





# Corporate Profile

Nuvo Research Inc. (Nuvo) is a publicly traded, Canadian specialty pharmaceutical company with a diverse portfolio of products and technologies. The Company operates two distinct business units: the Topical Products and Technology (TPT) Group and the Immunology Group. The TPT Group currently has four commercial products, 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, a development program for the treatment of allergic rhinitis and an immune system modulation platform that has the potential to support treatments for a broad range of immune system related disorders.

Nuvo trades on the Toronto Stock Exchange under the symbol NRI.



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

February 19, 2015 / The following information should be read in conjunction with the Nuvo Research® Inc. (Nuvo or the Company) Consolidated Financial Statements for the year ended December 31, 2014 which were prepared in accordance with International Financial Reporting Standards (IFRS) and filed on SEDAR on February 19, 2015. Additional information relating to the Company, including its Annual Information Form (AIF), can be found on SEDAR at [www.sedar.com](http://www.sedar.com).

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

## FORWARD-LOOKING STATEMENTS

Certain statements in this MD&A constitute forward-looking statements within the meaning of applicable securities laws. Forward-looking statements include, but are not limited to, statements made under the headings “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. Risk factors are discussed more fully in the Company’s AIF filed with the securities commissions in each Canadian province. 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” and as described from time to time in the reports and disclosure documents filed by the Company with Canadian securities regulatory agencies and commissions. This list is not exhaustive of the factors that may impact the Company’s forward-looking statements. These and other factors should be considered carefully and readers should not place undue reliance on the Company’s forward-looking statements. As a result of the foregoing and other factors, no assurance can be given as to any such future results, levels of activity or achievements and neither the Company nor any other person assumes responsibility for the accuracy and completeness of these forward-looking statements.

The factors underlying current expectations are dynamic and subject to change. Although the forward-looking information contained in this MD&A is based upon what management believes are reasonable assumptions, there can be no assurance that actual results will be consistent with these forward-looking statements. Certain statements included in this MD&A may be considered “financial outlook” for purposes of applicable securities laws, and such financial outlook may not be appropriate for purposes other than this MD&A. 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.

## OVERVIEW

### Background

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

As of December 31, 2014, the Company and its subsidiaries employed a total of 66 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.

### Topical Products and Technology Group

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

*TPT Group – Licensed Products:*

The following table summarizes our licensed products, where our partners are working to obtain regulatory approval:

<b>Brand</b>	<b>Therapeutic Area</b>	<b>Licensee or Distributor</b>	<b>Licensed Territories</b>	<b>Intellectual Property</b>
Pennsaid	Osteoarthritis of the knee	NovaMedica LLC	Russia; some Community of Independent States	None.
Pennsaid 2%	Osteoarthritis of the knee	Paladin Labs Inc.	Canada	Patent application allowed in Canada. Anticipated expiry date is 2027.
		NovaMedica LLC	Russia; some Community of Independent States	One patent granted in Russia expiring in 2027.
Rapydan <sup>2</sup>	Local Dermal Analgesia (Patch)	Eurocept B.V.	Russia, Turkey, Israel and People's Republic of China	Seven patents granted worldwide <sup>1</sup> with latest expiry in 2019.
Heated Lidocaine/ Tetracaine Patch		Paladin Labs Inc.	Canada	

(1) Worldwide refers to one or more countries other than Europe and the U.S.

(2) Rapydan is the brand name for the heated lidocaine/tetracaine patch (HLT Patch) in the respective jurisdiction.

*TPT Group – Commercial Products:*

The following table summarizes our commercialized products:

<b>Brand</b>	<b>Therapeutic Area</b>	<b>Licensee or Distributor</b>	<b>Licensed Territories</b>	<b>Intellectual Property</b>
Pennsaid <sup>1</sup>	Osteoarthritis of the knee	Paladin Labs Inc.	Canada	None.
		Vianex S.A.	Greece	None.
		Italchimici S.p.A.	Italy	None.
		Movianto UK Limited	U.K.	None.
Pennsaid 2%	Osteoarthritis of the knee	Horizon Pharma plc <sup>1</sup>	United States	Seven granted U.S. patents listed in the FDA's Orange Book with latest expiry in 2030.
Synera <sup>2</sup>	Local Dermal Analgesia (Patch)	Galen US Incorporated	United States	Nine granted U.S. patents of which seven have been listed in the FDA's Orange Book with latest expiry in 2020.
Rapydan <sup>2</sup>			Europe	Two granted European patents validated in 10 countries with latest expiry in 2019.
Synera/ Rapydan			United States/ Europe	Method of manufacturing patents that expire 2019 (U.S.) and 2020 (Europe).
Pliaglis	Local Dermal Analgesia (Peelable Cream)	Galderma Pharma S.A. <sup>3</sup>	United States	Two granted U.S. patents listed in the FDA's Orange Book with latest expiry in 2019.
			Europe	Two granted European patents validated in 18 countries with latest expiry in 2020.
			Worldwide <sup>4</sup>	Four patents granted worldwide <sup>4</sup> with latest expiry in 2020.

(1) In October 2014, the Company sold the Pennsaid 2% U.S. rights to Horizon Pharma plc (Horizon) (see Significant Transactions – 2014 – Pennsaid 2% U.S. Asset Sale). Horizon assumed full responsibility for sales and marketing of Pennsaid 2% in the U.S. on January 1, 2015. Mallinckrodt Inc. (Mallinckrodt) returned the rights to Nuvo pursuant to the settlement agreement reached in September 2014 (see Litigation – Mallinckrodt). Effective January 1, 2015, Pennsaid was no longer available in the U.S.

(2) Synera and Rapydan are the brand names for the heated lidocaine/tetracaine patch (HLT Patch) in the respective jurisdictions.

(3) Galderma currently sells Pliaglis in the U.S., Western Europe and Argentina and launched in Brazil in March 2014. The Company expects Galderma to file for marketing approval in other countries around the world, including other South American countries, select Asian countries, South Africa and Australia.

(4) Worldwide refers to one or more countries other than Europe and the U.S.

### *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.

Pennsaid 2% was approved on January 16, 2014 in the U.S. for the treatment of 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. 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 million. Under the terms of this agreement, the Company earns revenue from product sales of Pennsaid 2% to Horizon (see Significant Transactions – 2014 – Pennsaid 2% U.S. Asset Sale). In early January 2015, Horizon launched its commercial sale and marketing of Pennsaid 2% in the U.S.

In November 2014, the Company reacquired the Pennsaid 2% marketing rights from Paladin Labs Inc. (Paladin) to South America, Central America, South Africa and Israel. As consideration for these rights, the Company provided its authorization to Paladin to market, sell and distribute an authorized generic version of Pennsaid in Canada.

Additional clinical and non-clinical studies may be required to support applications for the regulatory approval of Pennsaid 2% in other countries in which the Company, or other licensees and distributors, could potentially market the product. The Company was advised by regulatory authorities in Canada and the United Kingdom that the data from the Phase 2 study conducted by Mallinckrodt was insufficient to support approval of Pennsaid 2% in their respective countries and that additional clinical studies would be required. The Company plans to commence a Phase 3 clinical study of Pennsaid 2% for the treatment of acute pain to support regulatory approval applications for Pennsaid 2% in international jurisdictions. The study will be 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 Company anticipates that the Phase 3 study for Pennsaid 2% may commence in Q2 2015, subject to German regulatory approval. The Company anticipates that results could be available in Q4 2015. In addition, NovaMedica has advised the Company that they will be conducting clinical studies required to obtain regulatory approval in 2015 in their territory. There can be no assurance that the current trials and studies will be sufficient for regulatory authorities in any jurisdiction or that all studies will yield successful results or that the required regulatory approvals will be obtained.

### *Pennsaid*

Pennsaid, the Company's first commercialized topical pain product, is used to treat the signs and symptoms of OA of the knee. Pennsaid combines 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.

### **United States**

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

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

In September 2014, the Company settled its litigation with Mallinckrodt and under the terms of the settlement, Mallinckrodt agreed to return the U.S. rights to Pennsaid and Pennsaid 2% to Nuvo (see 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



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 (\$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 such time as a third generic version of Pennsaid was launched in the U.S. and then the royalty rate would decrease to 10% of its gross profits from product sales. This generic agreement was assigned to the Company as part of the settlement agreement with Mallinckrodt.

#### **Canada**

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

#### ***HLT Patch***

The heated lidocaine/tetracaine patch (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.

In the U.S., the HLT Patch is marketed under the brand name Synera. Synera is approved in the U.S. to provide local dermal analgesia for superficial venous access and superficial dermatological procedures, such as excision, electrodesiccation and shave biopsy of skin lesions. In July 2013, the Company sold the rights to market and sell Synera in the U.S. to Galen US Incorporated (Galen) for its current indication (see Significant Transactions – 2013 – Synera U.S. Licensing Agreement). In March 2014, the FDA approved a prior approval supplement that requested the removal of the “not for home use” condition from the label. In December 2014, the Company entered into a three-party agreement, which

included a covenant from the Company not to sue one of the parties for patent infringement. As consideration, Nuvo will receive a total of US\$175,000, to be paid in five equal non-refundable instalments based upon the timeline provided in the agreement.

Nuvo 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.

#### ***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 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.

Galderma Pharma S.A. (Galderma), a global pharmaceutical company specialized in dermatology, holds the worldwide sales and marketing rights for Pliaglis. Galderma launched Pliaglis in the U.S. in March 2013 and in the E.U. in April 2013. In the E.U., the regulatory approval required a post-approval commitment study, the cost of which will be shared equally by Galderma and Nuvo. In South America, Pliaglis is approved and marketed in Brazil and Argentina. The Brazil approval triggered a US\$2.0 million milestone payment which was received by the Company in early 2014. Pliaglis was launched in Brazil in March 2014. Pliaglis is also approved in Canada, but has not been launched in this market. The Company expects Galderma to file for marketing approval in other countries around the world, including other South American countries, select Asian countries, South Africa and Australia.

Pliaglis was initially approved by the FDA in June 2006 and launched by Galderma, but was voluntarily removed from the U.S. market in 2008, due to manufacturing issues at a former third-party contract manufacturing organization (CMO). As a result, Galderma negotiated an amendment to the licensing agreements. In October 2009, Galderma and ZARS Pharma, Inc. (ZARS) negotiated a first amendment to the North American Pliaglis License Agreement and the Rest of World Pliaglis

Licensing Agreement (the Pliaglis First Amendment). Under the terms of the Pliaglis First Amendment, ZARS received a cash payment of US\$6 million in exchange for agreeing to a downward adjustment to the royalty rates it was to receive on the global net sales of Pliaglis. These reduced royalty rates continue until such time as Pliaglis achieves a predetermined monetary milestone that is based on the cumulative aggregate sales of Pliaglis and the difference between the original and the adjusted royalty rates. In addition, if this milestone is not achieved by April 2015, the royalty rates will be reduced further until such time as the target is reached, subject to a minimum annual royalty rate being paid to the Company. Upon the sales thresholds being met, the royalty rates revert back to the amounts specified under the original agreements. The Company anticipates that the predetermined monetary milestone will not be

achieved by April 2015 at which time the royalty rates received on net sales of Pliaglis will decline.

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

### Pipeline Expansion and Early Stage Drug Development

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

#### Topical Products and Technology Product Candidate Development Pipeline:

The following table summarizes our key product candidates:

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

- (1) Region and country abbreviations defined as follows: Australia (AU), Canada (CA), China (CN), Denmark (DK), Europe (EP), France (FR), Germany (DE), Great Britain (GB), Greece (GR), Ireland (IE), Italy (IT), Netherlands (NL), Hong Kong (HK), Japan (JP), Mexico (MX), New Zealand (NZ), Russian Federation (RU), South Africa (ZA), Switzerland (CH), United States (U.S.).
- (2) Mical is a product being developed under the Ferndale collaboration (see Significant Transactions – 2014 – Ferndale Collaboration).



### **TPT Group – Drug Delivery Technology**

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

#### *DuraPeel*

The DuraPeel technology is self-occluding, film-forming cream/gel formulations that provide extended release delivery to the site of application. The cream/gel contains a drug applied to a patient's skin forming a pliable layer that releases drug into the skin for up to 12 hours. The benefits of the DuraPeel technology include proven compatibility with a variety of 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 allowed in China and Europe. Patent applications are pending in Australia, Canada, Brazil, India, Japan, Hong Kong and the U.S. through 2031.

#### *MMPE*

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

### **Immunology Group**

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

#### *WF10*

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

It is believed that WF10 focuses on supporting the immune system by targeting the macrophage, a type of white blood cell that coordinates much of the immune

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

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

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

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

#### *WF10 Development for the Treatment of Allergic Rhinitis*

##### **What is Allergic Rhinitis?**

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

### *Clinical Studies*

#### **Single-Centre Phase 2a Study**

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

#### **Multi-Centre Phase 2b Study**

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

- a) WF10;
- b) WF10 with chlorate and sulphate removed; and
- c) WF10 with chlorite and sulphate removed.

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

Topline findings of the trial are:

- The WF10 arm demonstrated a reduction in TNSS over the course of the observation period, similar to the reduction in TNSS demonstrated in the WF10 arm in the Company's previous 2010 Phase 2 proof-of-concept study;
- The placebo arm demonstrated a reduction in TNSS over the course of the observation period that was significantly greater than demonstrated in the placebo arm of the Company's 2010 Phase 2 proof-of-concept study;
- Each of the Active Arms demonstrated a greater reduction in TNSS than placebo; however,
  - a) the difference between the WF10 arm and the placebo arm did not achieve statistical significance 3 weeks after commencement of the trial which was the trial's primary endpoint; and
  - b) the difference between the Active Arms and the placebo arm did not achieve statistical significance at measured time points over the course of the observation period.
- Treatments administered in the Active Arms were well tolerated with favourable safety profiles.

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

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

#### *Funding*

In July 2012, the SAB agreed to provide the Company with €4.4 million of funding to support a number of preclinical studies relating to both WF10 and improved reformulated versions of WF10 (Reformulated WF10). These studies were conducted by the Company in partnership with the University of Leipzig and the

Fraunhofer Institute and were focused on demonstrating the efficacy, safety and stability of Reformulated WF10. The total cost of this development program was estimated to be €6.3 million and the SAB committed to provide up to €4.4 million in funding to support these projects, €3.7 million of which will be provided to the Company's co-operative partners and €0.7 million of which will be provided directly to the Company. The funding was in the form of a non-repayable reimbursement of specific development monies expended by the Company until October 2014.

#### *Intellectual Property*

##### **WF10**

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

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

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

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

##### **Reformulated WF10**

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

##### *Oxoferin™*

Oxoferin, a topical wound healing agent, contains the same active ingredient as WF10, but at a lower concentration. Chronic, hard-to-heal wounds are a serious problem with an increasing incidence. Chronic wounds can be caused by such conditions as burns, pressure sores and poor circulation in the lower

extremities. Co-morbid conditions, such as diabetes and atherosclerosis, reduce blood flow to the extremities and also increase the likelihood of developing chronic wounds such as diabetic foot ulcers and venous ulcers.

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

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

#### **Manufacturing and Facilities**

The Company has a manufacturing facility in Varennes, Québec that produces Pennsaid, Pennsaid 2% and the bulk drug products for the HLT Patch. The Company manufactures these products for all of its global partners for all markets where the products are sold. The facility is in compliance with current Good Manufacturing Practices (GMP). In September 2012 and February 2013, the plant passed two FDA inspections as part of the U.S. Pennsaid 2% 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 is threatened with, or is 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 studies required under the Pennsaid U.S. Licensing Agreement that are critical to a) securing an indication and product label for Pennsaid 2% in the U.S. that is equivalent to those for Pennsaid; b) providing evidence of robust efficacy of Pennsaid 2% for marketing in the U.S. and throughout the world, and c) obtaining regulatory approval for Pennsaid 2% outside the U.S.;
- Mallinckrodt made significant, negligent errors in certain clinical studies for which it was responsible, including failure to properly conduct PK studies which led to the delay of the FDA's approval of Pennsaid 2% in the U.S.;
- Mallinckrodt willfully failed to apply requisite efforts to commercialize Pennsaid in the U.S. resulting in significantly lower sales and royalties payable to the Company; and
- Mallinckrodt willfully refused to pay the full milestone payments due to Nuvo under the Pennsaid U.S. Licensing Agreement.

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

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

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

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

On September 4, 2014, the Company reached a full settlement with Mallinckrodt of Nuvo's claims and Mallinckrodt's counterclaim relating to Nuvo's license to Mallinckrodt of the right to sell and market Pennsaid and Pennsaid 2% in the U.S. Under the terms of the settlement agreement, Mallinckrodt returned all U.S. rights to Pennsaid and Pennsaid 2% to Nuvo and paid US\$10 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, short-term investments, 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 sales 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; and
- Oxoferin – Venezuela and 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 and other legacy ventures. At December 31, 2014, the Company had an accumulated deficit of \$192.9 million, including net income of approximately \$38.6 million for the year ended December 31, 2014. Included in net income is a one-time gain of \$52.3 million related to the litigation settlement with Mallinckrodt (see Litigation – Mallinckrodt). As at December 31, 2014, the Company had cash of \$48.3 million and short-term investments of \$10.0 million. The Company received US\$10 million (\$11.2 million) from its litigation settlement with Mallinckrodt (see Litigation – Mallinckrodt) and US\$45 million (\$50.4 million) from the Pennsaid 2% U.S. Asset Sale (see Significant Transactions – 2014 – Pennsaid 2% U.S. Asset Sale).

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 success of the Company's Phase 3 clinical study using Pennsaid 2% as a treatment for acute sprains and strains which is expected to commence in the spring of 2015;
- the ability of Horizon to increase the number of prescriptions written for Pennsaid 2% in the U.S., as the Company earns revenue from selling Pennsaid 2% to Horizon;
- the commercial success of Pennsaid outside of the U.S., as the Company earns revenue from selling Pennsaid to its licensees and distributors in all territories where Pennsaid is sold, as well as royalties on net sales in Canada;
- the financial impact of the generic version of Pennsaid that launched in Canada in March 2014, as this may reduce revenue and cash flow;
- its ability to continue the development of WF10, as subsequent to the year-end, the Company announced the topline results of the Phase 2 WF10

clinical trial that failed to meet the primary endpoint. The Company is currently assessing the secondary data from this trial; 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 and short-term investments 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 2016. 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, 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.

**SELECTED FINANCIAL INFORMATION**

<i>in thousands (except per share)</i>	<b>Year ended December 31, 2014</b>	Year ended December 31, 2013
<b>OPERATIONS</b>		
Product sales	\$ 6,470	\$ 4,432
Royalties	5,458	6,098
Research and other contract revenue	505	272
Licensing fees	624	7,607
<b>TOTAL REVENUE</b>	<b>13,057</b>	18,409
<b>Total operating expenses</b>	<b>27,080</b>	22,483
<b>Loss from operations</b>	<b>(14,023)</b>	(4,074)
Other (income) expenses	(52,632)	6,187
<b>Income (loss) before income taxes</b>	<b>38,609</b>	(10,261)
Income tax expense	19	117
<b>Net income (loss)</b>	<b>38,590</b>	(10,378)
Other comprehensive income	38	666
<b>TOTAL COMPREHENSIVE INCOME (LOSS)</b>	<b>38,628</b>	(9,712)
<b>SHARE INFORMATION</b>		
Net income (loss) per share		
– basic	\$ 3.85	\$ (1.17)
– diluted	3.76	(1.17)
Average number of common shares outstanding for the year		
– basic	10,023	8,841
– diluted	10,269	8,841
<b>FINANCIAL POSITION</b>		
Cash	\$ 48,275	\$ 12,621
Short-term investments	10,000	–
Total assets	65,140	21,621
Finance lease & other obligations, including current portion	328	5,441
Total liabilities	9,477	9,423
Total equity	55,663	12,198



### **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, R&D expenses, general and administrative (G&A) expenses, sales and marketing (S&M) expenses and net interest expense. 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**

### **2014**

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

On October 17, 2014, the Company entered into an asset purchase agreement with Horizon pursuant to which the Company sold the sales and marketing rights, intellectual property and other assets with respect to Pennsaid 2% in the U.S. (Pennsaid 2% U.S. Sale Agreement) for cash consideration of US\$45 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 sales and marketing for Pennsaid 2% in the U.S. in early January 2015 and is now responsible for all matters related to Pennsaid 2% in the U.S.

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

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

### *Litigation Settlement*

On September 4, 2014, the Company reached a full settlement with Mallinckrodt of Nuvo's claims and Mallinckrodt's counterclaim related to Nuvo's license to Mallinckrodt to sell and market Pennsaid and Pennsaid 2% in the U.S. Under the terms of the settlement agreement, Mallinckrodt returned all U.S. rights to Pennsaid and Pennsaid 2% to Nuvo and paid the Company US\$10 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 studies. It is anticipated that the product candidates will then be made available for outlicensing. 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 entitles the holder to purchase one common share of the Company at a price of \$3.00 for a 24-month period. The Private Placement Warrants are subject to an acceleration feature, where the Company at its option, can force the exercise of the Private Placement Warrants following a specified date if the ten-day volume weighted share price for the Company's common shares is equal to or exceeds \$3.50 on the Toronto Stock Exchange (TSX) at any time during the warrant term. If the acceleration feature is used, any Private Placement Warrants that are not exercised prior to such date will expire.

As at December 31, 2014, 429,999 of the Private Placement Warrants were exercised and 15,650 were issued upon the exercise of 31,300 Broker Warrants.

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

## **2013**

### *Pennsaid Russia Licensing Agreement*

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

### *Synera U.S. Licensing Agreement*

In July 2013, the Company entered into a product acquisition and license agreement with Galen that sold the exclusive rights to sell and market Synera in the U.S. for its current indication. Under the terms of the agreement, Galen made an upfront payment to Nuvo of US\$4.5 million (Galen Upfront Payment) on closing and Nuvo receives royalties of 10% of net sales and is eligible to receive a US\$5.0 million milestone payment upon gross annual sales reaching US\$25.0 million and a further US\$5.0 million upon gross annual sales reaching US\$50.0 million.

### *Paladin Loan*

In July 2013, the Company completed an amendment to the loan agreement with Paladin that was executed in May 2012. Under the terms of the May 2012 loan agreement, Paladin agreed to loan the Company \$8.0 million in two equal tranches of \$4.0 million each (Paladin Debt). The first tranche was advanced on closing and the second tranche could be drawn by Nuvo, at its option, upon the achievement of predefined milestones. The loan bore interest at a rate of 15% per annum and would have matured on

May 25, 2016. Under the terms of the May 2012 loan agreement, the Company paid 10% of all royalty payments received by the Company on the sale of Pennsaid and Pennsaid 2% in the U.S.; 10% of all royalty and milestone payments received by the Company on the sale of Pliaglis; and Paladin offset and retained 100% of the royalties payable to the Company on Canadian distribution of Pennsaid. The loan was secured by a charge over Nuvo's assets, excluding the Immunology Group's assets.

The amended arrangement included a provision to borrow an additional \$4.0 million (the Third Tranche) upon the achievement of predefined milestones increasing the total debt available under the agreement to \$12.0 million (Amended Paladin Debt). The second tranche of \$4.0 million was advanced on closing of the Amended Paladin Debt arrangement. Under the terms of the Amended Paladin Debt, when the second tranche was drawn by Nuvo, Paladin was issued warrants to acquire 50,000 Nuvo common shares at \$1.82 per share which represented 130% of the 5-day trailing value weighted average trading price (VWAP)

of Nuvo common shares on the Toronto Stock Exchange (TSX). The warrants expire on July 10, 2016 and no warrants have been exercised to date. If Nuvo had exercised its option to draw down the Third Tranche of the loan, Paladin would have been entitled to warrants to acquire an additional 50,000 Nuvo common shares at 130% of the 5-day trailing VWAP of Nuvo common shares, as of the date that Nuvo draws the Third Tranche.

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

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

## RESULTS OF OPERATIONS

### Product Sales

<i>in thousands</i>	Year ended December 31, 2014 \$	Year ended December 31, 2013 \$
Pennsaid 2%	2,343	–
Pennsaid	3,412	3,133
Oxoferin	638	603
HLT patch	77	696
Total product sales	6,470	4,432

Product sales which represent the Company's sales to our licensees and distributors were \$6.5 million for the year ended December 31, 2014 compared to \$4.4 million for the year ended December 31, 2013.

#### *Pennsaid 2%*

Product sales of Pennsaid 2% were \$2.3 million for the year ended December 31, 2014 compared to \$nil for the year ended December 31, 2013 and represent the Company's sales of the Pennsaid 2% commercial format and its physician sample format to its licensees in the U.S. market. Pennsaid 2% was originally launched in the U.S. market in February 2014 by Mallinckrodt and all Pennsaid 2% product sales relate

to the U.S. market as the product has not received regulatory approval in any other territory.

In September 2014, the Company reached a settlement related to its litigation with Mallinckrodt. Under the terms of the settlement agreement, Mallinckrodt returned the U.S. sales and marketing rights to Pennsaid 2% to Nuvo (see Litigation – Mallinckrodt). In October 2014, the Company sold the U.S. rights to Pennsaid 2% to Horizon for US\$45 million. Under the terms of this agreement, 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.

*Pennsaid*

Product sales of Pennsaid were \$3.4 million for the year ended December 31, 2014 compared to \$3.1 million for the year ended December 31, 2013. Pennsaid product sales increased by \$0.5 million to the Company's Canadian partner and also include sales of an authorized generic version of Pennsaid that was launched by the Company's Canadian partner in the fourth quarter to compete with a generic version of Pennsaid that launched in May 2014. Partially offsetting this increase was a \$0.2 million decrease in sales to the Company's U.S. licensee.

As a result of the litigation settlement with Mallinckrodt, the U.S. rights to Pennsaid were returned to the Company. Under the terms of the Pennsaid 2% U.S. Sale Agreement, the Company agreed to discontinue the manufacture, sale and marketing of Pennsaid in the U.S. Pennsaid is no longer available in the U.S. as a branded pharmaceutical product, although generic versions of Pennsaid are available. Pennsaid was available in the U.S. market from April 2010 to December 2014.

Geographically for the year ended December 31, 2014, sales in the U.S. were \$0.7 million or 21% of total Pennsaid product sales [December 31, 2013 – \$0.9 million or 28%], sales in the E.U. were \$1.9 million or 56% of Pennsaid product sales [December 31, 2013 – \$1.9 million or 61%] and sales in Canada were \$0.8 million representing 23% of Pennsaid product sales [December 31, 2013 – \$0.3 million or 11%].

The Company expects that Pennsaid product sales may decline as Pennsaid is no longer distributed in the U.S. market, effective January 1, 2015 and in Canada,

a generic version of Pennsaid was launched in the first quarter of 2014 and a second generic version of Pennsaid is approved in Canada, but has not launched. Although, the Company's Canadian partner launched an authorized generic in Canada in late 2014, this initiative may not reduce the impact of the generic version of Pennsaid.

*Oxoferin*

Product sales of Oxoferin (a topical wound healing agent, contains the same active ingredient as WF10, but at a lower concentration) and WF10 were consistent at \$0.6 million for the years ended December 31, 2014 and 2013. In 2014, Ranbaxy launched Oxoferin in Morocco and Malaysia, the increase in sales from the launch and higher sales to the Company's distributor in Pakistan was offset by lower sales to the Company's distributor in Venezuela.

*HLT Patch sales*

Sales were \$0.1 million for the HLT Patch for the year ended December 31, 2014 compared to sales of \$0.7 million for the year ended December 31, 2013. In 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 CMO in the U.S. that manufactures the HLT Patch. In July 2013, the Company sold the U.S. rights for Synera to Galen (see Significant Transactions – 2013 – Synera U.S. Licensing Agreement) and now receives a royalty on net sales in the U.S. market instead of product sales as it did prior to the sale to Galen.

**OTHER REVENUE**

<i>in thousands</i>	<b>Year ended December 31, 2014</b>	Year ended December 31, 2013
	\$	\$
Royalties	5,458	6,098
Research and other contract revenue	505	272
Licensing fees	624	7,607
	<b>6,587</b>	13,977

## ROYALTY REVENUE

In 2014, the Company received royalties from: Mallinckrodt, its original U.S. licensee for Pennsaid and Pennsaid 2%, Paladin, its Canadian licensee for Pennsaid, Galderma, its global licensee for Pliaglis, Eurocept, its European licensee for Rapydan and 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, the Company started earning royalties from a generic company calculated at 50% of gross profits from their sales of a generic version of Pennsaid in the U.S. The royalty rate will decline to 10% when a third generic version of Pennsaid is launched (currently there are two generic versions of Pennsaid selling in the U.S. market). The settlement agreement was assigned to the Company under the terms of the litigation settlement with Mallinckrodt. 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 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. In addition, the Company agreed to discontinue the manufacture, sale and marketing of Pennsaid in the U.S. so there will no longer be royalties earned on Pennsaid sales in the U.S.

Royalty revenue decreased to \$5.5 million for the year ended December 31, 2014 compared to \$6.1 million for the year ended December 31, 2013.

### *Pennsaid Royalties*

	Year ended December 31, 2014	Year ended December 31, 2013
Pennsaid U.S. scripts	44,000	144,000
Pennsaid U.S. 150ml bottles dispensed	55,000	189,000

In the U.S., according to IMS Health, a provider of dispensed prescription data, approximately 44,000 Pennsaid prescriptions were dispensed in 2014 compared to 144,000 prescriptions in 2013. Royalty revenue on U.S. net sales of Pennsaid decreased to \$0.9 million for the year ended December 31, 2014 compared to \$4.7 million for the year ended December 31, 2013. The decrease in Pennsaid prescriptions and royalty revenue was related to the launch of Pennsaid 2% that occurred in February 2014, as Mallinckrodt worked to switch the market from Pennsaid to Pennsaid 2%, and the launch of two generic versions of Pennsaid in the U.S. market in 2014. Under the terms of the licensing agreement with

Mallinckrodt, upon the launch of a generic version of Pennsaid in the U.S., the royalty rate the Company received on the net sales of Pennsaid decreased from 20% to 15% of net sales with the launch of the first generic which occurred in May 2014 and the royalty rate declined to 10% when the second generic launched in December. The royalty rate for Pennsaid 2% remained at 20%.

Royalty revenue on Canadian net sales of Pennsaid was \$0.9 million for the year ended December 31, 2014 compared to \$1.1 million for the year ended December 31, 2013.

### *Pennsaid 2% Royalties*

	Year ended December 31, 2014	Year ended December 31, 2013
Pennsaid 2% U.S. scripts	59,000	–
Pennsaid 2% U.S. 150ml bottles dispensed	72,000	–

In February 2014, Pennsaid 2% was launched in the U.S. and according to IMS Health, approximately 59,000 Pennsaid 2% prescriptions were dispensed in 2014. For each prescription, approximately 1.24 bottles of Pennsaid 2% were dispensed.

Royalty revenue on U.S. net sales of Pennsaid 2% was \$3.0 million for the year ended December 31, 2014 compared to \$nil for the year ended December 31, 2013.

#### *Pennsaid Generic Royalties*

Royalty revenue related to sales of a generic version of Pennsaid in the U.S. was \$0.2 million for the year ended December 31, 2014 compared to \$nil for the year ended December 31, 2013. Under the terms of a settlement agreement with a generic company, the Company is entitled to royalties calculated at 50% of gross profits from sales of a generic version of Pennsaid in the U.S. The royalty rate will decline to 10% when a third generic version of Pennsaid is launched (currently there are two generic versions of Pennsaid selling in the U.S. market). The settlement agreement was assigned to the Company under the terms of the litigation settlement with Mallinckrodt and this generic version of Pennsaid was launched in the U.S. market in December 2014.

#### *Pliaglis Royalties*

Royalties related to the global net sales of Pliaglis were \$0.2 million for the year ended December 31, 2014 compared to \$0.1 million for the year ended December 31, 2013. The increase in royalties related to the launch of Pliaglis in Brazil which commenced in March. In the comparative period, royalties related to the initial launch quantities to support the launch of Pliaglis in the U.S. and the E.U.

#### *HLT Patch Royalties*

Royalties related to sales of Synera in the U.S. and Rapydan in the E.U. were \$0.2 million for the year ended December 31, 2014 compared to \$0.1 million for the year ended December 31, 2013. In the comparative period, the Company started earning royalties on U.S. net sales of Synera on July 10, 2013, the date the Company sold Synera to Galen (see Significant Transactions – 2013 – Synera U.S. Licensing Agreement).

#### **Research and Other Contract Revenue**

Research and other contract revenue for the year ended December 31, 2014 was \$0.5 million compared with \$0.3 million for the year ended December 31, 2013. These revenues were mainly derived from development services provided by the Company to Mallinckrodt.

#### **License Fees**

License fees were \$0.6 million for the year ended December 31, 2014 compared to \$7.6 million for the year ended December 31, 2013. 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 which is consistent with the comparative period. The amortization of this license fee ended in February 2014.

In 2013, license fee revenue consisted primarily of the Galen Upfront Payment related to the sale of Synera for the U.S. market (see Significant Transactions – 2013 – Synera U.S. Licensing Agreement) and the US\$2.0 million milestone payment (\$2.1 million) earned in the quarter pursuant to the Company's license agreement with Galderma related to the marketing approval for Pliaglis in Brazil.

#### **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:

<i>in thousands, except percentages</i>	<b>Year ended December 31, 2014</b>	Year ended December 31, 2013
Four largest customers	<b>\$ 10,558</b>	\$ 9,459
% of total revenue	<b>81%</b>	51%
Largest customer as % of total revenue	<b>51%</b>	32%



## OPERATING EXPENSES

<i>in thousands</i>	Year ended December 31, 2014 \$	Year ended December 31, 2013 \$
Cost of goods sold	5,537	4,769
Research and development	8,051	7,027
General and administrative	12,978	9,467
Sales and marketing	-	649
Interest expense, net	514	571
<b>Total operating expenses</b>	<b>27,080</b>	<b>22,483</b>

Total operating expenses for the year ended December 31, 2014 were \$27.1 million, an increase from \$22.5 million for the year ended December 31, 2013. The increase was primarily due to higher stock-based compensation (SBC) costs which are primarily included in G&A costs for the year.

### Cost of Goods Sold (COGS)

COGS for the year ended December 31, 2014 was \$5.5 million compared to \$4.8 million for the year ended December 31, 2013. In 2014, the increase in COGS was associated with increased Pennsaid and Pennsaid 2% product sales. The increase in product sales improved the gross margin to \$0.9 million for the year ended December 31, 2014 compared to a negative margin of \$0.3 million for the year ended December 31, 2013. For the year, the gross margin as a percentage of product sales was 15%.

### Research and Development

R&D expenses were \$8.1 million for the year ended December 31, 2014 compared to \$7.0 million for the year ended December 31, 2013. In 2014, the costs associated with the Company's Phase 2 clinical trial for WF10 were slightly offset by the savings realized from the closure of the Company's facility in Salt Lake City and the TPT Group office in 2013.

In the Immunology Group, R&D expenses were \$5.9 million for the year ended December 31, 2014 compared to \$3.2 million for the year ended December 31, 2013. The increase in R&D spending in the year related to the costs associated with the Phase 2 clinical trial using WF10 as a treatment for moderate to severe allergic rhinitis. 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 or its main constituents (sodium

chlorite and sodium chlorate) with saline in patients with refractory allergic rhinitis. The trial measured TNSS and other secondary endpoints and was completed in December 2014 with 179 patients completing the trial. The trial did not meet its primary endpoint and the Company is currently conducting a detailed review of the data and expects to release further information and analysis of the data including information on secondary endpoints when the analysis is completed. For a detailed description of the results, see Overview – Immunology Group.

In the TPT Group, R&D expenses were \$2.2 million for the year ended December 31, 2014 compared to \$3.8 million for the year ended December 31, 2013. The decrease in year-to-date spending related to the savings realized from the closure of the Company's facility in Salt Lake City and the TPT Group office in 2013. The R&D expenditures primarily related to the costs of the R&D facility at Varennes and the Company's share of the post approval commitment for Pliaglis. The R&D facility is focused on the collaboration agreement with Ferndale to develop two topical dermatology products based on Nuvo's patented MMPE technology (see Significant Transactions – 2014 – 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 \$13.0 million for the year ended December 31, 2014 compared to \$9.5 million for the year ended December 31, 2013. The increase was related to a \$4.5 million increase in SBC in the year primarily from

the adjustment to market value for the outstanding Share Appreciation Rights (SARs) and Deferred Share Units (DSUs) at December 31, 2014. The share price increased from \$2.15 at December 31, 2013 to \$7.00 at December 31, 2014. The growth in the share price was directly related to the significant increase in SBC. Partially offsetting the increase in SBC was a decrease of \$0.6 million in non-cash charges related to amortization of the Company's intangible assets and a decrease of \$0.3 million in termination costs related to the closure of the TPT Group offices in 2013.

#### Sales and Marketing

S&M expenses were \$nil for the year ended December 31, 2014 compared to \$0.6 million for the year ended December 31, 2013. In July 2013, the Company sold the U.S. rights to Synera to Galen (see Significant Transactions – 2013 – Synera U.S. Licensing Agreement). Subsequent to the transaction, the Company eliminated its S&M infrastructure.

#### Interest

Interest expense was \$0.7 million for the year ended December 31, 2014 compared to \$0.6 million for the year ended December 31, 2013. 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 (see – Significant Transactions – 2013 – Paladin Loan). The final payment to settle the Paladin Debt included a 5% prepayment interest penalty. Interest expense also includes 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.

Interest income increased to \$0.2 million for the year ended December 31, 2014 compared to \$0.1 million for the year ended December 31, 2013. 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 it invested in the fourth quarter in short-term investments.

The aggregate result was net interest expense of \$0.5 million for the year ended December 31, 2014 compared to net interest expense of \$0.6 million for the year ended December 31, 2013.

#### Loss from Operations

Loss from operations was \$14.0 million for the year ended December 31, 2014 compared to \$4.1 million for the year ended December 31, 2013. The increased loss from operations was attributable to higher revenue in the comparative period related to licensing fee revenue and an increase in operating expenses in the current period related to higher SBC costs. In the prior year, license fees consisted primarily of the Galen Upfront Payment related to the sale of Synera for the U.S. market (see Significant Transactions – 2013 – Synera U.S. Licensing Agreement) and the US\$2.0 million milestone payment (\$2.1 million) earned in the quarter pursuant to the Company's license agreement with Galderma related to the marketing approval for Pliaglis in Brazil.

#### OTHER INCOME EXPENSES

<i>in thousands</i>	Year ended December 31, 2014 \$	Year ended December 31, 2013 \$
Litigation settlement	(52,343)	–
Impairment of intangible assets	1,664	6,358
Loss (gain) on disposal of property, plant and equipment	(296)	10
Foreign currency gain	(1,657)	(181)
<b>Total other (income) expenses</b>	<b>(52,632)</b>	<b>6,187</b>

### 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 and has paid US\$10 million. 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. The Pennsaid Rights were valued at US\$45 million, as this represented the fair market value as evidenced by the sale in October 2014 to Horizon (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 includes the net cash settlement payment of \$8.8 million and the non-cash portion of \$43.5 million, net of direct costs to sell of \$6.9 million.

### 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 approximates 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. In the comparative period, the Company recorded an impairment charge for the HLT Patch of \$0.3 million and an impairment charge for Pliaglis of \$6.1 million.

### Foreign Currency Gain

The Company experienced a net foreign currency gain of \$1.7 million for the year ended December 31, 2014 compared to \$0.2 million for the year ended December 31, 2013. In the year, the Company realized a \$1.1 million foreign currency gain on the litigation settlement with Mallinckrodt. In addition, the stronger U.S. dollar increased the value of U.S. dollar denominated cash and receivables.

### Loss (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. In the comparative period, the Company recognized a loss of \$10,000 on disposal of leasehold improvements, furniture and fixtures and computer equipment from the closure of its offices in the U.S.

## NET INCOME (LOSS) AND TOTAL COMPREHENSIVE INCOME (LOSS)

<i>in thousands</i>	Year ended December 31, 2014 \$	Year ended December 31, 2013 \$
Net income (loss) before income taxes	38,609	(10,261)
Income tax expense	19	117
Net income (loss)	38,590	(10,378)
Unrealized gains on translation of foreign operations	38	666
<b>Total comprehensive income (loss)</b>	<b>38,628</b>	<b>(9,712)</b>

**Net Income (Loss)**

Net income was \$38.6 million for the year ended December 31, 2014 compared to a net loss of \$10.4 million for the year ended December 31, 2013. In the current year, the Company's \$14.0 million loss from operations was entirely offset by other income of \$52.6 million primarily related to the \$52.3 million gain on its litigation settlement with Mallinckrodt. In the comparative period, the Company's net loss of \$10.4 million primarily included a loss from operations of \$4.1 million and other losses of \$6.2 million which included an impairment charge of \$6.4 million.

**Total Comprehensive Income (Loss)**

Total comprehensive income was \$38.6 million for the year ended December 31, 2014 compared to a total comprehensive loss of \$9.7 million for the year ended December 31, 2013. The current year included an unrealized gain of \$38,000 on the translation of foreign operations compared to \$0.7 million in the comparative year.

**Net Income (Loss) Per Common Share**

Net income per common share was \$3.85 for the year ended December 31, 2014 versus net loss per common share of \$1.17 for the year ended December 31, 2013. On a diluted basis, net income per common share was \$3.76 for the year ended December 31, 2014 versus net loss per common share of \$1.17 for the year ended December 31, 2013.

The weighted average number of common shares outstanding on a basic and diluted basis was 10.0 million and 10.3 million for the year ended December 31, 2014. For the year ended December 31, 2013, the weighted average number of common shares outstanding on a basic and diluted basis was 8.8 million.

**Segments**

On a segmented basis, the TPT Group, which includes all Pennsaid, Pennsaid 2%, Pliaglis and the HLT Patch activities, incurred net income before income taxes of \$45.1 million for the year ended December 31, 2014 compared to a loss before income taxes of \$5.7 million for the year ended December 31, 2013. The current year includes a net gain of \$52.3 million related to the litigation settlement with Mallinckrodt. In addition, the impairment charge on intangible assets recorded in both years related to the TPT Group.

The Immunology Group, which includes all WF10 activities, incurred a loss before income taxes of \$6.4 million for the year ended December 31, 2014 compared to \$4.5 million for the year ended December 31, 2013. The increase in net loss in the Immunology Group was due to the costs associated with the Company's Phase 2 clinical trial for WF10 for the treatment of allergic rhinitis.

**LIQUIDITY AND CAPITAL RESOURCES**

<i>in thousands</i>	Year ended December 31, 2014 \$	Year ended December 31, 2013 \$
Net income (loss)	38,590	(10,378)
Items not involving current cash flows	(41,463)	7,630
Cash used in operations	(2,873)	(2,748)
Net change in non-cash working capital	5,513	1,013
Cash provided by (used in) operating activities	2,640	(1,735)
Cash provided by (used in) investing activities	33,708	(229)
Cash provided by (used in) financing activities	(815)	2,195
	35,533	231
Effect of exchange rates on cash	121	241
Net change in cash during the year	35,654	472
Cash beginning of year	12,621	12,149
<b>Cash end of year</b>	<b>48,275</b>	<b>12,621</b>

### **Cash**

Cash was \$48.3 million at December 31, 2014, an increase of \$35.7 million compared to \$12.6 million at December 31, 2013. In 2014, the Company received US\$10 million (\$11.2 million) from its litigation settlement with Mallinckrodt (see Litigation – Mallinckrodt) and US\$45 million (\$50.4 million) from the Pennsaid 2% U.S. Asset Sale (see Significant Transactions – 2014 – Pennsaid 2% U.S. Asset Sale).

### **Operating Activities**

Cash used in operations was \$2.9 million for the year ended December 31, 2014 compared to \$2.7 million for the year ended December 31, 2013. The increase in cash used in operations related to the increase in net income that was entirely offset by the change in non-cash items. The significant increase in net income in the current year related to the \$52.3 million gain on the litigation settlement, of which \$43.5 million was a non-cash item.

Overall cash provided by operating activities was \$2.6 million for the year ended December 31, 2014 compared to cash used in operating activities of \$1.7 million for the year ended December 31, 2013. The improvement related to a significant increase in the recovery of non-cash working capital of \$4.5 million partially offset by an increase in cash used in operations. The \$5.5 million recovery in working capital in the current year 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. In 2013, the recovery of working capital was primarily attributable to \$0.8 million related to the sale of Synera to Galen. Under the terms of the Synera U.S. Licensing Agreement, Galen purchased the Synera inventory which decreased inventory and assumed responsibility for the FDA products and establishments user fee which decreased other assets.

### **Investing Activities**

Net cash provided by investing activities totaled \$33.7 million for the year ended December 31, 2014 compared to net cash used in investing activities of \$0.2 million for the year ended December 31, 2013. Cash provided by investing activities was primarily attributable 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). These proceeds were partially offset by an investment of \$10.0 million in short-term investments. In 2013, cash used in investing activities was primarily attributable to 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 used in financing activities totaled \$0.8 million for the year ended December 31, 2014 compared to net cash provided by financing activities of \$2.2 million for the year ended December 31, 2013. During the year, the Company raised \$2.9 million net of financing fees through the Private Placement (see – Significant Transactions – 2014 – Private Placement) and \$1.4 million from the exercise of warrants related to the Private Placement. The increase in cash provided by financing activities was offset by payments towards the Company's loan, which was repaid in full in the year and payments towards the five-year consulting agreement recognized as part of the non-controlling interest in 2011. In the comparative period, cash provided by financing activities related to the \$4.0 million loan received from Paladin (see – Significant Transactions – 2013 – Paladin Loan) representing the second tranche of the loan, which was partially offset by payments towards the loan from Paladin and payments towards the five-year consulting agreement recognized as part of the consideration paid for the 2011 acquisition of the non-controlling interest in Nuvo Research AG.

**SELECTED QUARTERLY INFORMATION (UNAUDITED)**

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

	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
<i>in thousands, except per share data</i>	\$	\$	\$	\$
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)	4.85 <sup>(2)</sup>	(0.58) <sup>(1)</sup>
– diluted	(0.31)	(0.23)	4.80 <sup>(2)</sup>	(0.56) <sup>(1)</sup>
	March 31, 2013	June 30, 2013	September 30, 2013	December 31, 2013
	\$	\$	\$	\$
Revenue	2,251	3,320	9,137 <sup>(3)(4)</sup>	3,701
Net loss before income taxes	(3,242)	(2,191)	(2,919) <sup>(3)(4)(5)</sup>	(1,909)
Net loss per common share				
– basic and diluted	(0.37)	(0.25)	(0.34) <sup>(3)(4)(5)</sup>	(0.22)

- (1) The quarter ended December 31, 2014 included a \$1.7 million impairment charge on intangible assets related to Pliaglis and the HLT Patch.
- (2) 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).
- (3) The quarter ended September 30, 2013 included US\$2.0 million in licensing fees from Galderma representing the milestone payment for the marketing approval of Pliaglis in Brazil.
- (4) The quarter ended September 30, 2013 included the Galen Upfront Payment (see Significant Transactions – 2013 – Synera U.S. Licensing Agreement).
- (5) The quarter ended September 30, 2013 included a \$6.4 million impairment charge on intangible assets related to Pliaglis and the HLT Patch.

**FOURTH QUARTER RESULTS**

<i>in thousands</i>	Three months ended December 31, 2014 \$	Three months ended December 31, 2013 \$
Product sales	1,586	1,327
Royalties	1,226	1,761
License fees	567	609
Research and other contract revenue	48	4
	3,427	3,701
Cost of goods sold	1,601	1,175
Research and development	2,785	1,899
General and administrative expenses	4,255	2,497
Interest expense, net	56	190
Operating expenses	8,697	5,761
Other (income) expenses	842	(151)
Net loss before income taxes	(6,112)	(1,909)
Income taxes	31	33
<b>Net loss</b>	<b>(6,143)</b>	<b>(1,942)</b>
Other comprehensive income	39	137
Total comprehensive loss	<b>(6,104)</b>	<b>(1,805)</b>



## KEY DEVELOPMENTS

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

### WF10

- In January, the Company announced topline results of its Phase 2 clinical trial to investigate the safety and efficacy of WF10 in patients with refractory allergic rhinitis. As expected, the WF10 arm reduced allergy symptoms as evidenced by recorded patient Total Nasal Symptom Scores (TNSS). The placebo arm demonstrated an unexpected reduction in patient TNSS scores that was not only greater than the placebo arm in the Company's 2010 Phase 2 proof-of-concept clinical study, but also lasted much longer. While the WF10 arm and the 2 separate arms that included constituent elements of WF10 all performed better than placebo, the differences were not statistically significant.

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

### Pennsaid 2%

- In October, the Company sold its Pennsaid 2% U.S. rights to Horizon for US\$45 million. The Company will manufacture Pennsaid 2% for Horizon pursuant to a long-term supply agreement. Horizon launched the sale and marketing of Pennsaid 2% in January 2015;
- In November, the Company announced its plans to conduct a Phase 3 clinical trial in Germany of Pennsaid 2% for the treatment of acute pain to support regulatory approval applications for Pennsaid 2% in international jurisdictions. Commencement of the trial, which is subject to German regulatory approval, is expected in Q2 2015 with topline results expected Q4 2015; and
- In November, the Company reacquired from Paladin the rights to market Pennsaid 2% in South America, Central America, South Africa and Israel. As consideration for these rights, the Company provided its authorization to Paladin to market, sell and distribute an authorized generic version of Pennsaid in Canada.

### Paladin Loan Repayment

- In October, the Company paid \$3.7 million to Paladin in full repayment of its outstanding loan. All obligations of the Company were satisfied and all security was released and discharged.

## Operating Results

Total revenue for the three months ended December 31, 2014 was \$3.4 million compared to \$3.7 million for the three months ended December 31, 2013. The decrease in revenue was attributable to lower royalty revenue of \$0.5 million as a result of a \$1.3 million decrease in U.S. royalties related to net sales of Pennsaid which was only partially offset by an increase of \$0.8 million in U.S. royalties related to net sales of Pennsaid 2%. The decrease in royalty revenue was partially offset by an increase in product sales of \$0.3 million related to sales of Pennsaid 2% to Horizon to prepare for their launch of Pennsaid 2% in January 2015 that was partially offset by lower Pennsaid product sales to the Company's distributor in Greece.

Total operating expenses for the three months ended December 31, 2014 increased to \$8.7 million versus \$5.8 million for the three months ended December 31, 2013. The increase in operating expenses was primarily due to an increase in SBC expenses of \$2.8 million in the quarter.

COGS for the three months ended December 31, 2014 was \$1.6 million compared to \$1.2 million for the three months ended December 31, 2013. The increase in COGS was primarily related to an increase in product sales to our partners and distributors and an inventory charge related to obsolete inventory.

R&D expenses increased to \$2.8 million for the three months ended December 31, 2014 compared to \$1.9 million for the three months ended December 31, 2013. The increase in the quarter was primarily attributable to increased drug development spending related to the Company's Phase 2 clinical trial using WF10 as a treatment for allergic rhinitis.

G&A expenses increased to \$4.3 million for the three months ended December 31, 2014 compared to \$2.5 million for the three months ended December 31, 2013. The increase in the quarter was primarily related to increased SBC expense.

Other expenses were \$0.8 million for the three months ended December 31, 2014 which included 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 of \$0.3 million related to the sale of unused land at the Company's manufacturing site in Varennes, Québec. In the comparative period, the Company recognized other income of \$0.2 million primarily related to a foreign exchange gain.

Net loss for the three months ended December 31, 2014 was \$6.1 million compared to \$1.9 million for the three months ended December 31, 2013. The increase in net loss related to higher SBC expenses and the impairment charge.

### Liquidity

<i>in thousands</i>	<b>Three months ended December 31, 2014</b>	Three months ended December 31, 2013
	\$	\$
Net loss	<b>(6,143)</b>	(1,942)
Items not involving current cash flows	<b>2,564</b>	47
Cash used in operations	<b>(3,579)</b>	(1,895)
Net change in non-cash working capital	<b>10,864</b>	241
Cash provided by (used in) operating activities	<b>7,285</b>	(1,654)
Cash provided by (used in) investing activities	<b>33,876</b>	(40)
Cash used in financing activities	<b>(2,592)</b>	(459)
	<b>38,569</b>	(2,153)
Effect of exchange rates on cash	<b>24</b>	128
Net change in cash	<b>38,593</b>	(2,025)
Cash beginning of period	<b>9,682</b>	14,646
<b>Cash end of year</b>	<b>48,275</b>	12,621

Cash was \$48.3 million at December 31, 2014, an increase of \$38.6 million compared to \$9.7 million at September 30, 2014.

Cash provided by operating activities was \$7.3 million for the three months ended December 31, 2014 compared to cash used in operating activities of \$1.7 million for the three months ended December 31, 2013. The increase in cash used in operations was offset by a significant recovery of non-cash working capital in the quarter from the receipt of the US\$10 million litigation settlement proceeds.

Net cash provided by investing activities totaled \$33.9 million for the three months ended December 31, 2014 compared to net cash used in investing activities of \$40,000 for the three months ended December 31, 2013. Cash provided by investing activities related to the 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). These proceeds were

Total comprehensive loss was \$6.1 million for the three months ended December 31, 2014 compared to \$1.8 million for the three months ended December 31, 2013. Included in the comprehensive loss was a \$39,000 unrealized gain on the translation of foreign operations for the three months ended December 31, 2014 compared to \$137,000 for the three months ended December 31, 2013.

partially offset by an investment of \$10.0 million in short-term investments.

Net cash used in financing activities totaled \$2.6 million for the three months ended December 31, 2014 compared to \$0.5 million for the three months ended December 31, 2013. In the fourth quarter of 2014, the Company paid \$3.7 million to settle the Paladin Debt. In addition, the Company received \$0.9 million in proceeds from the exercise of warrants. In the comparative period, net cash used in financing activities related to repayments of other obligations.

### FINANCIAL INSTRUMENTS

#### Fair Values

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, 2014 and 2013.

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 of 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)
<i>in thousands</i>	\$	\$	\$	\$
<b>Assets:</b>				
Short-term Investments	10,000	10,000	-	-
<b>Total Assets</b>	<b>10,000</b>	<b>10,000</b>	<b>-</b>	<b>-</b>
<b>Liabilities:</b>				
Deferred Share Units	2,770	2,770	-	-
Stock Appreciation Rights	2,876	-	2,876	-
<b>Total Liabilities</b>	<b>5,646</b>	<b>2,770</b>	<b>2,876</b>	<b>-</b>

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis as at December 31, 2013:

	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)
<i>in thousands</i>	\$	\$	\$	\$
<b>Assets:</b>				
<b>Total Assets</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Liabilities:</b>				
Deferred Share Units	449	449	-	-
Stock Appreciation Rights	50	-	50	-
<b>Total Liabilities</b>	<b>499</b>	<b>449</b>	<b>50</b>	<b>-</b>

Level 1 assets include guaranteed investment certificates or other securities held by the Company that are valued at quoted market prices. The Company accounts for its investment at fair value on a recurring basis.

Level 1 liabilities include obligations of the Company for the DSU. 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 is 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

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 \$48.3 million in cash and \$10.0 million in short-term investments as at December 31, 2014, 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. A generic version of Pennsaid was approved and launched in the first quarter of 2014 and this generic may have an impact on the Company's future cash flows and revenues. In the U.S., the Company received royalties based on net sales of Pennsaid 2% in 2014; however, the Company sold the U.S. rights to Pennsaid 2% to Horizon and no longer receives royalties after January 1, 2015, when ownership of Pennsaid 2%

transferred to Horizon. The Company will receive product revenues from Horizon pursuant to a long-term exclusive supply agreement. The Company will also receive royalties on the sale of a generic version of Pennsaid in the U.S. market as part of a settlement agreement that was reached with a generic company.

The Company has contractual obligations related to accounts payable and accrued liabilities, purchase commitments and other obligations of \$12.0 million that are due in less than a year and \$0.4 million of contractual obligations that are payable from 2016 to 2018.

#### Credit Risk

The Company's cash and short-term investments subject the Company to a significant concentration of credit risk. At December 31, 2014, the Company had \$47.8 million invested with one financial institution in various bank accounts as per its practice of protecting its capital rather than maximizing investment yield through additional risk. This financial institution is a major Canadian bank which the Company believes lessens the degree of credit risk. The Company invested \$10.0 million in short-term investments with additional Schedule 1 Canadian banks and 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. At December 31, 2014, the Company's four largest customers located in North America and the E.U. represented 60% [December 31, 2013 – 88%] of accounts receivable and accounts receivable from customers located outside of North America and the E.U. represented 8% [December 31, 2013 – 8%] of accounts receivable.

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

<i>in thousands</i>	Year ended December 31, 2014 \$	Year ended December 31, 2013 \$
Current	2,940	4,031
0-30 days past due	43	34
31-60 days past due	20	–
Over 90 days past due	2	124
	<b>3,005</b>	<b>4,189</b>

### 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:

<i>in thousands</i>	Euros		U.S. Dollars	
	2014 €	2013 €	2014 \$	2013 \$
Cash	1,266	1,039	665	1,536
Accounts receivable	242	322	2,205	3,496
Other current assets	159	150	–	–
Accounts payable and accrued liabilities	(943)	(326)	(601)	(1,440)
Finance lease and other long-term obligations	–	–	(281)	(384)
	<b>724</b>	<b>1,185</b>	<b>1,988</b>	<b>3,208</b>

Based on the aforementioned net exposure as at December 31, 2014, 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 \$231 on total comprehensive income (loss) and a 10% appreciation or depreciation of the Canadian dollar against the euro would have an effect of \$102 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 five 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

running trials and other studies at U.S. sites, 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 its Canadian manufacturing facility and revenue generated in U.S. dollars from licensing 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 licensing 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:

<i>in thousands</i>	<b>Total</b>	2015	2016	2017 and thereafter
	\$	\$	\$	\$
Finance lease obligations	2	2	–	–
Operating leases	420	224	179	17
Purchase obligations	2,501	2,501	–	–
Other obligations <sup>(1)</sup>	9,490	9,287	174	29
	<b>12,413</b>	12,014	353	46

(1) 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

In the first quarter of 2014, certain officers of the Company participated in the Private Placement (See – Significant Transactions – 2014 – Private Placement) and acquired 67,768 Units on the same terms as the other purchasers. Proceeds raised from the Company's officers totaled \$152,000.

During 2013, the Company had a consulting arrangement with one of its independent directors that was terminated in the third quarter of 2013. Expenses under this agreement for 2013 were \$35,000.

### OUTSTANDING SHARE DATA

The number of common shares outstanding as at December 31, 2014 was 10.8 million compared to 8.8 million at December 31, 2013. The increase was due to the issuance of approximately 1.4 million shares issued with the Company's Private Placement (see – Significant Transactions – 2014 – Private Placement)

and 0.5 million shares issued upon the exercise of warrants from the Private Placement.

As at December 31, 2014, there were 886,742 options outstanding of which 556,771 were 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, 2014.

### **Critical Accounting Estimates**

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

(i) *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.

(ii) *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.

(iii) *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.

(iv) *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 remeasured at 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.

(v) *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.

### **RECENT ACCOUNTING PRONOUNCEMENTS**

Certain new standards, interpretations, amendments and improvements to existing standards were issued by the International Accounting Standards Board (IASB) or IFRS Interpretations Committee (IFRIC) that are mandatory for fiscal periods beginning on January 1, 2015 or later. The standards that may be applicable to the Company are as follows:

#### **IFRS 9 – Financial Instruments**

In October 2010, the IASB issued IFRS 9 *Financial Instruments* 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 Consolidated 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, 2017. 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 financial statements.

The Company assesses the impact of adoption of future standards on its Consolidated Financial Statements, but does not anticipate significant changes in 2015.

## **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.

As at December 31, 2014, the system of DCP has been 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 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, 2014. 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**

In 2013, the Committee of Sponsoring Organizations of the Treadway Commission issued an updated Internal Control Framework known as COSO (2013). The Company has transitioned to this updated framework on December 15, 2014, the required transition date. The Company has updated its documentation and processes under the new framework and there were no significant changes to its internal controls over financial reporting.

## **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.

### **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 outlicensed and these revenues are not sufficient to cover the costs of operating the business. The Company earns revenue from product sales of Pennsaid, Pennsaid 2%, WF10 and Oxoferin, but is dependent on its partners to sell these products in their respective licensed territories. The Company also earns revenue from royalties on the net sales of Pennsaid in Canada, on gross profits from the sales of a generic version of Pennsaid in the U.S., on the global net sales of Pliaglis and the net sales of the HLT Patch – branded as Synera in the U.S. and Rapydan in Europe. In Canada, royalty revenue for Pennsaid is expected to decline as a generic version of this product has launched in this market. The Company's partner in this market has launched an authorized generic to try to maintain market share. The Company will earn revenues from product sales and royalties related to the authorized generic. Royalties earned from Pliaglis and the HLT Patch are minimal.

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

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

### **Economic Environment**

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

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

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

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

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

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

The Company has minimal influence in the worldwide sales and marketing activities for Pliaglis, as these decisions are made by Galderma. Although the Company has three seats on the Joint Steering Committee that was established to monitor the development and commercial activities related to Pliaglis, the Company has no direct control over the technical, regulatory and commercial activities for the product. In addition, Galderma is responsible for the worldwide

commercialization of Pliaglis and, as such, the Company will rely on Galderma to successfully execute a worldwide commercialization program. Delays in obtaining the appropriate regulatory approvals for Pliaglis in territories or an unsuccessful launch in any major territory may have an adverse effect on the Company's royalty income and cash flows. In addition, an unsuccessful commercialization program may decrease the royalties and the royalty rate that the Company is eligible to receive and this may impact cash flows (see "Overview – Topical Products and Technology Group – Pliaglis").

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

### **Generic Drug Manufacturers**

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

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

In the U.S., under the "Hatch-Waxman Act", the FDA can approve an ANDA for a generic version of a branded drug or a variation of an existing branded drug, without undertaking the clinical testing necessary to obtain approval to market a new drug. This is referred to as the "ANDA process". In place of such clinical studies, an ANDA applicant usually needs to

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

In the U.S., Pennsaid 2% is protected by multiple patents listed in the FDA Orange Book and has received 3-year exclusivity under the “Hatch-Waxman Act”. All of the intellectual property for Pennsaid 2% for the U.S. is owned by Horizon and it is their responsibility to litigate any claims against these

patents from generic companies. The approval or launch of generic versions of Pennsaid 2% in the U.S. market could have an adverse effect on the Company’s future revenue from product sales.

#### **Obtaining Government and Regulatory Approvals**

The research, testing, manufacturing, packaging, labeling, approval, storage, selling, marketing and distribution of drug products are subject to extensive regulation in the U.S. by the FDA, in Canada by the Therapeutic Products Directorate (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, chemistry, manufacturing and controls (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 Notice of Compliance (NOC) for a New Drug Submission (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 pharmaceutical ingredients (API) or critical raw materials depending on the drug product, this means compliance to current GMPs for APIs and submission of all data related to the manufacture, control and testing of the API for quality, purity, identity and stability, as well as a complete description of the process, equipment, controls and standards used for the production of the API. This is usually submitted to the FDA in the form of a Drug Master File (DMF) by the manufacturer and referenced by the sponsor of the NDA. The DMF information and data is reviewed by the FDA as a critical component of the approvability of the NDA.

As a result, in the case where only one supplier of a particular API or critical raw material meets all of the FDA's (or other regulatory agencies) requirements and

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

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

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

- The Company may encounter difficulties in achieving volume production, quality control and quality assurance, as well as relating to shortages of qualified personnel. Accordingly, the Company might not be able to manufacture sufficient quantities to meet its clinical trial needs or to commercialize its products;
- The Company's manufacturing facilities are required to undergo satisfactory current GMP inspections prior to regulatory approval and are obliged to operate in accordance with FDA, E.U. and other nationally mandated GMP, which govern manufacturing processes, stability testing, record keeping and quality standards. Failure to establish and follow GMPs and to document adherence to such practices, may lead to significant delays in the availability of material for clinical studies and may

delay or prevent filing or approval of marketing applications for the Company's products; and

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

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

### **Patents, Trademarks and Proprietary Technology**

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

enforce or defend a patent infringement or proprietary rights violation action. Moreover, if the Company's products infringe patents, trademarks or proprietary rights of others, the Company could, under certain circumstances, become liable for substantial damages which could also have a material adverse effect.

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

The laws of some countries do not protect intellectual property rights to the same extent as the laws of Canada and the U.S. and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favour the enforcement of patents, trademarks and other intellectual property protection, particularly those protections relating to biotechnology and pharmaceuticals, which could make it difficult for the Company to stop the infringement of its patents. Proceedings to enforce patent rights in foreign jurisdictions could result in substantial cost and divert efforts and attention from other aspects of the business.

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

### **Inability to Achieve Drug Development Goals within Expected Time Frames**

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

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

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

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

In January 2015, the Company announced that it failed to meet the primary endpoint in its 16 week, double-blind, placebo controlled, Phase 2 clinical trial to investigate the safety and efficacy of WF10 in patients with refractory allergic rhinitis. See Overview – Immunology Group for more information on the results of this trial. The return on the Company's investment in Nuvo Research AG depends on the successful development of WF10 for allergic rhinitis or other conditions, the successful completion of reformulation activities, attaining new intellectual property protection,

clinical development, regulatory approvals and subsequent commercialization of WF10. At this time, the Company is conducting a detailed review of the data from the Phase 2 clinical trial that missed its primary endpoints and expects to release further information and analysis of the data including information on secondary endpoints when the analysis is completed. The review of this data will determine the future pathway for WF10. If the Company decides to continue investing in WF10, its reformulation efforts, future clinical trials and preclinical and clinical development programs with WF10 for allergic rhinitis and other disease indications and the pursuit of new intellectual property protection could yield additional disappointing or negative results, further diminishing or eliminating the Company's ability to commercialize WF10 or recover its investment in Nuvo Research AG.

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

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

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

The Company and its drug development partners must demonstrate through preclinical studies and clinical trials that the product being developed is safe and efficacious before obtaining regulatory approval for the commercial sale of such product. The results of preclinical studies and previous clinical trials are not necessarily predictive of future results and the Company's current product candidates may not have favourable results in later testing or trials. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study PK and pharmacodynamics and to understand the side effects of products at various doses and schedules. Success in

preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful and such success is not necessarily predictive of final results. Favourable results in early trials may not be repeated in later trials and positive interim results do not ensure success in final results. Even after the completion of Phase 3 clinical trials, the FDA, TPD, EMA or other regulatory authorities may disagree with the clinical trial design and interpretation of data and may require additional clinical trials to demonstrate the efficacy of product candidates.

A number of companies in the biotechnology and pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials and preclinical studies. The Company suffered a similar setback with the recent results of its Phase 2 clinical trial using WF10 for the treatment of allergic rhinitis where WF10 failed to meet its primary endpoint (see Overview – 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 Good Clinical Practice (GCPs) and that its preclinical studies are conducted in accordance with Good Laboratory Practice (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, a competitor's generic version of Pennsaid was launched in 2014. In addition, our partner launched an authorized generic to protect market share. The launch of these generic versions of Pennsaid may have an adverse impact on the Company's future revenue from Canada. In addition, 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.

### **Publications of Negative Study or Clinical Trial Results**

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

these products compete, the business, financial condition, results of operations and cash flows of the Company may be adversely affected.

### **Reimbursement and Product Pricing**

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

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

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



organizations such as health maintenance organizations and reforms to healthcare and government insurance programs, could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for the Company's products.

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

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

#### **Potential Product Liability**

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

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

distribution of its products, resulting in a material adverse effect on the Company.

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

#### **Litigation and Regulation**

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

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

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

#### **International Operations**

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

- different regulatory requirements for approval of its product candidates;
- dependence on local distributors;
- longer payment cycles and problems in collecting accounts receivable;

- adverse changes in trade and tax regulations;
- absence or substantial lack of legal protection for intellectual property rights;
- difficulty in managing widespread operations;
- political and economic instability;
- increased costs and complexities associated with financial reporting; and
- currency risks.

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

### **Taxes**

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

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

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

The Company, from time-to-time, has executed multiple reorganization transactions impacting its tax structure.

If a tax authority has a different interpretation from the Company's, it could potentially impose additional taxes, penalties or fines.

### **Volatility of Share Price**

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

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

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

### **Compliance with Laws and Regulations Affecting Public Companies**

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

to comply with the new laws, rules and regulations could result in enforcement actions, the assessment of other penalties and civil suits.

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

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

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

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

#### **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
- Products may fail to achieve market acceptance
- Publications of negative study or clinical trial results
- Hazardous materials and environmental
- Operating losses
- Quarterly fluctuations
- Personnel
- Information technology infrastructure
- Acquisitions and integration of complementary technology or businesses
- Inability to achieve expected savings from restructurings
- Losses due to foreign currency fluctuations
- Issuance of preferred shares
- Absence of dividends
- Active trading market for common shares
- 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](http://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 19, 2015



President and  
Co-Chief Executive Officer  
February 19, 2015



Vice President  
and Chief Financial Officer  
February 19, 2015

# 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, 2014 and 2013 and the consolidated statements of income (loss) and comprehensive income (loss), changes in equity and cash flows for the years ended December 31, 2014 and 2013, 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, 2014 and 2013, and their financial performance and cash flows for the years ended December 31, 2014 and 2013 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 earned net income of \$38,590,000 during the year ended December 31, 2014, which included other income of \$52,343,000 related to a litigation settlement, and, as of that date the Company had an accumulated deficit of \$192,939,000. 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.

The logo for Ernst & Young LLP, featuring the company name in a stylized, cursive script font.

February 19, 2015  
Toronto, Canada

Chartered Professional Accountants  
Licensed Public Accountants

# Consolidated Statements of Financial Position

<i>(Canadian dollars in thousands)</i>	As at December 31, 2014 \$	As at December 31, 2013 \$
<b>ASSETS</b>		
<b>CURRENT</b>		
Cash	48,275	12,621
Short-term investments <i>(note 20)</i>	10,000	–
Accounts receivable <i>(note 20)</i>	3,005	4,189
Inventories <i>(note 4)</i>	1,929	990
Other current assets <i>(note 5)</i>	770	541
<b>TOTAL CURRENT ASSETS</b>	<b>63,979</b>	<b>18,341</b>
<b>NON-CURRENT</b>		
Property, plant and equipment <i>(note 6)</i>	1,161	1,411
Intangible assets <i>(note 7)</i>	–	1,869
<b>TOTAL ASSETS</b>	<b>65,140</b>	<b>21,621</b>
<b>LIABILITIES AND EQUITY</b>		
<b>CURRENT</b>		
Accounts payable and accrued liabilities	9,149	3,925
Current portion of other obligations <i>(note 9)</i>	140	2,114
Deferred revenue <i>(note 8)</i>	–	57
<b>TOTAL CURRENT LIABILITIES</b>	<b>9,289</b>	<b>6,096</b>
Other obligations <i>(note 9)</i>	188	3,327
<b>TOTAL LIABILITIES</b>	<b>9,477</b>	<b>9,423</b>
<b>EQUITY</b>		
Common shares <i>(note 10)</i>	233,568	229,068
Contributed surplus <i>(notes 10, 11)</i>	13,910	13,573
Accumulated other comprehensive income (AOCI)	1,124	1,086
Deficit	(192,939)	(231,529)
<b>TOTAL EQUITY</b>	<b>55,663</b>	<b>12,198</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>65,140</b>	<b>21,621</b>

Commitments (Note 19)

See accompanying Notes.

On behalf of the Board of Directors



Anthony E. Dobranowski, Director



Dr. Klaus von Lindeiner, Director



# Consolidated Statements of Income (Loss) and Comprehensive Income (Loss)

<i>(Canadian dollars in thousands, except per share and share figures)</i>	Year ended December 31, 2014 \$	Year ended December 31, 2013 \$
<b>REVENUE</b>		
Product sales	6,470	4,432
Royalties	5,458	6,098
Research and other contract revenue	505	272
Licensing fees <i>(notes 8, 12)</i>	624	7,607
<b>TOTAL REVENUE</b>	<b>13,057</b>	<b>18,409</b>
<b>OPERATING EXPENSES</b>		
Cost of goods sold <i>(notes 4, 11, 16)</i>	5,537	4,769
Research and development expenses <i>(notes 11, 16)</i>	8,051	7,027
General and administrative expenses <i>(notes 11, 16)</i>	12,978	9,467
Sales and marketing expenses <i>(note 16)</i>	–	649
Interest expense	713	649
Interest income	(199)	(78)
<b>TOTAL OPERATING EXPENSES</b>	<b>27,080</b>	<b>22,483</b>
<b>OTHER EXPENSES (INCOME)</b>		
Litigation settlement, net <i>(note 13)</i>	(52,343)	–
Impairment of intangible assets <i>(note 7)</i>	1,664	6,358
Loss (gain) on disposal of property, plant and equipment <i>(note 6)</i>	(296)	10
Foreign currency gain	(1,657)	(181)
Other expense (income)	(52,632)	6,187
<b>Net income (loss) before income taxes</b>	<b>38,609</b>	<b>(10,261)</b>
Income tax expense	19	117
<b>NET INCOME (LOSS)</b>	<b>38,590</b>	<b>(10,378)</b>
<b>Other comprehensive income to be reclassified to net income in subsequent periods</b>		
Unrealized gains on translation of foreign operations	38	666
<b>TOTAL COMPREHENSIVE INCOME (LOSS)</b>	<b>38,628</b>	<b>(9,712)</b>
<b>Net loss per common share</b>		
– basic <i>(note 15)</i>	\$3.85	\$(1.17)
– diluted <i>(note 15)</i>	\$3.76	\$(1.17)
<b>Average number of common shares outstanding (in thousands)</b>		
– basic <i>(note 15)</i>	10,023	8,841
– diluted <i>(note 15)</i>	10,269	8,841

See accompanying Notes.

# Consolidated Statements of Changes in Equity

	Common Shares	Contributed Surplus	AOCI	Deficit	Total	
(Canadian dollars in thousands, except for number of shares)	(000s)	\$	\$	\$	\$	
Notes	10, 11	10, 11	9, 10, 11			
<b>Balance, December 31, 2012</b>	<b>8,735</b>	<b>228,705</b>	<b>13,495</b>	<b>420</b>	<b>(221,151)</b>	<b>21,469</b>
Stock option compensation expense	-	-	173	-	-	173
Unrealized gains on translation of foreign operations	-	-	-	666	-	666
Performance stock unit compensation expense	-	-	84	-	-	84
Warrants issued	-	-	30	-	-	30
Shares issued under Share Bonus Plan	29	209	(209)	-	-	-
Employee contributions to Share Purchase Plan	43	77	-	-	-	77
Employer's portion of Share Purchase Plan	43	77	-	-	-	77
Net loss	-	-	-	-	(10,378)	(10,378)
<b>Balance, December 31, 2013</b>	<b>8,850</b>	<b>229,068</b>	<b>13,573</b>	<b>1,086</b>	<b>(231,529)</b>	<b>12,198</b>
Shares issued, net of issue costs	1,390	2,582	-	-	-	2,582
Warrants issued, net of issuance costs	-	-	281	-	-	281
Warrants exercised	464	1,553	(174)	-	-	1,379
Stock option compensation expense	-	-	274	-	-	274
Unrealized gains on translation of foreign operations	-	-	-	38	-	38
Performance stock unit compensation expense	-	-	23	-	-	23
Shares issued under Share Bonus Plan	10	57	(57)	-	-	-
Employee contributions to Share Purchase Plan	23	135	-	-	-	135
Employer's portion of Share Purchase Plan	23	135	-	-	-	135
Stock options exercised	15	38	(10)	-	-	28
Net income	-	-	-	-	38,590	38,590
<b>Balance, December 31, 2014</b>	<b>10,775</b>	<b>233,568</b>	<b>13,910</b>	<b>1,124</b>	<b>(192,939)</b>	<b>55,663</b>

See accompanying Notes.

# Consolidated Statements of Cash Flows

<i>(Canadian dollars in thousands)</i>	Year ended December 31, 2014 \$	Year ended December 31, 2013 \$
<b>OPERATING ACTIVITIES</b>		
Net income (loss)	38,590	(10,378)
Items not involving current cash flows:		
Non-cash portion of litigation settlement <i>(note 13)</i>	(43,554)	–
Impairment of intangible assets <i>(note 7)</i>	1,664	6,358
Depreciation and amortization <i>(note 16)</i>	715	1,338
Deferred license revenue recognized <i>(note 8)</i>	(57)	(341)
Equity-settled stock-based compensation <i>(note 11)</i>	432	334
Unrealized foreign exchange gain	(652)	(126)
Loss (gain) on disposal of property, plant and equipment <i>(note 6)</i>	(296)	10
Inventory write-down <i>(note 4)</i>	192	5
Interest and accretion of long-term other obligations	77	68
Other	16	(16)
	(2,873)	(2,748)
Net change in non-cash working capital <i>(note 17)</i>	5,513	1,013
<b>CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES</b>	<b>2,640</b>	<b>(1,735)</b>
<b>INVESTING ACTIVITIES</b>		
Acquisition of short-term investments <i>(note 20)</i>	(10,000)	–
Acquisition of property, plant and equipment <i>(note 6)</i>	(224)	(229)
Proceeds from sale of property, plant and equipment <i>(note 6)</i>	378	–
Proceeds from disposal of asset held for sale, net <i>(note 14)</i>	43,554	–
<b>CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES</b>	<b>33,708</b>	<b>(229)</b>
<b>FINANCING ACTIVITIES</b>		
Proceeds from other obligations	–	4,000
Issuance of common shares <i>(notes 10, 11)</i>	3,026	77
Exercise of warrants <i>(note 10)</i>	1,379	–
Repayment of other obligations <i>(note 9)</i>	(5,220)	(1,882)
<b>CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES</b>	<b>(815)</b>	<b>2,195</b>
Effect of exchange rate changes on cash	121	241
Net change in cash during the year	35,654	472
Cash, beginning of year	12,621	12,149
<b>CASH, END OF YEAR</b>	<b>48,275</b>	<b>12,621</b>
<b>Interest paid'</b>	<b>700</b>	<b>551</b>
<b>Interest received'</b>	<b>149</b>	<b>69</b>
<b>Income taxes paid'</b>	<b>55</b>	<b>105</b>

1. 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.

# Notes to 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 specialty pharmaceutical company with a diverse portfolio of products and technologies. The Company operates two distinct business units: the Topical Products and Technology (TPT) Group and the Immunology Group. The TPT Group has four commercial products, a pipeline of topical and transdermal products focusing on 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, a development program for the treatment of allergic rhinitis and an immune system modulation platform that has the potential to support treatments for a broad range of immune system related disorders. The Company's registered office and principal place of business is located at 7560 Airport Road, Unit 10, Mississauga, Ontario L4T 4H4.

### Topical Products and Technology Group

The TPT Group has four commercialized products: Pennsaid® 2%, Pennsaid, the heated lidocaine/tetracaine patch (HLT Patch) and Pliaglis.

Pennsaid 2% is a topical non-steroidal anti-inflammatory drug (NSAID) containing 2% diclofenac sodium compared to 1.5% for original 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 13 – 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 14 – 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 more viscous than Pennsaid, is supplied in a metered dose pump bottle and has been approved for twice daily dosing compared to four times a day for Pennsaid. Pennsaid 2% is not approved in any country outside the U.S. Pennsaid 2% is currently manufactured by the Company for sale to Horizon.

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. rights to Pennsaid were returned to the Company (see Note 13 – Litigation Settlement). Under the terms of the agreement with Horizon for the sale of the Pennsaid 2% rights, the Company agreed to discontinue the manufacture, sale and marketing of Pennsaid in the U.S. Pennsaid is no longer available in the U.S. as a branded pharmaceutical product, although generic versions of Pennsaid are available. Pennsaid was available in the U.S. market from April 2010 to December 2014.

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 various brand names including Rapydan.

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

## **Immunology**

The Immunology Group is focused on developing drug products that modulate chronic inflammation processes resulting in a therapeutic benefit. Such pathological, inflammatory processes play an important role in the onset of several diseases including allergic rhinitis, allergic asthma, rheumatoid arthritis and inflammatory bowel diseases. 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., Asia and South America as a topical wound healing agent under the trade names Oxoferin and Oxovasin™.

## **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, 2014, the Company had an accumulated deficit of \$192,939 including net income of \$38,590 during the year ended December 31, 2014, of which \$52,343 related to the litigation settlement with Mallinckrodt recognized in the third quarter (see Note 13 – Litigation Settlement). The Company's ability to continue as a going concern depends on:

- the success of the Company's Phase 3 clinical study using Pennsaid 2% as a treatment for acute sprains and strains which is expected to commence in the spring of 2015;
- the ability of Horizon to increase the number of prescriptions written for Pennsaid 2% in the U.S., as the Company earns revenue from selling Pennsaid 2% to Horizon;
- the commercial success of Pennsaid outside of the U.S., as the Company earns revenue from selling Pennsaid to its licensees and distributors in all territories where Pennsaid is sold, as well as royalties on net sales in Canada;
- the financial impact of the generic version of Pennsaid that launched in Canada in March 2014, as this may reduce revenue and cash flow;
- its ability to continue the development of WF10, as subsequent to the year-end, the Company announced the topline results of the Phase 2 WF10 clinical study that failed to meet the primary endpoint. The Company is currently assessing the secondary data from this study; 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 and short-term investments, together with the revenues it expects to generate from product sales and royalty payments will be sufficient to execute its current business plan into 2016. 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 19, 2015, 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). The 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) *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.

(ii) *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.

(iii) *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.

(iv) *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 remeasured at 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. Details of the assumptions used are included in Note 11.

(v) *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.

**Basis of Consolidation**

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

	% Ownership	
	December 31, 2014	December 31, 2013
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 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 OCI with the cumulative gain or loss reported in 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 which 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.

## Notes to Consolidated Financial Statements

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

### Cash

Cash is comprised of 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 are comprised of 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.

## **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, 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 is applied to combined elements as a single unit of accounting.

## Notes to Consolidated Financial Statements

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

### *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 which 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.

## Notes to Consolidated Financial Statements

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

### **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 Plan for non-employee directors, the Deferred Share Unit Plan for employees and the Stock Appreciation Rights Plan. All are described in Note 11.

#### *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.

#### *Performance Share Unit Plan*

A Performance Share Unit (PSU) issued to an employee under the Share Bonus Plan, provides an employee with an opportunity to earn common shares of the Company, if certain predefined annual corporate non-market performance objectives (PSU Objectives) are achieved. If these PSU Objectives are achieved, the PSUs are earned by the employee (Earned PSUs). Each Earned PSU then vests over the two calendar years subsequent to the year in which the PSU Objectives were achieved in three equal installments. At each vesting date, one Nuvo common share is issued to the employee for each vesting PSU.

Upon the issuance of PSUs to an employee, the Company must calculate the fair value of the grant (PSU Grant Value) by estimating the number of PSUs that will become Earned PSUs and determine the fair value of each of these PSUs. For each PSU that is anticipated to become an Earned PSU, the fair value is determined using the market price of the underlying common shares on the grant date. This value is amortized to income as compensation expense over the relevant vesting period with the corresponding credit recorded as contributed surplus. At each subsequent reporting date prior to final determination of whether a PSU becomes an Earned PSU, management must make an estimate of the number of PSUs expected to be earned by the employees based on the PSU Objectives and, if necessary, adjust the PSU Grant Value accordingly. When a PSU vests and common shares are issued to the employee, the PSU Grant Value related to the vesting PSUs is transferred from contributed surplus to common shares.

#### *Deferred Share Unit Plan*

The Deferred Share Unit (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*

Stock Appreciation Rights (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**

During the year, the Company adopted IAS 32 *Offsetting Financial Assets and Liabilities* and this adoption did not have a material impact on 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 mandatory for fiscal periods beginning on January 1, 2015 or later. The standards that may be applicable to the Company are as follows:

#### *IFRS 9 – Financial Instruments*

In October 2010, the IASB issued IFRS 9 *Financial Instruments* 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 Consolidated 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, 2017. 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 financial statements.

The Company assesses the impact of adoption of future standards on its Consolidated Financial Statements, but does not anticipate significant changes in 2015.

## Notes to Consolidated Financial Statements

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

### 4. INVENTORIES

Inventories consist of the following at:

	December 31, 2014	December 31, 2013
	\$	\$
Raw materials	515	393
Work in process	146	204
Finished goods	1,268	393
	1,929	990

During the year ended December 31, 2014, inventories in the amount of \$4.5 million [December 31, 2013 – \$3.9 million] were recognized as cost of goods sold. During the year ended December 31, 2014, \$138 of raw materials in the TPT Group were written down [December 31, 2013 – \$24 of raw materials and \$20 of finished goods] and there were no reversals of prior write downs [December 31, 2013 – \$25]. For the Immunology Group, \$54 (€38) of finished goods were written down during the year ended December 31, 2014 [December 31, 2013 – \$nil] and there were no reversals of prior write downs during the year ended December 31, 2014 [December 31, 2013 – \$14 (€10)].

### 5. OTHER CURRENT ASSETS

Other current assets consist of the following at:

	December 31, 2014	December 31, 2013
	\$	\$
Other receivables (i)	543	296
Prepaid expenses	182	198
Deposits	45	47
	770	541

(i) Includes \$223 [December 31, 2013 – \$219] related to R&D expenditures which the Company is eligible for reimbursement under funding agreements with the Development Bank of Saxony (SAB) for the development of WF10 related projects. The amounts reimbursed are included in R&D expenses.

## 6. PROPERTY, PLANT AND EQUIPMENT

PP&E consists of:

<b>Cost</b>	Land <sup>(i)</sup>	Buildings	Leasehold Improvements	Furniture & Fixtures	Computer Equipment	Production Laboratory & Other Equipment <sup>(ii)</sup>	Total
	\$	\$	\$	\$	\$	\$	\$
Balance, December 31, 2012	124	1,977	173	276	1,004	3,276	6,830
Foreign exchange movements	–	94	5	7	3	29	138
Additions	–	11	–	–	1	217	229
Disposals	–	–	(64)	(12)	(4)	–	(80)
<b>Balance, December 31, 2013</b>	<b>124</b>	<b>2,082</b>	<b>114</b>	<b>271</b>	<b>1,004</b>	<b>3,522</b>	<b>7,117</b>
Foreign exchange movements	–	(38)	–	(1)	(2)	(9)	(50)
Additions	–	15	–	–	37	172	224
Disposals	(82)	–	–	–	–	–	(82)
<b>Balance, December 31, 2014</b>	<b>42</b>	<b>2,059</b>	<b>114</b>	<b>270</b>	<b>1,039</b>	<b>3,685</b>	<b>7,209</b>

### Accumulated depreciation

Balance, December 31, 2012	–	1,416	150	267	896	2,487	5,216
Foreign exchange movements	–	95	2	6	3	22	128
Depreciation expense	–	59	18	5	63	287	432
Disposals	–	–	(56)	(10)	(4)	–	(70)
<b>Balance, December 31, 2013</b>	<b>–</b>	<b>1,570</b>	<b>114</b>	<b>268</b>	<b>958</b>	<b>2,796</b>	<b>5,706</b>
Foreign exchange movements	–	(37)	–	(3)	(1)	(7)	(48)
Depreciation expense	–	58	–	2	30	300	390
<b>Balance, December 31, 2014</b>	<b>–</b>	<b>1,591</b>	<b>114</b>	<b>267</b>	<b>987</b>	<b>3,089</b>	<b>6,048</b>

NBV at December 31, 2013	124	512	–	3	46	726	1,411
<b>NBV at December 31, 2014</b>	<b>42</b>	<b>468</b>	<b>–</b>	<b>3</b>	<b>52</b>	<b>596</b>	<b>1,161</b>

- (i) 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.
- (ii) Production, laboratory and other equipment at December 31, 2014 included a cost of \$56 [December 31, 2013 – \$56] and accumulated depreciation of \$55 [December 31, 2013 – \$53] for assets under finance leases. Depreciation of PP&E was \$2 for the year ended December 31, 2014 [December 31, 2013 – \$3] related to assets under finance leases.

## Notes to Consolidated Financial Statements

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

### 7. INTANGIBLE ASSETS

<b>Cost</b>	Pliaglis	HLT Patch	<b>Total</b>
	Intellectual Property	Intellectual Property	
	\$	\$	\$
Balance, December 31, 2012	15,097	1,449	16,546
Foreign exchange movements	1,044	102	1,146
Balance, December 31, 2013	16,141	1,551	17,692
Foreign exchange movements	1,465	140	1,605
<b>Balance, December 31, 2014</b>	<b>17,606</b>	<b>1,691</b>	<b>19,297</b>
<b>Accumulated amortization</b>			
Balance, December 31, 2012	7,213	594	7,807
Foreign exchange movements	697	55	752
Impairment charge	6,098	260	6,358
Amortization expense	783	123	906
Balance, December 31, 2013	14,791	1,032	15,823
Foreign exchange movements	1,362	100	1,462
Amortization expense	251	97	348
Impairment charge	1,202	462	1,664
<b>Balance, December 31, 2014</b>	<b>17,606</b>	<b>1,691</b>	<b>19,297</b>
Net carrying amount as at December 31, 2013	1,350	519	1,869
<b>Net carrying amount as at December 31, 2014</b>	<b>-</b>	<b>-</b>	<b>-</b>

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).

In the prior year, the Company reviewed the carrying values of the intangible assets for potential impairment at December 31, 2013, as commercial efforts for the HLT Patch and the launch of Pliaglis did not meet expectations. Management determined that each asset was impaired, such that recoverable amounts were lower than the carrying amounts. Consistent with the current year approach, the recoverable amount and value in use (being the present value of expected future cash flows) was calculated using licensing partner revenue forecasts, net of direct costs forecasted by management, discounted at an after-tax rate of 15% which approximated the Company's weighted average cost of capital for the period. As at December 31, 2013, the Company recorded an impairment charge for the HLT Patch of \$260 and an impairment charge for Pliaglis of \$6,098 in impairment of intangible assets in the Consolidated Statements of Income (Loss) and Comprehensive Income (Loss).

## 8. DEFERRED REVENUE

Under the Canadian licensing arrangements with Paladin in 2005 and 2006, certain payments were received for the Canadian marketing rights to Pennsaid. All amounts were amortized to income systematically based on the expected-performance period. During the year ended December 31, 2014, the Company recorded licensing revenue of \$0.1 million [December 31, 2013 – \$0.3 million] pertaining to amounts received in 2005. As at December 31, 2014, the Company's deferred revenue balance was \$nil as the amortization term for the Canadian licensing arrangements had ended [December 31, 2013 – \$0.1 million].

## 9. OTHER OBLIGATIONS

Other obligations consist of the following as at:

	December 31, 2014	December 31, 2013
	\$	\$
Other loan	–	5,028
Long-term consulting agreement from acquisition of non-controlling interest	326	408
Finance lease obligations	2	5
	328	5,441
Less amounts due within one year	140	2,114
Long-term balance	188	3,327

### Other loan

In May 2012, the Company signed a loan agreement with Paladin, its Canadian licensing partner for Pennsaid and the HLT Patch that was amended in July 2013 (Loan Agreements). Under this loan facility, the Company could borrow up to \$12.0 million from Paladin in three equal tranches of \$4.0 million each (Paladin Debt). The first tranche was advanced on closing of the May 2012 agreement, the second tranche was advanced on closing of the July 2013 amendment and the third tranche could be drawn by the Company, at Nuvo's option, upon the achievement of predefined milestones. The loan bore interest at a rate of 15% per annum and would have matured on May 25, 2016. The loan was collateralized by a charge over the assets of the TPT Group. Under the terms of the Loan Agreements, the Company paid 10% of all royalty payments received by the Company on the sale of Pennsaid and Pennsaid 2% in the U.S.; 10% of all royalty and milestone payments received by the Company on the sale of Pliaglis; excluding the US\$6.0 million in Pliaglis milestone payments and 10% of all royalty payments and milestones received by the Company on the sale of Synera in the U.S. by Galen, excluding the US\$4.5 million upfront payment for the acquisition of the U.S. rights for Synera. In addition, Paladin had offset and retained 100% of the royalties payable to the Company on Canadian distribution of Pennsaid until February 28, 2014.

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 warrants expire on July 10, 2016.

The fair value of the warrants issued with the second tranche was measured using the Black-Scholes option pricing model at a value of \$0.60 per warrant using the following inputs: share price – \$1.45, strike price – \$1.82, expected life – 3 years, risk-free interest rate – 1.25% and a volatility factor of 71.56%. The total warrant value of \$30 was recorded as a discount to the second tranche.

In addition to normal repayment terms throughout the year, the Company paid \$3.7 million to Paladin to settle the Paladin Debt on October 16, 2014. The payment included a 5% prepayment penalty charge. As a result of the payment, all obligations of Nuvo and the other obligors under the loan agreement were satisfied and all security was released and discharged.

## Notes to Consolidated Financial Statements

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

### 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 5-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 twelve-month periods ending December 31:

	\$
2015	174
2016	174
2017	29
Total payments	377
Less amount representing interest (approximately 15.5%)	(51)
Present value of obligation, including accretion	326
Less current portion	138
<b>Long-term balance</b>	<b>188</b>

## 10. 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 shareholder 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 consists of one common share of the Company and one-half of one common share purchase warrant of the Company (Unit). The Company issued 695,000 common share purchase warrants (Private Placement Warrants).

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



In connection with the Private Placement, a finder's fee consisted of (a) a 6% cash commission amounting to \$0.2 million, and (b) broker warrants to purchase Units at a price of \$2.54 per Unit (Broker Warrants), equal to 6% of the number of Units issued. The finder's fee was paid on Units purchased by new investors and not on Units purchased by management or its advisors. Each Broker Warrant unit entitles the holder to purchase one common share of the Company at a price of \$2.54 and includes one-half of one common share purchase warrant of the Company which entitles the holder to purchase one common share of the company at price of \$3.00 for a 24-month period. The Company issued 78,233 Broker Warrants.

The fair value of the Private Placement Warrants and the Broker Warrants was determined using the Binomial Lattice valuation model. The Binomial Lattice valuation model was believed by management to be the best available technique for these compound units because, in addition to providing for inputs such as trading market values, volatilities and risk-free rates, the Binomial Lattice valuation model also embodied simulated warrant values considering the acceleration feature and the probability of exercise. In addition to the strike price for the Private Placement Warrants and the Broker Warrants, the following inputs were used in the model: volatility factor of 80%, risk-free rate of 1.02% and a 24-month life. The Private Placement Warrants were valued at \$0.55 per unit, the Broker Warrants were valued at \$0.81 per unit and the embedded warrant within the Broker Warrant was valued at \$0.55 per unit.

The proceeds, net of commissions and fees, in addition to Broker Warrants were allocated between common shares and warrants based on relative fair values of common shares and warrants. The Company recorded \$2.6 million in common shares and \$0.3 million was recorded in the warrant reserve, within contributed surplus in the Consolidated Statements of Financial Position.

#### Warrants

The warrants outstanding by tranche are as follows:

	Expiry Date	Exercise price	December 31, 2014 \$	December 31, 2013 \$
Private Placement Warrants	March 31, 2016	\$3.00	277,501	–
Broker Warrants (i)	March 31, 2016	\$2.54	46,933	–
Paladin Warrants (ii)	July 10, 2016	\$1.82	50,000	50,000
			<b>374,434</b>	50,000

(i) 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.

(ii) See Note 9 for a description of the Paladin Warrants.

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, 2012	–	–
Issued	50,000	1.82
Balance, December 31, 2013	50,000	1.82
Issued	788,883	2.95
Exercised	(464,449)	2.97
<b>Balance, December 31, 2014</b>	<b>374,434</b>	<b>2.78</b>

## Notes to Consolidated Financial Statements

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

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

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

As at December 31, 2014, the number of options available and reserved for issue was 122,620.

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

	Number of Options 000s	Range of Exercise Price \$	Weighted Average Exercise Price \$
Balance, December 31, 2012	756	5.20 – 130.65	9.75
Granted	126	1.96	1.96
Forfeited	(96)	5.20 – 25.35	8.19
Expired	(1)	130.65	130.65
Balance, December 31, 2013	785	1.96 – 37.05	8.91
Granted	212	3.39	3.39
Exercised (i)	(15)	1.96	1.96
Forfeiture	(32)	5.53 – 13.00	7.09
Expired	(63)	19.50 – 37.05	20.61
<b>Balance, December 31, 2014</b>	<b>887</b>	<b>1.96 – 24.05</b>	<b>6.93</b>

(i) The weighted average share price for the options exercised in 2014 was \$6.92.

The following table summarizes the outstanding and exercisable options held by directors, officers, employees and consultants as at December 31, 2014:

Exercise Price Range \$	Outstanding			Exercisable	
	Number of Options (000s)	Remaining Contractual Life (years)	Weighted Average Exercise Price \$	Vested Options (000s)	Weighted Average Exercise Price \$
1.96 – 5.53	383	8.8	3.31	123	3.51
6.50 – 8.78	334	4.7	7.72	264	8.05
11.05 – 24.05	170	2.2	13.54	170	13.54
	<b>887</b>	<b>6.0</b>	<b>6.93</b>	<b>557</b>	<b>8.72</b>

The fair value of each tranche is measured at the date of grant using the Black-Scholes option pricing model. Options are valued with a calculated forfeiture rate of 7.0% [December 31, 2013 – 7.0%], and the remaining model inputs for options granted during the year ended December 31, 2014 were as follows:

Options (000s)	Grant Date	Share Price \$	Exercise Price \$	Risk-free Interest Rate %	Expected Life (years)	Volatility Factor %	Fair Values \$
212	May 6, 2014	3.20	3.39	1.1 – 1.4	2 – 5	71 – 78	1.26 – 1.85

#### 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 2014, employees contributed \$135 [December 31, 2013 – \$77] to the plan and the Company matched these contributions by issuing 23,305 common shares [December 31, 2013 – 43,112] with a fair value of \$135 [December 31, 2013 – \$77] that was recorded as compensation expense. The total number of shares issued under this plan during the year ended December 31, 2014 was 46,610 [December 31, 2013 – 86,224].

#### Share Bonus Plan

A PSU provides an employee with an opportunity to earn common shares of the Company if certain PSU objectives are achieved. If these PSU objectives are achieved, the PSUs are Earned PSUs. Each Earned PSU then vests over the subsequent two calendar years in three equal instalments. One PSU has a value equal to one Nuvo common share.

#### 2012 PSUs

In the first quarter of 2013, the Board of Directors assessed the PSU objectives at the end of the performance period, December 31, 2012 and determined that 32,565 of the 47,730 PSUs granted on March 29, 2012 were Earned PSUs (2012 PSUs). These 2012 PSUs had an aggregate value of \$201, but were adjusted to \$185 after certain PSUs were forfeited in December 2013. During the year ended December 31, 2014, \$23 of the aggregate value of the 2012 PSUs were recognized as compensation expense with a corresponding credit to contributed surplus [December 31, 2013 – \$64]. As at December 31, 2013, all tranches of the 2012 PSUs had vested and were issued in common shares with \$185 transferred from contributed surplus to common shares. The remaining aggregate value for the 2012 PSUs is \$nil.

## Notes to Consolidated Financial Statements

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

### Deferred Share Unit Plan

#### Directors

On January 1, 2009, the Company established the DSU Plan, a share-based compensation plan for non-employee directors. Under the DSU Plan, non-employee directors can be allotted and can 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 volume weighted average price of the Company's common shares immediately preceding the payment date.

#### Employees

On June 18, 2013, the Company established an employee DSU Plan that allows employees to 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 cost. 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, 2014, an expense of \$2,321 was recorded in G&A as compensation expense related to DSUs [\$247 for the year ended December 31, 2013]. The charge for the year ended December 31, 2014 consisted of \$614 for the fair value of the DSUs issued for director fees and employee compensation, combined with a \$1,707 increase in the aggregate DSU accrual to the market value of the underlying shares for the year ended December 31, 2014. The DSU accrual is included in accounts payable and accrued liabilities.

The following table summarizes the outstanding DSUs and related accrual at December 31, 2014:

	Number of DSUs 000s	Market Value \$	Accrual \$
Balance, December 31, 2012	52	3.90	202
Issued for employee compensation	97	1.93 – 2.03	162
Issued for directors' fees	59	1.93 – 3.57	193
Adjustment to market value	–	–	(108)
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
<b>Balance, December 31, 2014</b>	<b>395</b>	<b>7.00</b>	<b>2,770</b>

### Stock Appreciation Rights Plan

On October 30, 2013, 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 was measured at December 31, 2014 using the Black-Scholes option pricing model with the following inputs:

SARs (000s)	Grant Date	Exercise Price \$	Risk-free Interest Rate %	Expected Life (years)	Volatility Factor %	Fair Values \$
606	October 30, 2013	1.85	1.02	1 – 2	79 – 81	5.15 – 5.38
318	April 4, 2014	3.39	1.02 – 1.32	1 – 3	78 – 81	3.61 – 4.77

The following table summarizes the outstanding SARs and related accrual at December 31, 2014:

	Number of SARs 000s	Fair Value \$	Accrual \$
Balance, December 31, 2012	–	–	–
Granted	694	0.76 – 1.11	57
Forfeited	(88)	0.76 – 1.11	(7)
Balance, December 31, 2013	606	0.76 – 1.11	50
Granted	318	0.40 – 1.42	36
Adjustment to market value	–	–	2,790
<b>Balance, December 31, 2014</b>	<b>924</b>	<b>3.61 – 5.38</b>	<b>2,876</b>

#### Summary of Stock-Based Compensation

	Year ended December 31, 2014 \$	Year ended December 31, 2013 \$
Stock option compensation expense under the Share Option Plan	274	173
Shares issued to employees under Share Purchase Plan	135	77
DSUs – issued for settlement of directors' fees	223	162
DSUs – issued for employee compensation	391	193
DSUs – adjustment to market value	1,707	(108)
PSU compensation expense under the Share Bonus Plan	23	84
SARs compensation expense	2,826	50
<b>Stock-based compensation expense</b>	<b>5,579</b>	<b>631</b>
<i>Recorded in the Consolidated Statement of Income (Loss) and Comprehensive Income (Loss) as follows:</i>		
Cost of goods sold	38	20
Research and development expenses	494	70
General and administrative expenses	5,047	541
	<b>5,579</b>	<b>631</b>

## Notes to Consolidated Financial Statements

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

### 12. LICENSE FEES

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 and has been received subsequent to year-end. In addition, the Company recorded \$166 in royalty revenue for the year ended December 31, 2014.

In the fourth quarter of 2013, the Company entered into a supply and distribution agreement providing NovaMedica LLC (NovaMedica) with the exclusive rights to market and sell Pennsaid and Pennsaid 2% in Russia and some of the Community of Independent States (CIS). Under the terms of the agreement, NovaMedica made an upfront payment to Nuvo of US\$0.5 million (\$0.5 million) that was recorded in revenue in the period as significant performance obligations were complete. Nuvo will manufacture and supply Pennsaid and Pennsaid 2% to NovaMedica and will share in the future profits. In addition, NovaMedica is responsible for conducting required clinical studies and obtaining regulatory approval for the products in the licensed territories. The Company is entitled to receive a milestone payment of US\$0.5 million when predefined sales targets for Pennsaid 2% have been achieved.

In the third quarter of 2013, the Company entered into a product acquisition and licensing agreement with Galen that sold the exclusive rights to market and sell Synera in the U.S. for its current indication. Under the terms of the agreement, Galen made an upfront payment to Nuvo of US\$4.5 million (\$4.7 million) that was recorded in revenue in the period. The Company receives royalties of 10% of net sales and is eligible to receive a US\$5.0 million milestone payment upon gross annual sales reaching US\$25.0 million and a further US\$5.0 million upon gross annual sales reaching US\$50.0 million. Galen has acquired the U.S. rights to the current FDA approved indication for Synera. In addition, Galen assumed all financial commitments associated with owning the New Drug Application (NDA) for Synera. Nuvo retains the right to develop and seek FDA approval for future additional indications including acute musculoskeletal pain.

The Company holds a license agreement with Galderma, its worldwide marketing partner for Pliaglis. During the third quarter of 2013, Galderma received marketing approval for Pliaglis in Brazil, which entitled Nuvo to receive a US\$2.0 million milestone payment (\$2.1 million). The milestone payment was received in the first quarter of 2014.

### 13. 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 has paid US\$10.0 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) for the funds received from Mallinckrodt.

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 Note 14 – Pennsaid 2% U.S. Asset Sale). During the third quarter, the Company recorded the Pennsaid 2% asset as held for sale at its fair value of US\$45.0 million, less costs to sell of US\$5.5 million for an asset value of US\$39.5 million (\$44.3 million) and recorded a net gain of \$43.5 million and a foreign exchange gain of \$0.8 million.

The total gain on the litigation settlement for the year ended December 31, 2014 was \$52.3 million which includes the net cash settlement payment of \$8.8 million and the non-cash portion of \$43.5 million, net of direct costs to sell.



#### 14. 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. As stipulated in the Pennsaid 2% U.S. Sales Agreement, effective January 1, 2015, Pennsaid was no longer marketed in the U.S.

#### 15. NET INCOME (LOSS) PER COMMON SHARE

Earnings (loss) per share is computed as follows:

<i>(in thousands, except per share and share figures)</i>	Year ended December 31, 2014 \$	Year ended December 31, 2013 \$
<b>Basic earnings (loss) per share:</b>		
Net income (loss)	38,590	(10,378)
Average number of shares outstanding during the year	10,023	8,841
Basic earnings (loss) per share	\$3.85	\$(1.17)
<b>Diluted earnings (loss) per share:</b>		
Net income (loss), assuming dilution	38,590	(10,378)
Average number of shares outstanding during the year	10,023	8,841
Dilutive effect of:		
Stock options	119	-
Warrants	127	-
Weighted average common shares outstanding, assuming dilution	10,269	8,841
Diluted earnings (loss) per share	\$3.76	\$(1.17)

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, 2014 000s	December 31, 2013 000s
Common shares issued and outstanding	10,775	8,850
Stock options outstanding <i>(note 11)</i>	887	785
Warrants <i>(note 10)</i>	374	50
PSUs outstanding <i>(note 11)</i>	-	11
	12,036	9,696

## Notes to Consolidated Financial Statements

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

### 16. 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, 2014 \$	Year ended December 31, 2013 \$
Short-term employee wages, bonuses and benefits	8,109	9,225
Share-based payments	4,457	582
Post-employment benefits	14	23
Termination benefits	36	1,156
<b>Total employee costs</b>	<b>12,616</b>	<b>10,986</b>
<b>Included in:</b>		
Cost of goods sold	2,377	1,829
Research and development expenses	3,163	4,238
Sales and marketing expenses	-	434
General and administrative expenses	7,076	4,485
<b>Total employee costs</b>	<b>12,616</b>	<b>10,986</b>

(b) Depreciation and amortization:

	Year ended December 31, 2014 \$	Year ended December 31, 2013 \$
Cost of goods sold	252	249
Research and development expenses	87	108
General and administrative expenses (i)	376	981
<b>Total depreciation and amortization</b>	<b>715</b>	<b>1,338</b>

(i) G&A expenses include \$348 of amortization of intangible assets for the year ended December 31, 2014 [December 31, 2013 – \$906].

### 17. NET CHANGE IN NON-CASH WORKING CAPITAL

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

	Year ended December 31, 2014 \$	Year ended December 31, 2013 \$
Accounts receivable	1,696	(210)
Inventories	(1,129)	212
Other current assets	(252)	566
Accounts payable and accrued liabilities	5,198	445
<b>Net change in non-cash working capital</b>	<b>5,513</b>	<b>1,013</b>

## 18. 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, 2014 \$	Year ended December 31, 2013 \$
Non-capital loss carryforwards	15,829	26,470
U.S. Federal and State research and development credits	1,352	1,240
Canadian Scientific Research and Experimental Development (SR&ED) expenditure pool carryforward	–	2,063
Investment tax credits	1,340	1,486
Tax basis of property, plant and equipment and intangibles in excess of accounting value	3,190	4,179
Financing costs, deferred revenue and other	19	22
Deferred tax assets not recognized	<b>21,730</b>	<b>35,460</b>

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

	Year ended December 31, 2014 %	Year ended December 31, 2013 %
Statutory rate	26.7	26.6
Items not deducted for tax	(1.4)	2.6
Impact of foreign income tax rate differential	(2.9)	15.3
Utilization of previously unused losses	(25.0)	–
Revaluation of deferred taxes as a result of enacted tax rate changes and other	–	(0.1)
Losses not benefitted	(4.3)	(44.4)
Other	6.9	(1.1)
	–	(1.1)

## Notes to Consolidated Financial Statements

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

### 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:

	Expiry Period	Non-capital losses \$	Future tax asset \$
Canada	2030 to 2031	1,523	406
United States (i)	2025	24	9
United States (ii)	2023 to 2029	7,635	2,848
United States	2026 to 2034	24,597	9,175
Switzerland	2015 to 2021	13,411	1,301
Germany	Indefinite	7,227	2,096
		54,417	15,835

(i) These U.S. losses carried forward relate to losses acquired upon the purchase of fqubed in 2005. Due to the acquisition of control of this entity, there are restrictions imposed on the use of these losses.

(ii) These U.S. losses carried forward relate to losses acquired upon the purchase of ZARS in 2011. Due to the acquisition of control of this entity, there are restrictions imposed on the use of these losses.

The Company has approximately \$nil [December 31, 2013 – \$7.8 million] 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 \$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	438	2015
December 31, 2006	688	2026
December 31, 2007	335	2027
December 31, 2008	225	2028
December 31, 2009	142	2029
	1,828	

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

## 19. COMMITMENTS

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

	Research and Other Service Contracts \$	Operating Leases \$	Total \$
2015	2,501	224	2,725
2016	–	179	179
2017 and thereafter	–	17	17
	2,501	420	2,921

For the year ended December 31, 2014, payments under operating leases totaled \$211 [December 31, 2013 – \$245].

In three separate transactions, the first of which closed on August 16, 2005, the Company completed the sale of 100% of the common shares of Dimethaid Health Care Limited to Paladin and the transfer of Canadian sales and marketing rights for Pennsaid to Paladin. Among other things, as part of these arrangements, Nuvo is contractually obligated to manufacture Pennsaid for Paladin.

Under the terms of the Pennsaid 2% U.S. Asset Sale with Horizon, Nuvo is contractually obligated to manufacture Pennsaid 2%. Under the supply agreement, Nuvo is obligated to supply Pennsaid 2% and Horizon is obligated to obtain 100% of their requirements for Pennsaid 2% from Nuvo and will pay an agreed-upon transfer price under the supply agreement. The transfer price is subject to semi-annual adjustments based on Nuvo's raw material costs and annual adjustments based upon changes in the national manufacturing cost for pharmaceutical products.

The 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, 2014 or 2013.

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 Pliaqlis.

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 Dr. Kuehne. 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.

## Notes to Consolidated Financial Statements

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

### 20. FINANCIAL INSTRUMENTS AND RISK MANAGEMENT

#### Fair Values

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, 2014 and 2013.

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 of December 31, 2014:

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

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis as at December 31, 2013:

	Total \$	Using Quoted Prices in Active Markets for Identical Assets (Level 1) \$	Using Significant Other Observable Inputs (Level 2) \$	Using Significant Unobservable Inputs (Level 3) \$
Assets:				
<b>Total Assets</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
Liabilities:				
Deferred Share Units	449	449	-	-
Stock Appreciation Rights	50	-	50	-
<b>Total Liabilities</b>	<b>499</b>	<b>449</b>	<b>50</b>	<b>-</b>



Level 1 assets include guaranteed investment certificates or other securities held by the Company that are valued at quoted market prices. The Company accounts for its investment at fair value on a recurring basis.

Level 1 liabilities include obligations of the Company for the DSU described in Note 11. 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 11. The fair values of each tranche of SARs issued and outstanding is 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 \$48.3 million in cash and \$10.0 million in short-term investments as at December 31, 2014, 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. A generic version of Pennsaid was approved and launched in the first quarter of 2014 and this generic may have an impact on the Company's future cash flows and revenues. In the U.S., the Company received royalties based on net sales of Pennsaid 2% in 2014; however, the Company sold the U.S. rights to Pennsaid 2% to Horizon (see Note 14 – Pennsaid 2% U.S. Asset Sale) and no longer receives royalties after January 1, 2015 when ownership of Pennsaid 2% transferred to Horizon. The Company will receive product revenues from Horizon pursuant to a long-term exclusive supply agreement. The Company will also receive royalties on the sale of a generic version of Pennsaid in the U.S. market as part of a settlement agreement that was reached with a generic company.

The Company has contractual obligations related to accounts payable and accrued liabilities, purchase commitments and other obligations of \$12.0 million that are due in less than a year and \$0.4 million of contractual obligations that are payable from 2016 to 2018.

#### **Credit Risk**

The Company's cash and short-term investments subject the Company to a significant concentration of credit risk. At December 31, 2014, the Company had \$47.8 million invested with one financial institution in various bank accounts as per its practice of protecting its capital rather than maximizing investment yield through additional risk. This financial institution is a major Canadian bank which the Company believes lessens the degree of credit risk. The Company invested \$10.0 million in short-term investments with additional Schedule 1 Canadian banks and 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

## Notes to Consolidated Financial Statements

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

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. At December 31, 2014, the Company's four largest customers located in North America and the E.U. represented 60% [December 31, 2013 – 88%] of accounts receivable and accounts receivable from customers located outside of North America and the E.U. represented 8% [December 31, 2013 – 8%] of accounts receivable.

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

	Year ended December 31, 2014 \$	Year ended December 31, 2013 \$
Current	2,940	4,031
0-30 days past due	43	34
31-60 days past due	20	–
Over 90 days past due	2	124
	<b>3,005</b>	<b>4,189</b>

### 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	
	2014 €	2013 €	2014 \$	2013 \$
Cash	1,266	1,039	665	1,536
Accounts receivable	242	322	2,205	3,496
Other current assets	159	150	–	–
Accounts payable and accrued liabilities	(943)	(326)	(601)	(1,440)
Finance lease and other long-term obligations	–	–	(281)	(384)
	<b>724</b>	<b>1,185</b>	<b>1,988</b>	<b>3,208</b>

Based on the aforementioned net exposure as at December 31, 2014, 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 \$231 on total comprehensive income (loss) and a 10% appreciation or depreciation of the Canadian dollar against the euro would have an effect of \$102 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 five 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 running trials and other studies at U.S. sites, 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 licensing 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 licensing agreements with Horzion, 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.

## **21. 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, short-term investments 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 \$48.3 million at December 31, 2014, revenue from product sales and royalty payments to fund its operations. The Company currently anticipates that its cash, short-term investments and the revenues it expects to generate from product sales and royalty payments will be sufficient to fund operations into 2016. 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 fund-raising 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.

## Notes to Consolidated Financial Statements

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

### 22. SEGMENTED INFORMATION

#### Segments

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:

	TPT Group	Immunology Group	Total
Year ended December 31, 2014	\$	\$	\$
Total revenue (i)	12,419	638	13,057
Depreciation of property, plant and equipment and amortization of intangibles assets	692	23	715
Interest income	199	-	199
Interest expense	713	-	713
Net income (loss) before income taxes (ii) (iii)	45,058	(6,449)	38,609
Assets	63,720	1,420	65,140
Property, plant and equipment	1,096	65	1,161
Additions to property, plant and equipment	191	33	224
<hr/>			
Year ended December 31, 2013	\$	\$	\$
Total revenue (i)	17,806	603	18,409
Depreciation of property, plant and equipment and amortization of intangibles assets	1,315	23	1,338
Interest income (expense)	1,351	(1,273)	78
Interest expense	649	-	649
Net loss before income taxes (iii)	(5,718)	(4,543)	(10,261)
Assets	20,058	1,563	21,621
Property, plant and equipment	1,354	57	1,411
Additions to property, plant and equipment	209	20	229

(i) The Immunology Group currently derives all of its revenue from product sales.

(ii) The total gain on litigation settlement of \$52.3 million for the year ended December 31, 2014 was included in the results of the TPT Group.

(iii) Impairment of intangible assets of \$1.7 million in 2014 and \$6.4 million in 2013 were included in the results of the TPT Group.

#### 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 December 31, 2014 \$	Year ended December 31, 2013 \$
United States	7,809	11,196
Europe	2,193	2,210
Canada	1,797	2,350
Other foreign countries	1,258	2,653
	13,057	18,409

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

	December 31, 2014 \$	December 31, 2013 \$
Canada	1,095	1,345
Europe and other	66	66
	<b>1,161</b>	<b>1,411</b>

### Significant Customers

For the year ended December 31, 2014, the Company's four largest customers (excluding upfront payments and milestones from licensing arrangements) represented 81% [December 31, 2013 – 51%] of total revenue and the Company's largest customer represented 51% [December 31, 2013 – 32%] of total revenue. The Company's largest customers are in the TPT Group.

## 23. 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, 2014 \$	Year ended December 31, 2013 \$
Short-term wages, bonuses and benefits	3,325	2,872
Share-based payments	4,338	532
Post-employment benefits	–	6
Termination benefits	–	266
<b>Total key management compensation</b>	<b>7,663</b>	<b>3,676</b>
<i>Included in:</i>		
Research and development	935	550
General and administrative expenses	6,728	3,126
<b>Total key management compensation</b>	<b>7,663</b>	<b>3,676</b>

For the year ended December 31, 2014, certain officers of the Company participated in the Private Placement described in Note 10 and acquired 67,768 Units on the same terms as the other purchasers. Proceeds raised from the Company's officers totaled \$152.

# Corporate Information

## HEAD OFFICE

7560 Airport Road, Unit 10  
Mississauga, Ontario, Canada L4T 4H4  
Tel. (905) 673-6980  
Fax. (905) 673-1842  
Email: info@nuvoresearch.com  
Website: www.nuvoresearch.com

## STOCK EXCHANGE LISTING

**The Toronto Stock Exchange**  
Symbol: NRI

## AUDITORS

**Ernst & Young LLP**  
Chartered Professional Accountants  
Licensed Public Accountants  
Toronto, Canada

## LEGAL COUNSEL

**Goodmans LLP**  
Toronto, Canada

## TRANSFER AGENT/REGISTRAR

**Common Shares**  
CST Trust Company  
P.O. Box 700, Station B  
Montreal, QC  
H3B 3K3  
Canada  
Telephone: 1 (800) 387-0825 or outside  
Canada and U.S. (416) 682-3860  
Fax: 1 (888) 249-6189 or outside  
Canada and U.S. (514) 985-8843  
Email: inquiries@canstockta.com  
Website: www.canstockta.com

## INVESTOR RELATIONS

Email: ir@nuvoresearch.com

## 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 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.

## We invite you to the Annual Meeting of Shareholders:

May 13, 2015  
9:00 a.m. ET  
Gallery – TMX Broadcast Centre  
The Exchange Tower  
130 King Street West  
Toronto, Ontario

# Board of Directors and Executive Officers

**Daniel N. Chicoine** BComm, CPA, CA  
*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, CA  
*Vice President Finance & Chief Financial Officer*

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

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

**Anthony E. Dobranowski** BSc, MBA, CPA, CA  
*Director*

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

**Theodore H. Stanley** MD  
*Director*

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

## **FORWARD-LOOKING STATEMENTS**

Certain statements in this document constitute forward-looking statements within the meaning of applicable securities laws. Forward-looking statements include, but are not limited to statements concerning the Company's future objectives, strategies to achieve those objectives, as well as statements with respect to management's beliefs, plans, estimates, and intentions, and similar statements concerning anticipated future events, results, circumstances, performance or expectations that are not historical facts. Forward-looking statements generally can be identified by the use of forward-looking terminology such as "outlook", "objective", "may", "will", "expect", "intend", "estimate", "anticipate", "believe", "should", "plans" or "continue", or similar expressions suggesting future outcomes or events. Such forward-looking statements reflect management's current beliefs and are based on information currently available to management. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those contemplated by such statements. Factors that could cause such differences include general business and economic uncertainties and adverse market conditions as well as other risk factors included in the Company's Annual Information Form dated February 19, 2015 under the heading "Risks Factors" and as described from time to time in the reports and disclosure documents filed by the Company with Canadian securities regulatory agencies and commissions. This list is not exhaustive of the factors that may impact the Company's forward-looking statements. These and other factors should be considered carefully and readers should not place undue reliance on the Company's forward-looking statements. As a result of the foregoing and other factors, no assurance can be given as to any such future results, levels of activity or achievements and neither the Company nor any other person assumes responsibility for the accuracy and completeness of these forward-looking statements. The factors underlying current expectations are dynamic and subject to change. Although the forward-looking information contained in this document is based upon what management believes are reasonable assumptions, there can be no assurance that actual results will be consistent with these forward-looking statements. All forward-looking statements in this document are qualified by these cautionary statements. The forward-looking statements contained herein are made as of the date of this document 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.



