate amount contributed by each participating employee.

During 2015, employees contributed \$49 [December 31, 2014 - \$135] to the plan and the Company matched these contributions by issuing 7,450 common shares [December 31, 2014 - 23,305] with a fair value of \$49 [December 31, 2014 - \$135] that was recorded as compensation expense. The total number of shares issued under this plan during the year ended December 31, 2015 was 14,900 [December 31, 2014 - 46,610].

# **Deferred Share Unit Plan**

#### **Directors**

Under the DSU Plan, non-employee directors can be allotted and elect to receive a portion of their annual retainers and other Board-related compensation in the form of DSUs. One DSU has a cash value equal to the market price of one of the Company's common shares and the number of DSUs issued to a director's DSU account for any payment is determined using the five-day VWAP of the Company's common shares immediately preceding the payment date.

### **Employees**

Under the employee DSU Plan, employees can elect to have a portion of their quarterly earnings issued in units of the DSU Plan. Consistent with non-employee directors, one DSU has a cash value equal to the market price of one of the Company's common shares. The number of units to be credited to an employee will be calculated by dividing the elected portion of the compensation payable to the employee by the five-day VWAP of the Company's common shares immediately preceding the close of each quarter.

Upon issuance, the fair value of the DSUs is recorded as compensation expense and the DSU accrual is established. At all subsequent reporting dates, the DSU accrual is adjusted to the market value of the underlying shares and the adjustment is recorded as compensation expense. Within a specified time after retirement or termination, non-employee directors and employees receive a cash payment equal to the market value of their DSUs. For the year ended December 31, 2015, a \$539 expense reversal was recorded in G&A expenses which consisted of a charge of \$196 for the fair value of the DSUs issued for director fees, combined with a \$735 decrease in the aggregate DSU accrual to the market value of the underlying shares. The DSU accrual was included in accounts payable and accrued liabilities.

The following table summarizes the outstanding DSUs and related accrual as at December 31, 2015:

	Number of DSUs	Market Values	Accrual
	000s	\$	\$
Balance, December 31, 2013	208	2.15	449
Issued for employee compensation	104	2.59 - 6.93	391
Issued for directors' fees	83	2.03 - 6.93	223
Adjustment to market value	-	-	1,707
Balance, December 31, 2014	395	7.00	2,770
Issued for directors' fees	33	4.29 - 7.04	196
Adjustment to market value	-	-	(735)
Balance, December 31, 2015	428	5.21	2,231

#### **Stock Appreciation Rights Plan**

The Company established the SARs Plan for directors, officers, employees or designated affiliates to provide incentive compensation based on the appreciation in value of the Company's common shares. Under the SARs Plan, participants receive, upon vesting, a cash amount equal to the difference between the SARs fair market value and the grant price value, also known as the intrinsic value. Fair market value is determined by the closing price of the Company's common share on the TSX on the day preceding the exercise date. SARs vest in tranches prescribed at the grant date and each tranche is considered a separate award with its own vesting period and grant date fair value. Until SARs vest, compensation expense is measured based on the fair value of the SARs at the end of each reporting period, using a Black-Scholes option pricing model. The fair value of the liability is remeasured at the end of each reporting date and adjusted at the settlement date, when the intrinsic value is realized. The SARs accrual is included in accounts payable and accrued liabilities.

Fair values of each tranche issued and outstanding in the year were measured as at December 31, 2015 using the Black-Scholes option pricing model with the following inputs:

SARs Outstanding	Grant Date	Exercise Price	Risk-free Interest Rate	Expected Life	Volatility Factor	Fair Values
000s		\$	%	(years)	%	\$
304	October 30, 2013	1.85	0.62%	1	73	3.36 - 3.45
238	April 4, 2014	3.39	0.62%	1 - 2	73 - 77	1.82 - 2.82
246	January 7, 2015	7.20	0.62% - 0.80%	1 - 3	73 - 77	0.00 - 2.17

The SARs accrual is included in accounts payable and accrued liabilities. The following table summarizes the outstanding SARs and related accrual as at December 31, 2015:

	Number of SARs	Fair Values	Accrual
	000s	\$	\$
Balance, December 31, 2013	606	0.76 – 1.11	50
Granted	318	0.40 - 1.42	36
Adjustment to market value	-	-	2,790
Balance, December 31, 2014	924	3.61 - 5.38	2,876
Granted	246	0.59 - 1.92	30
Vested	(382)	3.61 - 5.15	(1,848)
Adjustment to market value	-	-	270
Balance, December 31, 2015	788	0.00 - 3.45	1,328

# **Summary of Stock-based Compensation**

	Year ended December 31, 2015	Year ended December 31, 2014
	\$	\$
Stock option compensation expense under the Share Option Plan	177	274
Shares issued to employees under Share Purchase Plan	49	135
DSUs – issued for settlement of directors' fees	196	223
DSUs – issued for employee compensation	-	391
DSUs – adjustment to market value	(735)	1,707
Preferred Stock Unit compensation expense under the Share Bonus		
Plan	-	23
SARs compensation expense	300	2,826
Stock-based compensation expense	(13)	5,579
Recorded in the Consolidated Statements of Income (Loss) and Comprehensive Income (Loss) as follows:		
Cost of goods sold	29	38
Research and development expenses	79	494
General and administrative expenses	(121)	5,047
	(13)	5,579

### 11. LICENSE FEES

In December 2015, the Company reacquired the development and marketing rights for Pliaglis for the U.S., Canada and Mexico. Under the terms of the agreement, Nuvo paid Galderma approximately \$174 (CHF125) that has been included in G&A expenses for the year ended December 31, 2015. The Company will pay an additional \$174 (CHF125) upon transfer of certain rights and documents. Galderma will continue to market Pliaglis in the U.S. and Canada and pay a royalty on net sales during the agreed upon transition period. The Company will receive a fixed single-digit royalty on net sales in the Galderma territories outside of North America.

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 of US\$0.5 million (\$0.6 million). In a patent infringement complaint against this generic company, the Company, along with Mallinckrodt, entered into a settlement agreement; whereby, this generic company would agree to pay an upfront, non-refundable milestone of US\$0.5 million upon the launch of its generic version of Pennsaid and agree to pay royalties calculated at 50% of gross profits from subsequent product sales until which time a third generic version of Pennsaid was launched and then the royalty rate would decrease to 10% of its gross profits from product sales. The US\$0.5 million milestone payment was recorded in license revenue for the year ended December 31, 2014. 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.

# 12. NET INCOME (LOSS) PER COMMON SHARE

Income (loss) per share is computed as follows:

	Year ended December 31, 2015	Year ended December 31, 2014
(in thousands, except per share and share figures)	\$	\$
Basic income (loss) per share:		
Net income (loss)	(7,120)	38,590
Average number of shares outstanding during the year	10,942	10,031
Basic income (loss) per share	\$(0.65)	\$3.85
Diluted income (loss) per share:  Net income (loss), assuming dilution  Average number of shares outstanding during the year  Dilutive effect of:	(7,120) 10,942	38,590 10,031
Stock options Warrants	-	119 250
Weighted average common shares outstanding, assuming dilution	10,942	10,400
Diluted income (loss) per share	\$(0.65)	\$3.71

The following table presents the maximum number of shares that would be outstanding if all dilutive and potentially dilutive instruments were exercised or converted as at:

	December 31, 2015	December 31, 2014
	000s	000s
Common shares issued and outstanding	11,145	10,775
Stock options outstanding (Note 10)	751	887
Warrants (Note 9) <sup>(i)</sup>	65	397
	11,961	12,059

<sup>(</sup>i) Includes 2,100 Private Placement Warrants that will be issued on the exercise of Broker Warrants [2014 – 23,466 Private Placement Warrants].

# 13. EXPENSES BY NATURE

The Consolidated Statements of Income (Loss) and Comprehensive Income (Loss) include the following expenses by nature:

# (a) Employee costs:

	Year ended December 31, 2015	Year ended December 31, 2014
	\$	\$
Short-term employee wages, bonuses and benefits	9,150	8,109
Share-based payments	164	4,457
Post-employment benefits	26	14
Termination benefits	101	36
Total employee costs	9,441	12,616
Included in:		
Cost of goods sold	3,508	2,377
Research and development expenses	2,777	3,163
General and administrative expenses	3,156	7,076
Total employee costs	9,441	12,616

# (b) Depreciation and amortization:

	Year ended	Year ended
	December 31, 2015 \$	December 31, 2014 \$
Cost of goods sold	213	252
Research and development expenses	87	87
General and administrative expenses (i)	13	376
Total depreciation and amortization	313	715

<sup>6</sup> G&A expenses include \$nil of amortization of intangible assets for the year ended December 31, 2015 [December 31, 2014 - \$348].

# 14. NET CHANGE IN NON-CASH WORKING CAPITAL

The net change in non-cash working capital consists of the following:

	Year ended December 31, 2015	Year ended December 31, 2014
	\$	\$
Accounts receivable	(2,065)	1,696
Inventories	(588)	(1,129)
Other current assets	(557)	(252)
Accounts payable and accrued liabilities	(131)	5,198
Net change in non-cash working capital	(3,341)	5,513

### 15. INCOME TAXES

#### **Deferred Tax Assets and Liabilities**

Deferred income taxes represent the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The following represents deferred tax assets which have not been recognized in these Consolidated Financial Statements:

	Year Ended December 31, 2015	Year Ended December 31, 2014
	\$	\$
Non-capital loss carryforwards	20,830	15,829
U.S. Federal and State research and development credits Canadian Scientific Research and Experimental Development (SR&ED) expenditure pool carryforward	1,612 455	1,352
Investment tax credits  Tax basis of property, plant and equipment and intangibles in excess of accounting value	1,809 2,649	1,340 3,190
Financing costs, deferred revenue and other	38	19
Deferred tax assets not recognized	27,393	21,730

A reconciliation between the Company's statutory and effective tax rates is presented below:

	Year Ended December 31, 2015	Year Ended December 31, 2014
	%	%
Statutory rate	26.8	26.7
Items not deducted for tax	9.6	(1.4)
Impact of foreign income tax rate differential	29.1	(2.9)
Utilization of previously unused losses Revaluation of deferred taxes as a result of enacted tax rate changes and other	(0.6)	(25.0)
Losses not benefitted	(64.8)	(4.3)
Other	(*,	6.9
	-	-

# Loss Carryforwards and Canadian SR&EDs

The Company and its subsidiaries have non-capital losses available for carryforward to reduce future years' taxable income, the benefit of which has not been recorded. These losses and the related future tax assets by jurisdiction are as follows:

		Non-capital losses	Future tax asset
	Expiry Period	\$	\$
Canada	2030 to 2031	3,423	917
United States	2025	24	9
United States (i)	2023 to 2029	9,110	2,848
United States	2026 to 2035	30,591	11,959
Switzerland	2016 to 2022	21,429	2,080
Germany	Indefinite	10,404	3,017
		74,981	20,830

<sup>(</sup>f) These U.S. losses carried forward relate to losses acquired upon the purchase of ZARS in 2011. The Company has \$32.1 million of U.S. losses carried forward relating to the portion of the acquired losses that are restricted due to the change in control, and therefore are not included in the table.

The Company has approximately \$1.7 million [December 31, 2014 - \$nil] of Canadian SR&ED expenditures for federal tax purposes that are available to reduce taxable income in future years and have an unlimited carryforward period, the benefit of which has not been reflected in these financial statements. SR&ED expenditures are subject to audit by the tax authorities and accordingly, these amounts may vary.

The Company has net capital losses of \$7.8 million [December 31, 2014 - \$6.1 million] in Canada available to offset net taxable capital gains in future years which have not been recognized.

# **Government Assistance**

A portion of the Company's R&D expenditures are eligible for Canadian federal investment tax credits that it may carry forward to offset any future Canadian federal income tax payable as follows:

Year of credit	Amount	Year of Expiry
	\$	
December 31, 2005	435	2015
December 31, 2006	688	2026
December 31, 2007	335	2027
December 31, 2008	225	2028
December 31, 2009	142	2029
December 31, 2010	395	2030
December 31, 2011	208	2031
December 31, 2012	43	2032
	2,471	

The benefits of these non-refundable Canadian federal investment tax credits have not been recognized in the financial statements.

### 16. COMMITMENTS

The Company has commitments under research contracts and minimum future rental payments under operating leases for the years ending December 31 as follows:

	Research and Other Service Contracts	Operating Leases	Total
	\$	\$	\$
2016	1,124	239	1,363
2017	-	47	47
2018 and thereafter	-	1	1
	1,124	287	1,411

For the year ended December 31, 2015, payments under operating leases totalled \$273 [December 31, 2014 - \$211].

Under the terms of the Pennsaid 2% U.S. Asset Sale with Horizon, Nuvo is contractually obligated to manufacture Pennsaid 2% for the U.S. market to December 2029. The agreement provides for tiered pricing based on volumes of product shipped. The Company is also required to maintain certain inventory levels of raw materials.

The Company has additional long-term supply contracts where the Company is contractually obligated to manufacture Pennsaid and Pennsaid 2% for its customers.

The Company has a long-term supply agreement with a third-party manufacturer for the supply of dimethyl sulfoxide, one of its key raw materials, which expires in December 2022. The agreement automatically renews for successive three-year terms, unless terminated in writing by either party at least 12 months prior to the expiration of the current term. The agreement obligates the Company to purchase 100% of its dimethyl sulfoxide requirements from the third party at specified pricing, but does not contain any minimum purchase commitments.

Under certain licensing agreements, the Company may be required to make payments upon the achievement of specific developmental, regulatory or commercial milestones. As it is uncertain if, and when, these milestones will be achieved, the Company did not accrue for any of these payments at December 31, 2015 or 2014.

Under certain licensing agreements, the Company is required to make royalty payments to two companies for a combined 2.5% of annual net sales of the HLT Patch and Pliaglis.

In December 2015, the Company reacquired the development and marketing rights for Pliaglis for the U.S., Canada and Mexico. Under the terms of the agreement, Nuvo will pay a second payment of \$174 (CHF125) upon transfer of certain rights and documents.

Under the terms of the 2004 agreement and as reiterated in the 2011 agreement to purchase the non-controlling interest in Nuvo Research AG, the Company is obligated to pay 6% of future WF10 licensing and royalty revenue and 6% of proceeds received from the sale of any portion of Nuvo Research AG to the former minority shareholder. No amounts have been paid or are payable.

#### Guarantees

The Company periodically enters into research, licensing, distribution or supply agreements with third parties that include indemnification provisions that are customary in the industry. These guarantees generally require the Company to compensate the other party for certain damages and costs incurred as a result of third-party intellectual property claims or damages arising from these transactions. In some cases, the maximum potential amount of future payments that could be required under these indemnification provisions is unlimited. These indemnification provisions generally survive termination of the underlying agreements. The nature of the intellectual property indemnification obligations prevents the Company from making a reasonable estimate of the maximum potential amount it could be required to pay. Historically, the Company has not made any indemnification payments under such agreements and no amount has been accrued in the accompanying Consolidated Financial Statements with respect to these indemnification obligations.

### 17. FINANCIAL INSTRUMENTS AND RISK MANAGEMENT

IFRS 7 - Financial Instruments: Disclosures requires disclosure of a three-level hierarchy that reflects the significance of the inputs used in making fair value measurements. Fair values of assets and liabilities included in Level 1 are determined by reference to quoted prices in active markets for identical assets and liabilities. Assets and liabilities in Level 2 include those where valuations are determined using inputs other than quoted prices for which all significant outputs are observable, either directly or indirectly. Level 3 valuations are those based on inputs that are unobservable and significant to the overall fair value measurement.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification on a quarterly basis. Changes to the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy. The Company did not have any transfer of assets and liabilities between Level 1, Level 2 and Level 3 of the fair value hierarchy during the years ended December 31, 2015 and 2014.

The Company has determined the estimated fair values of its financial instruments based on appropriate valuation methodologies. However, considerable judgment is required to develop these estimates. Accordingly, these estimated values are not necessarily indicative of the amounts the Company could realize in a current market exchange. The estimated fair value amounts can be materially affected by the use of different assumptions or methodologies.

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis as at December 31, 2015:

	Total \$	Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Using Significant Other Unobservable Inputs (Level 2)	Using Significant Unobservable Inputs (Level 3)
Assets:	-	<u> </u>	<u> </u>	
Total Assets	-	-	-	-
Liabilities:				
Deferred Share Units	2,231	2,231	-	-
Stock Appreciation Rights	1,328	-	1,328	-
Total Liabilities	3,559	2,231	1,328	-

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis as at December 31, 2014:

	Total	Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Using Significant Other Unobservable Inputs (Level 2)	Using Significant Unobservable Inputs (Level 3)
	\$	\$	\$	\$
Assets:				
Short-term Investments	10,000	10,000	-	-
Total Assets	10,000	10,000	-	-
Liabilities:				
Deferred Share Units	2,770	2,770	-	-
Stock Appreciation Rights	2,876	-	2,876	-
Total Liabilities	5,646	2,770	2,876	-

Level 1 assets include guaranteed investment certificates or other securities held by the Company that are valued at quoted market prices. The Company accounted for its investment at fair value on a recurring basis at December 31, 2014. The Company has no level 1 assets at December 31, 2015.

Level 1 liabilities include obligations of the Company for the DSU described in Note 10. One DSU has a cash value equal to the market price of one of the Company's common shares. The Company revalues the DSU liability each reporting period using the market value of the underlying shares.

Level 2 liabilities include obligations of the Company for the SARS Plan described in Note 10. The fair values of each tranche of SARs issued and outstanding are revalued at each reporting period using the Black-Scholes option pricing model.

The fair values of all other short-term financial assets and liabilities, presented in the Consolidated Statements of Financial Position approximate their carrying amounts due to the short period to maturity of these financial instruments.

Rates currently available to the Company for long-term obligations, with similar terms and remaining maturities, have been used to estimate the fair value of the finance lease and other obligations. These fair values approximate the carrying values for all instruments.

#### **Risk Factors**

The following is a discussion of liquidity, credit and market risks and related mitigation strategies that have been identified. This is not an exhaustive list of all risks nor will the mitigation strategies eliminate all risks listed.

### **Liquidity Risk**

While the Company had \$48.7 million in cash as at December 31, 2015, it continues to have an ongoing need for substantial capital resources to research, develop, commercialize and manufacture its products and technologies as the Company is not generating enough cash to fund its operations. The Company has limited participation in

Pennsaid and Pennsaid 2% revenues in countries where it is currently marketed. In Canada, the Company receives royalties based on Canadian net sales of Pennsaid. In the first quarter of 2014, a generic version of Pennsaid was launched that has negatively impacted the Company's royalty revenue in Canada. In the U.S., the Company receives product revenues from the sale of Pennsaid 2% to Horizon pursuant to a long-term exclusive supply agreement.

The Company has contractual obligations related to accounts payable and accrued liabilities, purchase commitments and other obligations of \$10.8 million that are due in less than a year and \$0.1 million of contractual obligations that are payable from 2017 to 2020.

#### Credit Risk

The Company's cash balances subject the Company to a significant concentration of credit risk. As at December 31, 2015, the Company had \$48.2 million invested with two financial institutions, in various bank accounts as per its practice of protecting its capital rather than maximizing investment yield through additional risk. These financial institutions are major Canadian banks which the Company believes lessens the degree of credit risk. The remaining \$0.5 million of cash balances are held in bank accounts in various geographic regions outside of Canada.

The Company, in the normal course of business, is exposed to credit risk from its global customers, most of whom are in the pharmaceutical industry. The accounts receivable are subject to normal industry risks in each geographic region in which the Company operates. In addition, the Company is exposed to credit-related losses on sales to its customers outside North America and the E.U. due to potentially higher risks of enforceability and collectability. The Company attempts to manage these risks prior to the signing of distribution or licensing agreements by dealing with creditworthy customers; however, due to the limited number of potential customers in each market, this is not always possible. In addition, a customer's creditworthiness may change subsequent to becoming a licensee or distributor, and the terms and conditions in the agreement may prevent the Company from seeking new licensees or distributors in these territories during the term of the agreement. As at December 31, 2015, the Company's four largest customers located in North America and the E.U. represented 89% [December 31, 2014 - 60%] of total accounts receivable and accounts receivable from customers located outside of North America and the E.U. represented 2% [December 31, 2014 - 8%] of total accounts receivable.

Pursuant to their collective terms, accounts receivable were aged as follows:

	December 31, 2015	December 31, 2014
	\$	\$
Current	5,497	2,940
0-30 days past due	36	43
31-60 days past due	-	20
Over 90 days past due	-	2
	5,533	3,005

#### Interest Rate Risk

All finance lease obligations are at fixed interest rates.

### **Currency Risk**

The Company operates globally, which gives rise to a risk that earnings and cash flows may be adversely affected by fluctuations in foreign currency exchange rates. The Company is primarily exposed to the U.S. dollar and euro, but also transacts in other foreign currencies. The Company currently does not use financial instruments to hedge these risks. The significant balances in foreign currencies were as follows:

	Euros		U.S. [	Dollars
	December 31,	December 31,	December 31,	December 31,
	2015	2014	2015	2014
	€	€	\$	\$
Cash	885	1,266	4,783	665
Accounts receivable	782	242	3,010	2,205
Other current assets	2	159	-	-
Accounts payable and accrued liabilities	(959)	(943)	(520)	(601)
Finance lease and other long-term obligations	-	-	(162)	(281)
	710	724	7,111	1,988

Based on the aforementioned net exposure as at December 31, 2015, and assuming that all other variables remain constant, a 10% appreciation or depreciation of the Canadian dollar against the U.S. dollar would have an effect of \$984 on total comprehensive income (loss) and a 10% appreciation or depreciation of the Canadian dollar against the euro would have an effect of \$107 on total comprehensive income (loss).

In terms of the euro, the Company has three significant exposures: its net investment and net cash flows in its European operations, its euro denominated cash held in its Canadian operations and sales of Pennsaid by the Canadian operations to European distributors. In terms of the U.S. dollar, the Company has four significant exposures: its net investment and net cash flows in its U.S. operations, its U.S. dollar denominated cash held in its Canadian operations, the cost of purchasing raw materials either priced in U.S. dollars or sourced from U.S. suppliers that are needed to produce Pennsaid, Pennsaid 2% or other products at the Canadian manufacturing facility and revenue generated in U.S. dollars from agreements with Horizon, Galderma, Galen and Eurocept.

The Company does not actively hedge any of its foreign currency exposures given the relative risk of currency versus other risks the Company faces and the cost of establishing the necessary credit facilities and purchasing financial instruments to mitigate or hedge these exposures. As a result, the Company does not attempt to hedge its net investments in foreign subsidiaries.

The Company does not currently hedge its euro cash flows. Sales to European distributors for Pennsaid are primarily contracted in euros. The Company receives payments from the distributors in its euro bank accounts and uses these funds to pay euro denominated expenditures and to fund the net outflows of the European operations as required. Periodically, the Company reviews the amount of euros held, and if they are excessive compared to the Company's projected future euro cash flows, they may be converted into U.S. or Canadian dollars. If the amount of euros held is insufficient, the Company may convert a portion of other currencies into euros.

The Company does not currently hedge its U.S. dollar cash flows. The Company's U.S. operations have net cash outflows, and currently these are funded using the Company's U.S. dollar denominated cash and payments received under the terms of the agreements with Horizon, Galderma and Galen. Periodically, the Company reviews its projected future U.S. dollar cash flows and if the U.S. dollars held are insufficient, the Company may convert a portion of its other currencies into U.S. dollars. If the amount of U.S. dollars held is excessive, they may be converted into Canadian dollars or other currencies, as needed for the Company's other operations.

### 18. CAPITAL MANAGEMENT

The Company's objectives in managing capital are to ensure sufficient liquidity to pursue the Company's development plans for each of its drug candidates and to maintain its ongoing operations. Product revenues from the Company's approved drug products are not yet significant enough to fund ongoing operations. As a result, to secure the capital necessary to pursue its development plans and fund ongoing operations, the Company will need to raise additional funds through the issuance of debt or equity, by entering into distribution and license agreements or by entering into co-development agreements.

The Company currently defines its capital to include its cash and shareholders' equity excluding AOCI. In the past, the Company has financed its operations primarily through the net proceeds received from the sale of common shares and warrants, issuance of secured debt and convertible debentures, finance lease obligations, proceeds from collaborative relationships and investment income earned on cash balances and short-term investments.

The Company expects to utilize its cash, which was \$48.7 million at December 31, 2015, revenue from product sales and royalty payments to fund its operations. As part of the Nuvo Strategic Transaction (see Note 1, *Nature of Business and Going Concern Assumption*), the Company plans to transfer \$35.0 million to Crescita as part of the reorganization. Completion of the reorganization is subject to a number of conditions including shareholder and court approval. If the proposed transaction is approved by shareholders and all other conditions are satisfied, Nuvo expects the transaction to be completed in Q1 2016.

The Company currently anticipates that its cash and the revenues it expects to generate from product sales and royalty payments will be sufficient to fund operations into 2017. Nonetheless, companies in the pharmaceutical industry typically require periodic funding in order to continue developing their drug candidate pipelines until they have successfully commercialized at least one of their drug candidates and receives sufficient ongoing revenue to fund their operations. Nuvo has not yet reached this stage and; therefore, the Company monitors, on a regular basis, its liquidity position, the status of its partners' commercialization efforts, the status of its drug development programs, including cost estimates for completing various stages of development, the scientific progress on each drug candidate, the potential to license or co-develop each drug candidate and continues to actively pursue fundraising possibilities through various means, including the sale of its equity securities. There can be no assurance, especially considering the economic environment, that additional financing would be available on acceptable terms, or at all, when and if required. If adequate funds are not available when required, the Company may have to substantially reduce or eliminate planned expenditures, terminate or delay clinical trials for its product candidates, curtail product development programs designed to expand the product pipeline or discontinue certain operations. If the Company is unable to obtain additional financing when and if required, the Company may be unable to continue operations.

# 19. SEGMENTED INFORMATION

#### **Segments**

IFRS 8 - Operating Segments, requires operating segments to be determined based on internal reports that are regularly reviewed by the chief operating decision maker for the purpose of allocating resources to the segment and to assessing its performance. Prior to September 30, 2015, the Company managed the business in the following operating segments: i) TPT Group and ii) Immunology Group. As discussed in Note 3(i), the Company realigned its operating segments as a result of strategic changes to the organizational structure. Accordingly, the Company has presented the following operating segments that are independently and regularly reviewed and managed: i) Nuvo Pharma and ii) Crescita. Crescita has two distinct business units: i) the TPT Group and ii) the Immunology Group.

From a financial perspective, executive management uses the net income (loss) before income taxes to assess the performance of each segment.

The following tables show certain information with respect to operating segments:

	Nuvo	Crescita		
	Pharma <sup>(ii)</sup>	TPT	Immunology	
		Group <sup>(ii)</sup>	Group	Total
Year ended December 31, 2015	\$	\$	\$	\$
Total revenue	20,495	228	629	21,352
Gross margin on product sales	8,804	-	128	8,932
Depreciation of property, plant and equipment	276	13	24	313
Interest income	515	-	-	515
Interest expense	-	40	-	40
Net income (loss) before income taxes(ii)	8,335	(7,230)	(8,218)	(7,113)
Assets (I)	57,944	316	872	59,132
Property, plant and equipment	1,100	31	49	1,180
Additions to property, plant and equipment	309	19	4	332

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	Pharma <sup>(ii)</sup>	TPT	Immunology		
		Group <sup>(ii)</sup>	Group	Total	
Year ended December 31, 2014	\$	\$	\$	\$	
Total revenue	12,227	192	638	13,057	
Gross margin on product sales	574	-	359	933	
Depreciation of property, plant and equipment and					
intangible assets (iii)	415	277	23	715	
Interest income	199	-	-	199	
Interest expense	661	52	-	713	
Net income (loss) before income taxes (ii), (iii), (iv), (v)	53,299	(8,241)	(6,449)	38,609	
Assets	63,504	216	1,420	65,140	
Property, plant and equipment	1,071	25	65	1,161	
Additions to property, plant and equipment	181	10	33	224	

<sup>(</sup>i) As part of the Nuvo Strategic Transaction (see Note 1, *Nature of Business and Going Concern Assumption*), the Company plans to transfer \$35.0 million to Crescita as part of the reorganization.

Corporate overhead costs are allocated to the Nuvo Pharma and TPT Group segments.

# **Geographic Information**

The Company's revenue is derived from sales to and licensing revenue derived from external customers located in the following geographic areas:

	Year ended	Year ended
	December 31, 2015	December 31, 2014
	\$	\$
United States	16,698	7,809
Europe	3,245	2,193
Canada	737	1,797
Other foreign countries	672	1,258
	21,352	13,057

The geographic location of the Company's PP&E was as follows as at:

	December 31, 2015	December 31, 2014
	\$	\$_
Canada	1,131	1,095
Europe and other	49	66
	1,180	1,161

### **Significant Customers**

For the year ended December 31, 2015, the Company's four largest customers (excluding upfront payments and milestones from licensing arrangements) represented 87% [December 31, 2014 - 81%] of total revenue and the Company's largest customer represented 71% [December 31, 2014 - 51%] of total revenue. The Company's largest customers are in the Nuvo Pharma segment.

During 2014, amortization of intangible assets of \$0.1 million and \$0.3 million was included in the results of the Nuvo Pharma and TPT Group segments.

During 2014, impairment of intangible assets of \$0.5 million and \$1.2 million was included in the results of the Nuvo Pharma and TPT Group segments.

<sup>(</sup>v) The total gain on the litigation settlement of \$52.3 million for the year ended December 31, 2014 was included in the results of Nuvo Pharma.

#### 20. RELATED PARTY TRANSACTIONS

### **Key Management Compensation**

Key management personnel are those persons having authority and responsibility for planning, directing and controlling the activities of the Company, including directors. Key management includes five executive officers and five non-employee directors. Compensation for the Company's key management personnel was as follows:

	Year Ended December 31, 2015	Year Ended December 31, 2014	
	\$	\$	
Short-term wages, bonuses and benefits (i)	1,863	3,325	
Share-based payments	94	4,338	
Total key management compensation	1,957	7,663	
Included in:			
Research and development expenses	470	935	
General and administrative expenses	1,487	6,728	
Total key management compensation	1,957	7,663	

For the year ended December 31, 2015, certain officers of the Company were assessed on the achievement of corporate objectives including: the success of the 2015 Pennsaid 2% phase 3 trial and the completion of a strategic restructuring transaction. The Company expects the achievement of these targets to be determined during the first quarter of 2016.

For the year ended December 31, 2015, certain officers of the Company exercised 33,884 Private Placement Warrants. Proceeds raised from the Company's officers totalled \$0.1 million.

For the year ended December 31, 2014, certain officers of the Company participated in the Private Placement described in Note 9, *Capital Stock* and acquired 67,768 on the same terms as the other purchasers. Proceeds raised from the Company's officers totalled \$0.2 million.

# **21. LITIGATION SETTLEMENT**

In September 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 market and sell 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% (Pennsaid Rights) to Nuvo valued at US\$45.0 million (\$50.4 million) and paid US\$10.0 million (\$11.2 million). During the year ended December 31, 2014, the Company recorded an \$8.8 million net gain [\$10.9 million of translated proceeds, net of \$2.1 million direct costs associated with the proceeds] and a foreign exchange gain of \$0.3 million in the Consolidated Statements of Income (Loss) and Comprehensive Income (Loss).

The Pennsaid Rights were valued at US\$45.0 million, as this represented the fair market value as evidenced by its sale in October 2014 (see Note 22, *Pennsaid 2% U.S. Asset Sale*). The total gain on the litigation settlement for the year ended December 31, 2014 was \$52.3 million, which included the net cash settlement payment of \$8.8 million and the non-cash portion of \$43.5 million, net of direct costs to sell.

### 22. PENNSAID 2% U.S. ASSET SALE

On October 17, 2014, the Company entered into an asset purchase agreement with Horizon pursuant to which the Company sold the sales and marketing rights, intellectual property and other assets with respect to Pennsaid 2% in the U.S. (Pennsaid 2% U.S. Sale Agreement), 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% for cash consideration of US\$45.0 million (\$50.4 million) received on the closing date. Proceeds of \$43.5 million, net of direct costs, were received in the fourth quarter of 2014, and these proceeds are presented in the Consolidated Statements of Cash Flows in investing activities.

#### 23. SUBSEQUENT EVENT - PRIVATE PLACEMENT AND BROKER WARRANTS EXPIRY

On November 30, 2015, the Company exercised its acceleration feature for the Private Placement Warrants and the Broker Warrants. The Company accelerated the expiry date to January 15, 2016 (Acceleration Expiry Date). In accordance with the terms of the Private Placement Warrants and the Broker Warrants, any Private Placement Warrants or Broker Warrants that were not validly exercised in accordance with their terms prior to the Accelerated Expiry Date would immediately expire and all rights of the holders of the Private Placement Warrants and the Broker Warrants would be terminated without any compensation to the holder thereof.

Subsequent to the year ended December 31, 2015, 49,044 Private Placement Warrants and 4,200 Broker Warrants were exercised for proceeds of \$0.2 million and 12,252 Private Placement Warrants expired.

#### 24. SUBSEQUENT EVENT - DISPOSAL OF IMMUNOLOGY GROUP

On February 16, 2016, the Board of Directors of Nuvo unanimously approved a proposal to initiate a divestiture or orderly wind down of the Company's Immunology Group segment (see Note 19, Segmented Information). The Immunology Group includes the Company's wholly owned subsidiary Nuvo Research AG and its subsidiaries Nuvo Manufacturing GmbH and Nuvo Research GmbH.

While the Company continues to explore a possible sale of the Immunology Group, if a divestiture transaction does not materialize, the wind down of the Immunology operations is expected to be completed by the end of 2016. The Company has accrued \$0.3 million for onerous WF10 contracts for the year ended December 31, 2015.

# **Corporate Information**

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### **CORPORATE GOVERNANCE**

A statement of the Company's current corporate governance practices is contained in the management information circular and proxy statement for the May 13, 2015 Annual and Special Meeting of Shareholders. The Company's website www.nuvoresearch.com contains the Company's corporate governance documents including Code of Conduct and Business Ethics, Corporate Disclosure Policy, Insider Trading Policy and Audit Committee Charter.

# **Board of Directors and Executive Officers**

**Daniel N. Chicoine**, BComm, CPA Chairman & Co-Chief Executive Officer

John C. London, LLB, LLM Director - President & Co-Chief Executive Officer

**Henrich R.K. Guntermann**, MD, MSc Director - President, Europe & Immunology Group

**Stephen L. Lemieux**, BA, MMPA, CPA Vice President & Chief Financial Officer

**Tina K. Loucaides,** MSc, LLB Vice President, Secretary & General Counsel

**David A. Copeland**, BMath, CPA Director - Chair of the Audit Committee

Anthony E. Dobranowski, BSc, MBA, CPA Director

Jacques Messier, DVM, MBA
Director - Chair of the Compensation & Corporate
Governance Committee

Samira Sakhia, MBA, CPA Director

**Theodore H. Stanley**, MD Director

**Klaus von Lindeiner**, Dr en droit (University of Geneva) Director