



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

May 12, 2015 / The following information should be read in conjunction with the Nuvo Research<sup>®</sup> Inc. (Nuvo or the Company) Consolidated Financial Statements for the year ended December 31, 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.

### Key Developments

During the quarter and prior to the release of the first 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 (the 2014 WF10 Trial). The WF10 arm and the 2 separate arms that included constituent elements of WF10 all performed better than placebo, however, the differences were not statistically significant (see Immunology Group – WF10); and

- In April, the Company announced it would conduct a new Phase 2 trial using WF10 for the treatment of allergic rhinitis (the 2015 WF10 Trial). Commencement of the trial, which is subject to Canadian regulatory approval, is expected in Q2 2015 with topline results expected in Q4 2015 or Q1 2016 (see Immunology Group – WF10).

#### Pennsaid 2%

- In November 2014, 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.

## 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 March 31, 2015, the Company and its subsidiaries employed a total of 69 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. 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:

Brand	Therapeutic Area	Licensee or Distributor	Licensed Territories	Intellectual Property
Pennsaid	Osteoarthritis of the knee	NovaMedica LLC	Russia; some Community of Independent States	-
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	

<sup>1</sup> Worldwide refers to one or more countries other than Europe and the U.S.

<sup>2</sup> 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:

Brand	Therapeutic Area	Licensee or Distributor	Licensed Territories	Intellectual Property
Pennsaid <sup>1</sup>	Osteoarthritis of the knee	Paladin Labs Inc.	Canada	-
		Vianex S.A.	Greece	-
		Italchimici S.p.A.	Italy	-
		Movianto UK Limited	U.K.	-
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>		Eurocept B.V.	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.

<sup>1</sup> 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).

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

<sup>3</sup> Galderma currently sells Pliaglis in the U.S., Western Europe, Argentina, Brazil and Columbia. 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.

<sup>4</sup> 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 the pain of osteoarthritis (OA) of the knee and is not currently approved for sale or marketing in any other jurisdiction. OA is the most common joint disease affecting middle-age and older people. It is characterized by progressive damage to the joint cartilage and causes changes in the structures around the joint. These changes can include fluid accumulation, bony overgrowth and loosening and weakness of muscles and tendons, all of which may limit movement and cause pain and swelling. In the U.S. market, Pennsaid 2% was originally licensed to Mallinckrodt. In September 2014, the Company reached a settlement related to its litigation with Mallinckrodt (see Litigation - Mallinckrodt). Under the terms of the settlement agreement, Mallinckrodt returned the U.S. sales and marketing rights to Pennsaid 2% to Nuvo. In October 2014, the Company sold the U.S. rights to Pennsaid 2% to Horizon Pharma plc (Horizon) for US\$45.0 million. 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 or Q1 2016. In addition, NovaMedica has advised the Company that they have commenced 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, a number of 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. 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 2014. This generic version of Pennsaid is negatively impacting 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.

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

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

### 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, which is in progress, 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 based on the cumulative aggregate sales of Pliaglis and the difference between the original and the adjusted royalty rates. In addition, if this milestone was not achieved by April 2015, the royalty rates would be reduced further until such time as the target was reached, subject to a minimum annual royalty rate being paid to the Company. The predetermined monetary milestone was not achieved by April 2015 and the royalty rates received on net sales of Pliaglis will decline as per the terms of the agreement.

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>	Dermatological skin treatment	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, CN and the U.S. with latest expiring in 2031. Applications allowed in RU and pending in 9 countries including EP. Latest anticipated expiry date is 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. expiring in 2029. Application pending in EP with anticipated expiry date in 2028.
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 the U.S. and pending in 4 other countries including EP. Latest anticipated expiry date is 2030.

<sup>1</sup> 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.).

<sup>2</sup> Mical is a product being developed under the Ferndale collaboration (see Significant Transactions – 2014 - Ferndale Collaboration).

### **Immunology Group**

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

#### WF10

WF10 is an immune system modulating drug containing chlorite and/or chlorate ions including its derivative formulations and dosage forms as formulated or developed by the Company. The immune system provides an essential defense 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 defense 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 (the 2014 WF10 Trial)

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): WF10; WF10 with chlorate and sulphate removed and WF10 with chlorite and sulphate removed.

Each of the Active Arms was compared to a placebo arm in which patients received saline. 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 were:

- 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.

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

The Company has completed its review of the 2014 WF10 Trial and has decided to conduct a new Phase 2 clinical trial to assess WF10 for the treatment of allergic rhinitis. The 2015 WF10 Trial will be a randomized, double-blind, placebo-controlled, single-center trial to assess the efficacy, safety and tolerability of a regimen of five WF10 infusions. The trial will enroll patients who have a moderate to severe allergy to grass and ragweed pollen. Patients' symptoms will be recorded prior to commencement of the grass allergy season in an Environmental Exposure Chamber (EEC), in the field throughout the grass and ragweed allergy seasons and again in the EEC after completion of the ragweed season. The 2015 WF10 Trial is expected to enroll approximately 146 patients and to be completed with topline results available in Q4 2015 or Q1 2016. The trial will be conducted in southern Ontario, Canada by Inflamm Research Inc. (Inflamax), a full service, specialty Contract Research Organization (CRO) that specializes in allergy, respiratory and EEC studies. Nuvo's external costs of conducting the trial will be approximately CDN\$5.0 million. Commencement of the 2015 WF10 Trial is subject to regulatory approval by Health Canada.

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.

## 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.

## Liquidity

The Company has incurred substantial losses since its inception, as it has invested significantly in drug development activities and other legacy ventures. At March 31, 2015, the Company had an accumulated deficit of \$193.2 million, including a net loss of approximately \$0.3 million for the three months ended March 31, 2015. At March 31, 2015, the Company had cash of \$46.8 million and short-term investments of \$10.0 million.

The Company expects that it will continue to incur losses as its revenue streams are not yet sufficient to fund: its operations, the infrastructure necessary to support a public company and the costs of selectively

advancing its drug development pipeline. The Company's ability to continue as a going concern depends on:

- the commercial success of Pennsaid 2% in the U.S., as the Company earns revenue from 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 success of the Company's clinical studies for WF10 for the treatment of allergic rhinitis and Pennsaid 2% for the treatment of acute sprains and strains; and
- its ability to secure additional licensing fees, secure co-development agreements, obtain additional capital when required, gain regulatory approval for other drugs and ultimately achieve profitable operations.

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

The Company anticipates that its current cash 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 Condensed Consolidated Interim 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

in thousands (except per share)

	Three Months ended March 31, 2015	Three Months ended March 31, 2014
<b>Operations</b>		
Product sales	3,903	1,156
Royalties	519	1,397
Research and other contract revenue	125	147
Licensing fees	-	57
<b>Total Revenue</b>	<b>4,547</b>	<b>2,757</b>
<b>Total operating expenses</b>	<b>5,084</b>	<b>5,643</b>
<b>Loss from operations</b>	<b>(537)</b>	<b>(2,886)</b>
Other income	(274)	(164)
<b>Loss before income taxes</b>	<b>(263)</b>	<b>(2,722)</b>
Income tax expense	7	21
<b>Net loss</b>	<b>(270)</b>	<b>(2,743)</b>
Other comprehensive income	(86)	87
<b>Total comprehensive loss</b>	<b>(356)</b>	<b>(2,656)</b>
<b>Share Information</b>		
Net loss per share		
Basic and diluted	(0.03)	(0.31)
Average number of common shares outstanding for the period		
Basic and diluted	10,831	8,898
<b>Financial Position</b>		
	As at March 31, 2015	As at December 31, 2014
Cash	46,779	48,275
Short-term investments	10,000	10,000
Total assets	61,721	65,140
Finance lease & other obligations, including current portion	322	328
Total liabilities	6,123	9,477
Total equity	55,598	55,663

### Non-IFRS Financial Measure

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

### Fluctuations in Operating Results

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

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

## Significant Transactions

### 2014

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

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

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

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

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

#### **Litigation Settlement**

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

### **Ferndale Collaboration**

In April 2014, the Company entered into a collaboration agreement with Ferndale Laboratories, Inc. (Ferndale) and a leading CRO to develop two topical dermatology products based on Nuvo's patented MMPE technology. The Company is currently developing both formulations. Under the terms of the collaboration agreement, Nuvo will utilize its proprietary MMPE technology to formulate two patented topical dermatology product candidates. Once the formulations are complete, Ferndale, in collaboration with the CRO, will oversee and fund the formulations' advancement through Phase 2 clinical studies. It is anticipated that the product candidates will then be made available for 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.

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.

As March 31, 2015, on an accumulated basis, 462,999 of the Private Placement Warrants had been exercised, 59,633 of the Broker Warrants had been exercised, and 29,817 Private Placement Warrants had been issued upon the exercise of Broker Warrants, of which 15,650 have exercised.

## **Results of Operations**

### **Product Sales**

in thousands

	<b>Three Months ended March 31, 2015</b>	Three Months ended March 31, 2014
	\$	\$
Pennsaid 2% sales	<b>2,220</b>	635
Pennsaid sales	<b>1,454</b>	384
WF10 sales	<b>188</b>	137
HLT bulk sales	<b>41</b>	-
<b>Total product sales</b>	<b>3,903</b>	1,156

Product sales which represent the Company's sales to our licensees and distributors were \$3.9 million for the three months ended March 31, 2015 compared to \$1.2 million for the three months ended March 31, 2014.

#### *Pennsaid 2%*

Product sales of Pennsaid 2% were \$2.2 million for the three months ended March 31, 2015 compared to \$0.6 million for the three months ended March 31, 2014 and represent the Company's sales of the Pennsaid 2% commercial format and its physician sample format to its licensee in the U.S. market. The significant increase in the quarter related to Horizon's efforts to relaunch Pennsaid 2% in the U.S. market. Product sales for the quarter consisted of \$1.2 million of the commercial format and \$1.0 million of the physician sample format compared to \$0.6 million of the commercial format in the comparative period. According to IMS Health, approximately 31,000 Pennsaid 2% prescriptions were dispensed in the three months ended March 31, 2015 compared to 18,000 prescriptions in the three months ended December 31, 2014 when Mallinckrodt last marketed the product. 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 \$1.5 million for the three months ended March 31, 2015 compared to \$0.4 million for the three months ended March 31, 2014. The increase was primarily attributable to an increase in sales of \$0.7 million to the Company's Greek partner, \$0.3 million to the Company's Canadian partner which included sales of an authorized generic version of Pennsaid that was launched by the Company's Canadian partner in the fourth quarter of 2014 to compete with a generic version of Pennsaid that launched in May 2014 and \$0.2 million to the Company's Italian partner, partially offset by a decrease in sales of \$0.2 million to the Company's U.S. partner in the prior year as they switched sales from Pennsaid to Pennsaid 2%.

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.

Geographically for the three months ended March 31, 2015, sales in the U.S. were \$nil of total Pennsaid product sales [March 31, 2014 - \$0.2 million or 49%], sales in the E.U. were \$1.0 million or 69% of Pennsaid product sales [March 31, 2014 - \$28,000 or 6%] and sales in Canada were \$0.5 million representing 31% of Pennsaid product sales [March 31, 2014 - \$0.2 million or 45%].

#### *WF10*

Product sales of WF10 and Oxoferin™ (a topical wound healing agent, contains the same active ingredient as WF10, but at a lower concentration) were \$0.2 million for the three months ended March 31, 2015 compared to \$0.1 million for the three months ended March 31, 2014. The increase in sales is a result of higher sales to the Company's distributors in Malaysia and Pakistan, slightly offset by lower sales to the Company's distributor in Thailand. In 2014, Ranbaxy launched Oxoferin in Malaysia.

#### *HLT Bulk*

Sales were \$41,000 for the bulk drug substance for the HLT Patch for the three months ended March 31, 2015 compared to sales of \$nil for the three months ended March 31, 2014. Sales related to the bulk drug substance that is used in the manufacturing of the HLT Patch for both the U.S. and E.U. markets. The bulk drug substance is shipped to a CMO in the U.S. that manufactures the HLT Patch.



## Other Revenue

in thousands

	Three Months ended March 31, 2015	Three Months ended March 31, 2014
	\$	\$
Royalties	519	1,397
Research and other contract revenue	125	147
Licensing fees	-	57
	644	1,601

## Royalty Revenue

The Company receives royalty revenue from: 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, its original U.S. licensee for Pennsaid and Pennsaid 2%, 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 the comparative period, the Company also received royalties from Mallinckrodt, its original U.S. licensee for Pennsaid and Pennsaid 2%. In September 2014, the Company settled its litigation with Mallinckrodt and under the terms of the settlement, Mallinckrodt agreed to return the U.S. rights to Pennsaid and Pennsaid 2% to Nuvo (see Litigation - Mallinckrodt). In October 2014, the Company sold the U.S. rights to Pennsaid 2% to Horizon (see Significant Transactions – 2014 – Pennsaid 2% U.S. Asset Sale). Under the terms of the Pennsaid U.S Sale Agreement, the Company no longer receives a royalty on Pennsaid 2% net sales in the U.S. as Horizon assumed sales and marketing responsibility on January 1, 2015.

Royalty revenue decreased to \$0.5 million for the three months ended March 31, 2015 compared to \$1.4 million for the three months ended March 31, 2014.

### *Pennsaid Royalties*

The Company receives royalty revenue from the net sales of Pennsaid in Canada and the U.S. and from the gross margin on sales of the generic version of Pennsaid in the U.S. market. For the three months ended, March 31, 2015, royalty revenue was \$0.4 million compared to \$0.7 million for the three months ended March 31, 2014. For the three months ended March 31, 2015, the Company received royalties of \$0.2 million from the generic sales of Pennsaid, \$0.2 million related to an adjustment of the net sales calculation as per the terms of an agreement with Mallinckrodt and \$43,000 related to net sales of Pennsaid in Canada. The Company expects royalties related to Pennsaid to decrease in the future as Pennsaid is no longer distributed in the U.S. and the royalty rate received on Pennsaid generic sales in the U.S. will decline as new generic versions of Pennsaid are launched. In Canada, the net sales of Pennsaid have been negatively impacted by a generic version that launched in 2014. In the comparative period, the Company earned royalties of \$0.5 million on the net sales of Pennsaid in the U.S. and \$0.2 million on the net sales of Pennsaid in Canada.

### *Pennsaid 2% Royalties*

Royalty revenue related to sales of Pennsaid 2% in the U.S. was \$nil for the three months ended March 31, 2015 compared to \$0.6 million for the three months ended March 31, 2014. In the comparative

period, the Company earned royalties on U.S. sales of Pennsaid 2% from the Company's former U.S. partner, Mallinckrodt. 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.

#### *Pliaglis and HLT Patch Royalties*

Royalties related to the global net sales of Pliaglis and the HLT Patch were \$74,000 for the three months ended March 31, 2015 compared to \$96,000 for the three months ended March 31, 2014.

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

Research and other contract revenue for three months ended March 31, 2015 was \$125,000 compared to \$147,000 for the three months ended March 31, 2014. These revenues were mainly derived from development services provided by the Company to its partners.

#### **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:

in thousands, except percentages	<b>Three Months ended March 31, 2015</b>	Three Months ended March 31, 2014
Four largest customers	<b>\$3,687</b>	\$2,497
% of total revenue	<b>81%</b>	91%
Largest customer as % of total revenue	<b>49%</b>	73%

#### **Operating Expenses**

in thousands

	<b>Three Months ended March 31, 2015</b>	Three Months ended March 31, 2014
	<b>\$</b>	<b>\$</b>
Cost of goods sold	<b>2,560</b>	1,209
Research and development	<b>1,998</b>	1,887
General and administrative	<b>663</b>	2,373
Interest (income) expense, net	<b>(137)</b>	174
<b>Total operating expenses</b>	<b>5,084</b>	5,643

Total operating expenses for the three months ended March 31, 2015 were \$5.1 million, a decrease from \$5.6 million for the three months ended March 31, 2014. The decrease was primarily due to the revaluation of cash-settled stock-based compensation (SBC) costs which are primarily included in G&A costs for the quarter partially offset by increased cost of goods sold (COGS) due to a greater volume of production sales.

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

COGS for the three months ended March 31, 2015 was \$2.6 million compared to \$1.2 million for the three months ended March 31, 2014. For the current quarter, the increase in COGS was associated with increased Pennsaid and Pennsaid 2% product sales. The increase in product sales improved the gross margin to \$1.3 million for the three months ended March 31, 2015 compared to a negative margin of \$0.1 million for the three months ended March 31, 2014. For the three months ended March 31, 2015, the gross margin as a percentage of product sales was 34%.

## **Research and Development**

R&D expenses were \$2.0 million for the three months ended March 31, 2015 compared to \$1.9 million for the three months ended March 31, 2014.

In the Immunology Group, R&D expenses were \$1.3 million for the three months ended March 31, 2015 compared to \$1.4 million for the three months ended March 31, 2014. In the current and comparative periods, the Immunology Group incurred R&D costs related to 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 179 patient trial measured TNSS and other secondary endpoints and was completed in December 2014. The trial did not meet its primary endpoint. For a detailed description of the results, see Overview – Immunology Group. The Company will be conducting a new phase 2 clinical trial for WF10 in Canada to assess the efficacy, safety and tolerability of WF10 for the treatment of moderate to severe allergies to grass and ragweed pollens. The external costs for this trial will be approximately \$5.0 million. The study is expected to commence in Q2 2015 subject to Canadian regulatory approval.

In the TPT Group, R&D expenses were \$0.7 million for the three months ended March 31, 2015 compared to \$0.5 million for the three months ended March 31, 2014. The increase in spending related to costs associated with the Pennsaid 2% Phase 3 trial for the treatment of acute pain to support regulatory approval applications for Pennsaid 2% in international jurisdictions. The study is being conducted in Germany to assess the efficacy of Pennsaid 2% for the relief of pain associated with acute, localized muscle or joint injuries such as sprains, strains or sports injuries. The study is expected to commence in Q2 2015 subject to German regulatory approval.

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 \$0.7 million for the three months ended March 31, 2015 compared to \$2.4 million for the three months ended March 31, 2014. The decrease was related to a \$1.8 million decrease in SBC in the quarter primarily from the adjustment to market value for the outstanding Share Appreciation Rights (SARs) and Deferred Share Units (DSUs) at March 31, 2015. Excluding this impact, G&A expenses were consistent with the comparative period at \$2.1 million.

## **Interest**

Interest expense was \$12,000 for the three months ended March 31, 2015 compared to \$0.2 million for the three months ended March 31, 2014. In the comparative period, the Company incurred a 15% per annum interest cost related to the outstanding loan with Paladin which was repaid in full in the fourth quarter of 2014. Interest expense for the current and comparative periods included non-cash accretion charges on the five-year consulting agreement as part of the consideration paid for the 2011 acquisition of the non-controlling interest in Nuvo Research AG.

Interest income was \$0.1 million for the three months ended March 31, 2015 compared to \$21,000 for the three months ended March 31, 2014. The increase in interest income related to the significantly higher balances in the interest bearing Canadian bank accounts, as well as the interest income the Company earned on the \$10.0 million it invested in short-term investments during the fourth quarter of 2014.

The aggregate result was net interest income of \$0.1 million for the three months ended March 31, 2015 compared to net interest expense of \$0.2 million for the three months ended March 31, 2014.

## **Loss from Operations**

Loss from operations was \$0.5 million for the three months ended March 31, 2015 compared to \$2.9 million for the three months ended March 31, 2014. The decreased loss from operations in the current period was attributable to higher Pennsaid and Pennsaid 2% product revenue and a decrease in

operating expenses in the current period related to lower SBC costs from the revaluation of SARs and DSUs to market value, partially offset by lower royalty revenues.

### Foreign Currency Gain

The Company experienced a net foreign currency gain of \$0.3 million for the three months ended March 31, 2015 compared to \$0.2 million for the three months ended March 31, 2014. The stronger U.S. dollar increased the value of U.S. dollar denominated cash and receivables.

### Net Loss and Total Comprehensive Loss

in thousands

	Three Months ended March 31, 2015	Three Months ended March 31, 2014
	\$	\$
Net loss before income taxes	(263)	(2,722)
Income tax expense	7	21
Net loss	(270)	(2,743)
Unrealized gains (losses) on translation of foreign operations	(86)	87
<b>Total comprehensive loss</b>	<b>(356)</b>	<b>(2,656)</b>

### Net Loss

Net loss was \$0.3 million for the three months ended March 31, 2015 compared to \$2.7 million for the three months ended March 31, 2014. The decreased net loss in the current period was attributable to higher Pennsaid and Pennsaid 2% product revenue and a decrease in operating expenses in the current period related to lower SBC costs from the revaluation of SARs and DSUs to market value, offset by lower royalty revenues.

### Total Comprehensive Loss

Total comprehensive loss was \$0.4 million for the three months ended March 31, 2015 compared to \$2.7 million for the three months ended March 31, 2014. The current year included an unrealized loss of \$0.1 million on the translation of foreign operations compared to \$0.1 million unrealized gain in the comparative period.

### Net Loss Per Common Share

Net loss per common share was \$0.03 for the three months ended March 31, 2015 versus net loss per common share of \$0.31 for the three months ended March 31, 2014.

The weighted average number of common shares outstanding on a basic and diluted basis was 10.8 million for the three months ended March 31, 2015 compared to 8.9 million for the three months ended March 31, 2014.

### 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 \$1.1 million for the three months ended March 31, 2015 compared to a net loss before income taxes of \$1.3 million for the three months ended March 31, 2014. The improvement of \$2.4 million in net income before income taxes was primarily related to higher Pennsaid and Pennsaid 2% product revenue and a decrease in operating expenses in the current period related to lower SBC costs from the revaluation of SARs and DSUs to market value, offset by lower royalty revenues.

The Immunology Group, which includes all WF10 activities, incurred a net loss before income taxes of \$1.4 million for the three months ended March 31, 2015, consistent with the three months ended March 31, 2014.

## Liquidity and Capital Resources

in thousands

	Three months ended March 31, 2015	Three months ended March 31, 2014
	\$	\$
Net loss	(270)	(2,743)
Items not involving current cash flows	38	58
Cash used in operations	(232)	(2,685)
Net change in non-cash working capital	(1,445)	1,785
Cash used in operating activities	(1,677)	(900)
Cash used in investing activities	(10)	(55)
Cash provided by financing activities	179	2,434
	(1,508)	1,479
Effect of exchange rates on cash	12	121
Net change in cash during the period	(1,496)	1,600
Cash beginning of the period	48,275	12,621
<b>Cash end of the period</b>	<b>46,779</b>	<b>14,221</b>

### Cash

Cash was \$46.8 million at March 31, 2015, a decrease of \$1.5 million compared to \$48.3 million at December 31, 2014. In 2014, the Company received US\$10.0 million from its litigation settlement with Mallinckrodt (see Litigation – Mallinckrodt) and US\$45.0 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 \$0.2 million for the three months ended March 31, 2015 compared to \$2.7 million for the three months ended March 31, 2014. The decrease in cash used in operations related to a reduction in net loss that resulted from higher Pennsaid and Pennsaid 2% product revenue and a decrease in operating expenses in the current period related to lower SBC costs from the revaluation of SARs and DSUs to market value, partially offset by lower royalty revenues.

Overall cash used in operating activities increased to \$1.7 million for the three months ended March 31, 2015 compared to \$0.9 million for the three months ended March 31, 2014. The increase in cash used in operating activities related to a \$1.4 million investment in working capital compared to a \$1.8 million recovery of non-cash working capital in the comparative period, partially offset by a decrease in cash used in operations. The \$1.4 million investment in working capital in the current year was primarily attributable to a decrease in accounts payable and accrued liabilities related to the payment of a tranche of SARs and the revaluation of SARs and DSUs to market value at March 31, 2015, partially offset by a decrease in accounts receivables. In the comparative period, the recovery of working capital was due to the receipt of the \$2.1 million (US\$2.0 million) milestone payment from Galderma for the marketing approval of Pliaglis in Brazil, partially offset by an increase in inventories and other current assets.

### Investing Activities

Net cash used in investing activities totaled \$10,000 for the three months ended March 31, 2015 compared to \$55,000 for the three months ended March 31, 2014. In both the current and comparative period, 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 provided by financing activities totaled \$0.2 million for the three months ended March 31, 2015 compared to \$2.4 million for the three months ended March 31, 2014. In the current quarter, the Company received cash from the exercise of warrants from the Private Placement. In the comparative period, the Company raised \$2.9 million net of financing fees through the Private Placement (see –

Significant Transactions – 2014 – Private Placement) which was offset by payments towards the Company's loan, which was repaid in full in October 2014 and payments towards the five-year consulting agreement recognized as part of the non-controlling interest in 2011.

## Selected Quarterly Information (unaudited)

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

in thousands, except per share data

	June 30, 2014	September 30, 2014	December 31, 2014	March 31, 2015
	\$	\$	\$	\$
Revenue	3,863	3,010	3,427	4,547
Net income (loss) before income taxes	(2,279)	49,722 <sup>(2)</sup>	(6,112) <sup>(1)</sup>	(263)
Net income (loss) per common share				
Basic	(0.23)	4.85 <sup>(2)</sup>	(0.58) <sup>(1)</sup>	(0.03)
Diluted	(0.23)	4.80 <sup>(2)</sup>	(0.56) <sup>(1)</sup>	(0.03)

  

	June 30, 2013	September 30, 2013	December 31, 2013	March 31, 2014
	\$	\$	\$	\$
Revenue	3,320	9,137 <sup>(3) (4)</sup>	3,701	2,757
Net loss before income taxes	(2,191)	(2,919) <sup>(3) (4) (5)</sup>	(1,909)	(2,722)
Net loss per common share				
Basic and diluted	(0.25)	(0.34) <sup>(3) (4) (5)</sup>	(0.22)	(0.31)

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

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

<sup>(3)</sup> 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.

<sup>(4)</sup> The quarter ended September 30, 2013 included a US\$4.5 million upfront payment from Galen for the exclusive rights to sell and market Synera in the U.S.

<sup>(5)</sup> The quarter ended September 30, 2013 included a \$6.4 million impairment charge on intangible assets related to Pliaglis and the HLT Patch.

## Financial 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 \$46.8 million in cash and \$10.0 million in short-term investments as at March 31, 2015, it continues to have an ongoing need for substantial capital resources to research, develop, commercialize and manufacture its products and technologies as the Company is not generating enough cash to fund its operations.

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

The Company has contractual obligations related to accounts payable and accrued liabilities, purchase commitments and other obligations of \$14.0 million that are due in less than a year and \$0.3 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 March 31, 2015, the Company had \$40.7 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 has \$5.0 million in a high interest savings account and \$10.0 million in short-term investments with additional Schedule 1 Canadian banks and the remaining \$1.1 million of cash balances are held in bank accounts in various geographic regions outside of Canada.

The Company, in the normal course of business, is exposed to credit risk from its global customers most of whom are in the pharmaceutical industry. The accounts receivable are subject to normal industry risks in each geographic region in which the Company operates. In addition, the Company is exposed to credit related losses on sales to its customers outside North America and the E.U. due to potentially higher risks of enforceability and collectability. The Company attempts to manage these risks prior to the signing of distribution or licensing agreements by dealing with creditworthy customers; however, due to the limited number of potential customers in each market, this is not always possible. In addition, a customer's creditworthiness may change subsequent to becoming a licensee or distributor and the terms and conditions in the agreement may prevent the Company from seeking new licensees or distributors in these territories during the term of the agreement. As at March 31, 2015, the Company's four largest customers located in North America and the E.U. represented 67% [December 31, 2014 - 60%] of accounts receivable and accounts receivable from customers located outside of North America and the E.U. represented 17% [December 31, 2014 - 8%] of accounts receivable.

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

In thousands	<b>March 31, 2015</b>	December 31, 2014
	<b>\$</b>	<b>\$</b>
Current	<b>1,687</b>	2,940
0-30 days past due	<b>122</b>	43
31-60 days past due	-	20
Over 90 days past due	<b>2</b>	2
	<b>1,811</b>	3,005

### Interest Rate Risk

All finance lease obligations are at fixed interest rates.

### Currency Risk

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

	Euros		U.S. Dollars	
	March 31, 2015 €	December 31, 2014 €	March 31, 2015 \$	December 31, 2014 \$
In thousands				
Cash	2,309	1,266	1,879	665
Accounts receivable	406	242	840	2,205
Other current assets	156	159	-	-
Accounts payable and accrued liabilities	(890)	(943)	(595)	(601)
Finance lease and other long-term obligations	-	-	(253)	(281)
	1,981	724	1,871	1,988

Based on the aforementioned net exposure as at March 31, 2015, and assuming that all other variables remain constant, a 10% appreciation or depreciation of the Canadian dollar against the U.S. dollar would have an effect of \$237 on total comprehensive loss and a 10% appreciation or depreciation of the Canadian dollar against the euro would have an effect of \$270 on total comprehensive 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 agreements with Horizon, Galderma, Galen and Eurocept.

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

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

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



## Contractual Obligations

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

in thousands	Total	2016	2017	2018 and thereafter
	\$	\$	\$	\$
Finance lease obligations	2	2	-	-
Operating leases	370	215	151	4
Purchase obligations	7,822	7,822	-	-
Other obligations <sup>(1)</sup>	6,165	5,991	174	-
	<b>14,359</b>	<b>14,030</b>	<b>325</b>	<b>4</b>

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

## Off-Balance Sheet Arrangements

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

## Related Party Transactions

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.

## Outstanding Share Data

The number of common shares outstanding as at March 31, 2015 was 10.9 million compared to 10.8 million at December 31, 2014. The increase was due to the issuance of approximately 0.1 million shares from the exercise of Private Placement Warrants and Broker Warrants issued with the Company's Private Placement (see – Significant Transactions – 2014 – Private Placement).

As at March 31, 2015, there were 880,343 options outstanding of which 644,669 were vested.

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of Condensed Consolidated Interim 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. 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.

## 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. On April 28, 2015, the IASB agreed to publish an Exposure Draft proposing a one-year deferral of the effective date of the revenue standard to January 1, 2018. 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.

At December 31, 2014, the system of DCP was evaluated, under the supervision of the Company's Chairman and Co-Chief Executive Officer, President and Co-Chief Executive Officer and Vice President and Chief Financial Officer. Based on this evaluation, the Company's management has concluded that the DCP are effective and provide reasonable assurance that all material information relating to the Company would be made known to them. While the Co-Chief Executive Officers and the Chief Financial Officer believe that the Company's DCP provide reasonable assurance, they are also aware that any control system can only provide reasonable, not absolute, assurance of achieving its control objectives.

### **Internal Controls Over Financial Reporting**

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

The design and operating effectiveness of the Company's ICFR were evaluated, under the supervision of the Company's Chairman and Co-Chief Executive Officer, President and Co-Chief Executive Officer and Vice President and Chief Financial Officer, in accordance with criteria established in the 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**

There were no changes to ICFR that occurred during the quarter ended March 31, 2015 that has materially affected, or is reasonable likely to materially effect, the Company's ICFR.

### **Risk Factors**

Prospects for companies in the biotechnology and pharmaceutical industry generally may be regarded as uncertain given the nature of the industry and, accordingly, investments in biotechnology and pharmaceutical companies should be regarded as speculative. R&D involves a high and significant degree of risk. An investor should carefully consider the risks and uncertainties discussed in detail in the MD&A filed on SEDAR on February 19, 2015 for the year ended December 31, 2014 and the "Risk Factors" section of the Company's AIF filed February 19, 2015 before making an investment decision.

### **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).

**NUVO RESEARCH INC.**  
**CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION**

	<i>Notes</i>	As at March 31, 2015	As at December 31, 2014
<i>(Canadian dollars in thousands)</i>		\$	\$
<b>ASSETS</b>			
<b>CURRENT</b>			
Cash	14	46,779	48,275
Short-term investments	14	10,000	10,000
Accounts receivable	14	1,811	3,005
Inventories	4	1,357	1,929
Other current assets	5	696	770
<b>TOTAL CURRENT ASSETS</b>		<b>60,643</b>	<b>63,979</b>
<b>NON-CURRENT</b>			
Property, plant and equipment	6	1,078	1,161
<b>TOTAL ASSETS</b>		<b>61,721</b>	<b>65,140</b>
<b>LIABILITIES AND EQUITY</b>			
<b>CURRENT</b>			
Accounts payable and accrued liabilities		5,801	9,149
Current portion of other obligations	7	158	140
<b>TOTAL CURRENT LIABILITIES</b>		<b>5,959</b>	<b>9,289</b>
Other obligations	7	164	188
<b>TOTAL LIABILITIES</b>		<b>6,123</b>	<b>9,477</b>
<b>EQUITY</b>			
Common shares	8	233,806	233,568
Contributed surplus	8,9	13,963	13,910
Accumulated other comprehensive income (AOCI)		1,038	1,124
Deficit		(193,209)	(192,939)
<b>TOTAL EQUITY</b>		<b>55,598</b>	<b>55,663</b>
<b>TOTAL LIABILITIES AND EQUITY</b>		<b>61,721</b>	<b>65,140</b>

Commitments (Note 13)  
See accompanying Notes.

**NUVO RESEARCH INC.  
CONSOLIDATED INTERIM STATEMENTS OF LOSS AND  
COMPREHENSIVE LOSS**

		Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
<i>(Canadian dollars in thousands, except per share and share figures)</i>	<i>Notes</i>	\$	\$
<b>REVENUE</b>			
Product sales		3,903	1,156
Royalties		519	1,397
Research and other contract revenue		125	147
Licensing fees		-	57
<b>Total revenue</b>		<b>4,547</b>	<b>2,757</b>
<b>OPERATING EXPENSES</b>			
Cost of goods sold	4,9,11	2,560	1,209
Research and development expenses	9,11	1,998	1,887
General and administrative expenses	9,11	663	2,373
Interest expense		12	195
Interest income		(149)	(21)
<b>Total operating expenses</b>		<b>5,084</b>	<b>5,643</b>
<b>OTHER INCOME</b>			
Foreign currency gain		(274)	(164)
<b>Net loss before income taxes</b>		<b>(263)</b>	<b>(2,722)</b>
Income tax expense		7	21
<b>NET LOSS</b>		<b>(270)</b>	<b>(2,743)</b>
<b>Other comprehensive income to be reclassified to net income in subsequent periods</b>			
Unrealized gains (losses) on translation of foreign operations		(86)	87
<b>TOTAL COMPREHENSIVE LOSS</b>		<b>(356)</b>	<b>(2,656)</b>
<b>Net loss per common share –</b>			
- Basic and diluted	10	(0.03)	(0.31)
<b>Average number of common shares outstanding (in thousands)</b>			
- Basic and diluted		10,831	8,898

See accompanying Notes.

**NUVO RESEARCH INC.**  
**CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY**

<i>(Canadian dollars in thousands, except for number of shares)</i>	Common Shares		Contributed Surplus	AOCI	Deficit	Total
	(000s)	\$	\$	\$	\$	\$
	<i>Notes</i>	8,9	8,9	9		
Balance, December 31, 2013	8,850	229,068	13,573	1,086	(231,529)	12,198
Shares issued, net of issue costs	1,390	2,582	-	-	-	2,582
Warrants issued, net of issuance costs	-	-	281	-	-	281
Stock option compensation expense	-	-	70	-	-	70
Unrealized gains on translation of foreign operations	-	-	-	87	-	87
Performance stock unit compensation expense	-	-	6	-	-	6
Net loss	-	-	-	-	(2,743)	(2,743)
<b>Balance, March 31, 2014</b>	<b>10,240</b>	<b>231,650</b>	<b>13,930</b>	<b>1,173</b>	<b>(234,272)</b>	<b>12,481</b>
Warrants exercised	464	1,553	(174)	-	-	1,379
Stock option compensation expense	-	-	204	-	-	204
Unrealized losses on translation of foreign operations	-	-	-	(49)	-	(49)
Performance stock unit compensation expense	-	-	17	-	-	17
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	-	-	-	-	41,333	41,333
<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>
Warrants exercised	74	222	(13)	-	-	209
Stock option compensation expense	-	-	69	-	-	69
Unrealized losses on translation of foreign operations	-	-	-	(86)	-	(86)
Stock options exercised	6	16	(3)	-	-	13
Net loss	-	-	-	-	(270)	(270)
<b>Balance, March 31, 2015</b>	<b>10,855</b>	<b>233,806</b>	<b>13,963</b>	<b>1,038</b>	<b>(193,209)</b>	<b>55,598</b>

See accompanying Notes.

**NUVO RESEARCH INC.**  
**CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS**

<i>(Canadian dollars in thousands)</i>	<i>Notes</i>	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
		\$	\$
<b>OPERATING ACTIVITIES</b>			
Net loss		(270)	(2,743)
Items not involving current cash flows:			
Depreciation and amortization	11	91	184
Deferred license revenue recognized		-	(57)
Equity-settled stock-based compensation	9	69	76
Unrealized foreign exchange gain		(184)	(213)
Inventory write-down	4	55	23
Interest and accretion of long-term other obligations		12	17
Other		(5)	28
		(232)	(2,685)
Net change in non-cash working capital	12	(1,445)	1,785
<b>CASH USED IN OPERATING ACTIVITIES</b>		<b>(1,677)</b>	<b>(900)</b>
<b>INVESTING ACTIVITIES</b>			
Acquisition of property, plant and equipment	6	(10)	(55)
<b>CASH USED IN INVESTING ACTIVITIES</b>		<b>(10)</b>	<b>(55)</b>
<b>FINANCING ACTIVITIES</b>			
Issuance of common shares		-	2,863
Exercise of warrants	8	209	-
Exercise of stock options	9	13	-
Repayment of other obligations	7	(43)	(429)
<b>CASH PROVIDED BY FINANCING ACTIVITIES</b>		<b>179</b>	<b>2,434</b>
Effect of exchange rate changes on cash		12	121
Net change in cash during the period		(1,496)	1,600
Cash, beginning of period		48,275	12,621
<b>CASH, END OF PERIOD</b>		<b>46,779</b>	<b>14,221</b>
<i>Interest paid</i> <sup>1</sup>		-	184
<i>Interest received</i> <sup>1</sup>		126	23
<i>Income taxes paid</i> <sup>1</sup>		1	35

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

See accompanying Notes.

**NUVO RESEARCH® INC.**  
**NOTES TO THE CONDENSED CONSOLIDATED INTERIM 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. 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. 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. In October 2014, the Company sold the U.S. rights to Pennsaid 2% to Horizon Pharma plc (Horizon) for US\$45.0 million. The details of these transactions are disclosed in the notes to the Company's Consolidated Financial Statements for the year ended December 31, 2014 filed on SEDAR at [www.sedar.com](http://www.sedar.com). In January 2015, Horizon launched its commercial sale and marketing of Pennsaid 2% in the U.S. Pennsaid 2% is currently manufactured by the Company for sale to Horizon. Pennsaid 2% is not approved in any country outside of the U.S.

Pennsaid is a topical NSAID containing 1.5% diclofenac sodium and is used to treat the signs and symptoms of OA of the knee. It is approved for sale and marketing in several countries including Canada where it is licensed to Paladin Labs Inc. (Paladin). As a result of the litigation settlement with Mallinckrodt, the U.S. sales and marketing rights to Pennsaid were returned to the Company. Under the terms of the agreement with Horizon for the sale of the Pennsaid 2% rights, the Company agreed to discontinue the manufacture, sale and marketing of Pennsaid in the U.S.

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 injections, pulsed-dye laser therapy, facial laser resurfacing and laser-assisted tattoo removal. The Company has licensed worldwide marketing rights to Galderma S.A. (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.

### **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 Condensed Consolidated Interim 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 March 31, 2015, the Company had an accumulated deficit of \$193,209 including a loss of \$270 during the quarter. The Company's ability to continue as a going concern depends on:

- the commercial success of Pennsaid 2% in the U.S., as the Company earns revenue from 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 success of the Company's clinical studies for WF10 for the treatment of allergic rhinitis and Pennsaid 2% for the treatment of acute sprains and strains; and
- its ability to secure additional licensing fees, secure co-development agreements, obtain additional capital when required, gain regulatory approval for other drugs and ultimately achieve profitable operations.

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

The Company anticipates that its current cash and short-term investments, together with the revenues it expects to generate from product sales and royalties 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 Condensed Consolidated Interim 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**

The Company prepares its Condensed Consolidated Interim Financial Statements in accordance with IAS 34 - *Interim Financial Reporting*. Accordingly, these Condensed Consolidated Interim Financial Statements do not include all disclosures required for annual financial statements and should be read in conjunction with the annual Consolidated Financial Statements of the Company for the year ended December 31, 2014 which are available on SEDAR at [www.sedar.com](http://www.sedar.com).

The preparation of financial statements in accordance with IAS 34 requires the use of certain critical accounting estimates. It also requires management to exercise judgment in applying the Company's accounting policies. The areas involving a higher degree of judgment or complexity or areas where assumptions and estimates are significant to the financial statements were the same as those that applied to the Company's annual Consolidated Financial Statements as at and for the year ended December 31, 2014.

## Basis of Measurement

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

## Basis of Consolidation

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

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

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

## Significant Accounting Policies

All significant accounting policies have been applied on a basis consistent with those followed in the most recent annual Consolidated Financial Statements. The policies applied in these Condensed Consolidated Interim Financial Statements are based on International Financial Reporting Standards (IFRS) issued and outstanding as at May 12, 2015, the date the Board of Directors approved these Condensed Consolidated Interim Financial Statements.

## Accounting Standards Issued But Not Yet Applied

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 impacted 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, which covers principles for reporting about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. On April 28, 2015, the IASB agreed to publish an Exposure Draft proposing a one-year deferral of the effective date of the revenue standard to January 1, 2018. 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.

### 3. CRITICAL ACCOUNTING POLICIES 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 Condensed Consolidated Interim 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. The significant estimates and judgments made by management are discussed in the annual Consolidated Financial Statements for the year ended December 31, 2014 filed on SEDAR at www.sedar.com.

### 4. INVENTORIES

Inventories consist of the following at:

	March 31, 2015	December 31, 2014
	\$	\$
Raw materials	716	515
Work in process	161	146
Finished goods	480	1,268
	<b>1,357</b>	<b>1,929</b>

During the three months ended March 31, 2015, inventories in the amount of \$2.3 million [\$1.0 million for the three months ended March 31, 2014] were recognized as cost of goods sold. During the three months ended March 31, 2015, \$nil of raw materials in the TPT Group were written down [\$23 for the three months ended March 31, 2014]. For the Immunology Group, \$55 (€40) of finished goods were written down during the three months ended March 31, 2015 [\$nil for the three months ended March 31, 2014] and no reversals of prior write-downs occurred during the three-month periods ended March 31, 2015 and 2014.

### 5. OTHER CURRENT ASSETS

Other current assets consist of the following at:

	March 31, 2015	December 31, 2014
	\$	\$
Other receivables <sup>(i)</sup>	441	543
Prepaid expenses	148	182
Deposits	107	45
	<b>696</b>	<b>770</b>

<sup>(i)</sup> Included \$213 [December 31, 2014 - \$223] related to R&D expenditures which the Company was eligible for reimbursement under funding agreements with the Development Bank of Saxony (SAB) that expired in October 2014 for the development of WF10 related projects. The amounts reimbursed were included in R&D expenses in prior years.

### 6. PROPERTY, PLANT AND EQUIPMENT

PP&E consists of:

	Land	Buildings	Leasehold Improvements	Furniture & Fixtures	Computer Equipment	Production Laboratory & Other Equipment <sup>(i)</sup>	Total
Cost	\$	\$	\$	\$	\$	\$	\$
Balance, December 31, 2014	42	2,059	114	270	1,039	3,685	7,209
Foreign exchange movements	-	(25)	-	(2)	(2)	(5)	(34)
Additions	-	-	-	-	1	9	10
<b>Balance, March 31, 2015</b>	<b>42</b>	<b>2,034</b>	<b>114</b>	<b>268</b>	<b>1,038</b>	<b>3,689</b>	<b>7,185</b>

<b>Accumulated depreciation</b>							
Balance, December 31, 2014	-	1,591	114	267	987	3,089	6,048
Foreign exchange movements	-	(24)	-	(2)	(1)	(5)	(32)
Depreciation expense	-	14	-	-	6	71	91
<b>Balance, March 31, 2015</b>	<b>-</b>	<b>1,581</b>	<b>114</b>	<b>265</b>	<b>992</b>	<b>3,155</b>	<b>6,107</b>
<hr/>							
NBV at December 31, 2014	42	468	-	3	52	596	1,161
<b>NBV at March 31, 2015</b>	<b>42</b>	<b>453</b>	<b>-</b>	<b>3</b>	<b>46</b>	<b>534</b>	<b>1,078</b>

<sup>(i)</sup> Production, laboratory and other equipment at March 31, 2015 included a cost of \$56 [December 31, 2014 - \$56] and accumulated depreciation of \$56 [December 31, 2014 - \$55] for assets under finance leases. Depreciation of PP&E was \$1 for the three months ended March 31, 2015 [December 31, 2014 - \$2] related to assets under finance leases.

## 7. OTHER OBLIGATIONS

Other obligations consist of the following as at:

	March 31, 2015	December 31, 2014
	\$	\$
Long-term consulting agreement from acquisition of non-controlling interest	320	326
Finance lease obligations	2	2
	<b>322</b>	<b>328</b>
Less amounts due within one year	158	140
Long-term balance	<b>164</b>	<b>188</b>

### 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 March 31:

	\$
2016	190
2017	174
Total payments	364
Less amount representing interest (approximately 15.5%)	44
Present value of obligation, including accretion	320
Less current portion	156
<b>Long-term balance</b>	<b>164</b>

## 8. 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.

### 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 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 during this period expire. During the three months ended March 31, 2015, 33,000 of the Private Placement Warrants were exercised.

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. During the three months ended March 31, 2015, 28,333 of Broker Warrants were exercised.

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.

In 2014, 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 Interim Statements of Financial Position.

On an accumulated basis, 462,999 of the Private Placement Warrants have been exercised, 59,633 of the Broker Warrants have been exercised, and 29,817 Private Placement Warrants have been issued upon the exercise of Broker Warrants, of which 15,650 have exercised.

## Warrants

The warrants outstanding by tranche are as follows:

	Expiry Date	Exercise price	March 31, 2015	December 31, 2014
Private Placement Warrants	March 31, 2016	\$3.00	<b>246,168</b>	277,501
Broker Warrants <sup>(i)</sup>	March 31, 2016	\$2.54	<b>18,600</b>	46,933
Paladin Warrants <sup>(ii)</sup>	July 10, 2016	\$1.82	<b>50,000</b>	50,000
			<b>314,768</b>	374,434

<sup>(i)</sup> 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.

<sup>(ii)</sup> Warrants previously issued to Paladin Labs Inc. under a loan facility.

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, 2014	374,434	2.78
Issued	14,167	3.00
Exercised	(73,833)	2.82
<b>Balance, March 31, 2015</b>	<b>314,768</b>	<b>2.79</b>

## 9. 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 Deferred Share Unit (DSU) Plan for non-employee directors, the DSU Plan for Employees and the Stock Appreciations Rights (SARs) Plan. Full descriptions of the six stock-based compensation plans are included in Note 11 "Stock-Based Compensation and Other Stock-Based Payments" to the Company's annual Consolidated Financial Statements for the year ended December 31, 2014.

### 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 March 31, 2015, the number of options available and reserved for issue was 190,734.

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, 2014	887	1.96 – 24.05	6.93
Exercised <sup>(i)</sup>	6	1.96	1.96
<b>Balance, March 31, 2015</b>	<b>881</b>	<b>1.96 – 24.05</b>	<b>6.97</b>

<sup>(i)</sup> The weighted average share price for the options exercised in 2015 was \$6.99.

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

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	377	8.6	3.33	176	3.61
6.50 – 8.78	334	4.5	7.72	299	7.87
11.05 – 24.05	170	1.9	13.54	170	13.54
	<b>881</b>	<b>5.7</b>	<b>6.97</b>	<b>645</b>	<b>8.20</b>

## Deferred Share Unit Plan

### 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 (VWAP) of the Company's common shares immediately preceding the payment date.

### Employees

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

Upon issuance, the fair value of the DSUs is recorded as compensation expense and the DSU accrual is established. At all subsequent reporting dates, the DSU accrual is adjusted to the market value of the underlying shares and the adjustment is recorded as compensation 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 three months ended March 31, 2015, a \$1,013 reversal of expense was recorded in general and administrative (G&A) expenses as compensation expense related to DSUs. The reversal for the three months ended March 31, 2015 consisted of a charge of \$131 for the fair value of the DSU's issued for director fees, combined with a \$1,144 decrease in the aggregate DSU accrual to the market value of the underlying shares for the three months ended March 31, 2015. The DSU accrual is included in accounts payable and accrued liabilities.

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

	Number of DSUs 000s	Market Values \$	Accrual \$
Balance, December 31, 2014	395	7.00	2,770
Issued for directors' fees	22	4.29 – 6.92	131
Adjustment to market value	-	-	(1,144)
<b>Balance, March 31, 2015</b>	<b>417</b>	<b>4.21</b>	<b>1,757</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 March 31, 2015 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	0.46	1 - 2	80 - 88	2.51 – 2.72
318	April 4, 2014	3.39	0.46	1 - 3	80 - 88	1.60 – 2.34
246	January 7, 2015	7.20	0.46 – 0.53	1 - 4	80 - 88	0.59 - 1.92

The following table summarizes the outstanding SARs and related accrual at March 31, 2015:

	Number of SARs 000s	Fair Values \$	Accrual \$
Balance, December 31, 2014	924	3.61 – 5.38	2,876
Granted	246	0.59 – 1.92	30
Vested	(382)	3.61 - 5.15	(1,848)
Adjustment to market value	-	-	(420)
<b>Balance, March 31, 2015</b>	<b>788</b>	<b>0.59 – 2.72</b>	<b>638</b>

### Summary of Stock-Based Compensation

	Three Months Ended March 31, 2015 \$	Three Months Ended March 31, 2014 \$
Stock option compensation expense under the Share Option Plan	69	70
DSUs – issued for settlement of directors' fees	131	131
DSUs – issued for employee compensation	-	89
DSUs – adjustment to market value	(1,144)	125
PSU compensation expense under the Share Bonus Plan	-	6
SARs compensation expense	(390)	126
<b>Stock-based compensation expense</b>	<b>(1,334)</b>	<b>547</b>
<i>Recorded in the Consolidated Interim Statements of Loss and Comprehensive Loss as follows:</i>		
Cost of goods sold	1	2
Research and development expenses	(45)	36
General and administrative expenses	(1,290)	509
	<b>(1,334)</b>	<b>547</b>

### 10. NET LOSS PER COMMON SHARE

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:

	March 31, 2015 000s	March 31, 2014 000s
Common shares issued and outstanding	10,855	10,240
Stock options outstanding (Note 9)	881	761
Warrants (Note 8)	315	823
PSUs outstanding	-	11
	<b>12,051</b>	<b>11,835</b>



## 11. EXPENSES BY NATURE

The Consolidated Interim Statements of Loss and Comprehensive Loss include the following expenses by nature:

(a) Employee costs:

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
	\$	\$
Short-term employee wages, bonuses and benefits	2,540	2,120
Share-based payments	(884)	337
Post-employment benefits	4	10
<b>Total employee costs</b>	<b>1,660</b>	<b>2,467</b>
<b>Included in:</b>		
Cost of goods sold	851	556
Research and development expenses	663	776
General and administrative expenses	146	1,135
<b>Total employee costs</b>	<b>1,660</b>	<b>2,467</b>

(b) Depreciation and amortization:

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
	\$	\$
Cost of goods sold	63	68
Research and development expenses	24	21
General and administrative expenses <sup>(i)</sup>	4	95
<b>Total depreciation and amortization</b>	<b>91</b>	<b>184</b>

<sup>(i)</sup> G&A expenses include \$nil of amortization of intangible assets for the three months ended March 31, 2015 [March 31, 2014 - \$87].

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

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

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
	\$	\$
Accounts receivable	1,341	2,125
Inventories	503	(474)
Other current assets	63	(205)
Accounts payable and accrued liabilities	(3,352)	339
<b>Net change in non-cash working capital</b>	<b>(1,445)</b>	<b>1,785</b>

## 13. COMMITMENTS

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

	Research and Other Service Contracts	Operating Leases	Total
	\$	\$	\$
2016	7,822	215	8,037
2017	-	151	151
2018 and thereafter	-	4	4
	<b>7,822</b>	<b>370</b>	<b>8,192</b>

For the three months ended March 31, 2015, payments under operating leases totaled \$63 [\$48 for the three months ended March 31, 2014].

## 14. FINANCIAL INSTRUMENTS AND RISK MANAGEMENT

### Risk Factors

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

### Liquidity Risk

While the Company had \$46.8 million in cash and \$10.0 million in short-term investments as at March 31, 2015, it continues to have an ongoing need for substantial capital resources to research, develop, commercialize and manufacture its products and technologies as the Company is not generating enough cash to fund its operations. The Company has limited participation in Pennsaid and Pennsaid 2% revenues in countries where it is currently marketed. In Canada, the Company receives royalties based on Canadian net sales of Pennsaid. In the first quarter of 2014, a generic version of Pennsaid was launched that has negatively impacted the Company's royalty revenues in Canada. In the U.S., the Company receives product revenues from Horizon pursuant to a long-term exclusive supply agreement.

The Company has contractual obligations related to accounts payable and accrued liabilities, purchase commitments and other obligations of \$14.0 million that are due in less than a year and \$0.3 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 March 31, 2015, the Company had \$40.7 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 has \$5.0 million in a high interest savings account, \$10.0 million in short-term investments with additional Schedule 1 Canadian banks and the remaining \$1.1 million of cash balances are held in bank accounts in various geographic regions outside of Canada.

The Company, in the normal course of business, is exposed to credit risk from its global customers most of whom are in the pharmaceutical industry. The accounts receivable are subject to normal industry risks in each geographic region in which the Company operates. In addition, the Company is exposed to credit related losses on sales to its customers outside North America and the E.U. due to potentially higher risks of enforceability and collectability. The Company attempts to manage these risks prior to the signing of distribution or licensing agreements by dealing with creditworthy customers; however, due to the limited number of potential customers in each market, this is not always possible. In addition, a customer's creditworthiness may change subsequent to becoming a licensee or distributor and the terms and conditions in the agreement may prevent the Company from seeking new licensees or distributors in these territories during the term of the agreement. As at March 31, 2015, the Company's four largest customers located in North America and the E.U. represented 67% [December 31, 2014 - 60%] of accounts receivable and accounts receivable from customers located outside of North America and the E.U. represented 17% [December 31, 2014 - 8%] of accounts receivable.

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

	March 31, 2015	December 31, 2014
	\$	\$
Current	1,687	2,940
0-30 days past due	122	43
31-60 days past due	-	20
Over 90 days past due	2	2
	<b>1,811</b>	<b>3,005</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	
	March 31, 2015	December 31, 2014	March 31, 2015	December 31, 2014
In thousands	€	€	\$	\$
Cash	2,309	1,266	1,879	665
Accounts receivable	406	242	840	2,205
Other current assets	156	159	-	-
Accounts payable and accrued liabilities	(890)	(943)	(595)	(601)
Finance lease and other long-term obligations	-	-	(253)	(281)
	1,981	724	1,871	1,988

Based on the aforementioned net exposure as at March 31, 2015, and assuming that all other variables remain constant, a 10% appreciation or depreciation of the Canadian dollar against the U.S. dollar would have an effect of \$237 on total comprehensive loss and a 10% appreciation or depreciation of the Canadian dollar against the euro would have an effect of \$270 on total comprehensive 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 agreements with Horizon, Galderma, Galen and Eurocept.

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

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

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

## 15. 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 \$
<b>Three months ended March 31, 2015</b>			
Total revenue	4,359	188	4,547
Depreciation of property, plant and equipment	85	6	91
Interest income	149	-	149
Interest expense	12	-	12
Net income (loss) before income taxes	1,087	(1,350)	(263)
Assets	59,545	2,176	61,721
Property, plant and equipment	1,017	61	1,078
Additions to property, plant and equipment	7	3	10

	TPT Group \$	Immunology Group \$	Total \$
<b>Three months ended March 31, 2014</b>			
Total revenue	2,620	137	2,757
Depreciation of property, plant and equipment and amortization of intangible assets	178	6	184
Interest income	21	-	21
Interest expense	195	-	195
Net loss before income taxes	(1,337)	(1,385)	(2,722)
Assets	20,237	1,652	21,889
Property, plant and equipment	1,316	56	1,372
Additions to property, plant and equipment	52	3	55

### Geographic Information

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

	Three Months Ended March 31, 2015 \$	Three Months Ended March 31, 2014 \$
United States	2,664	1,906
Europe	1,206	87
Canada	491	622
Other foreign countries	186	142
	<b>4,547</b>	<b>2,757</b>

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

	Three Months Ended March 31, 2015 \$	Three Months Ended March 31, 2014 \$
Canada	1,017	1,309
Europe and other	61	63
	<b>1,078</b>	<b>1,372</b>

### Significant Customers

For the three months ended March 31, 2015, the Company's four largest customers (excluding upfront payments and milestones from licensing arrangements) represented 81% [March 31, 2014 - 91%] of total revenue and the Company's largest customer represented 49% [March 31, 2014 - 73%] of total revenue. The Company's largest customers are in the TPT Group.

## **16. RELATED PARTY TRANSACTIONS**

For the three months ended March 31, 2015, there were no related party transactions. For the three months ended March 31, 2014, certain officers of the Company participated in the Private Placement described in Note 8 and acquired 67,768 Units on the same terms as the other purchasers. Proceeds raised from the Company's officers totaled \$152.