



Nuvo Pharmaceuticals Inc. Annual Report 2019



Dear Shareholders,

2019 was an exciting year for Nuvo, as we focused on successfully integrating the Aralez Canada operations and products into Nuvo. The strategy behind the acquisition was realized in a number of ways this year, including an increase in adjusted total revenue, adjusted EBITDA and gross profit, expansion of our Canadian business providing a platform for future growth, diversification of our products and revenue streams and the generation of significant cash flow from our combined business segments. In addition, we identified synergies and implemented organizational changes that resulted in a significant reduction in operating expenses during the second half of the year.

Our Q4 financial results\* include:

- **FY 2019 Adjusted Total Revenue - \$74.7 million; an increase of 265% over FY 2018**
  - **Q4 2019 Adjusted Total Revenue - \$19.6 million; an increase of 313% over Q4 2018**
- **FY 2019 Adjusted EBITDA - \$27.2 million; an increase of \$30.3 million over FY 2018**
  - **Q4 2019 Adjusted EBITDA\* - \$8.6 million; an increase of \$13.1 million over Q4 2018**
- **FY 2019 Gross Profit - \$43.1 million; an increase of 279% over FY 2018**
  - **Q4 2019 Gross Profit - \$13.1 million; an increase of 444% over Q4 2018**

The Company finished the year with \$23.0 million of cash, an increase of \$4.5 million during the fourth quarter. In November, we made a US\$2.5 million debt repayment towards our Bridge Loan (12.5% coupon rate) held by Deerfield Management Company, L.P. (Deerfield). In early January 2020, we repaid the remainder of the US\$6.0 million Bridge Loan.

Blexten® and Cambia® - two of our key growth assets - demonstrated significant growth in both prescriptions and market share during 2019. Both products have been well received over other more mature medications that treat the same conditions, by patients and physicians alike.

### **Blexten**

Blexten's fourth quarter performance continued to reflect the seasonality we see historically in the oral antihistamine market. With the colder weather of the fall and early winter comes a reduction in the severity of seasonal allergy triggers.

Despite the seasonal fluctuations of antihistamine prescriptions, Blexten demonstrated continued year-over-year growth of total prescriptions (TRx) and TRx market share during the year and quarter.

- **Blexten FY 2019 TRx increased 61% over FY 2018**
  - **Blexten Q4 2019 TRx increased 51% over Q4 2018**
- **Blexten FY 2019 TRx market share increased to 13.3% compared to 9.5% in FY 2018**
  - **Blexten Q4 2019 TRx market share increased to 13.6% compared to 10.3% in Q4 2018**

Our sales force continues to expand the prescriber base for Blexten. We expect ongoing growth and market share gains in the prescription antihistamine market in 2020 and beyond. The market leader, cetirizine (Reactine), currently holds approximately 58% (and declining) market share and Blexten continues to grow. Furthermore, we anticipate filing our Health Canada application for Blexten Pediatric during the first half of 2020. If approved by Health Canada, our Blexten portfolio will grow to include two additional unique formats specifically indicated for children.

\*Adjusted EBITDA and Adjusted Total Revenue are Non-IFRS measures. See "Non-IFRS Measures" in the Company's MD&A dated February 24, 2019 for a reconciliation of non-IFRS measures to IFRS

## Cambia

- **Cambia FY 2019 TRx increased 28% over FY 2018**
  - **Cambia Q4 2019 TRx increased 23% over Q4 2018**
- **Cambia FY 2019 TRx market share increased to 4.3% compared to 3.5% in FY 2018**
  - **Cambia Q4 2019 TRx market share increased to 4.4% compared to 3.7% in Q4 2018**

Cambia ended the year on a high note, with continued and consistent year-over-year growth in TRx and market share. As Cambia enters its 8<sup>th</sup> year on the market in Canada, we anticipate continued growth consistent with past performance.

## Vimovo Update

A generic version of Vimovo did not launch in the U.S. during 2019. As a result, Nuvo Ireland received the US\$7.5 million minimum annual royalty on the U.S. sales of Vimovo. During 2019, the United States Court of Appeals for the Federal Circuit denied our *en banc* petition and determined that two of our patents (U.S. Patent Nos. 6,926,907 and 8,557,285) related to Vimovo were invalid. We filed a petition to the U.S. Supreme Court to reconsider the Court of Appeals decision; however, the petition was denied. Last week, Dr. Reddy Laboratories (Dr. Reddy's) received final U.S. Food and Drug Administration (FDA) approval for one of its Abbreviated New Drug Applications (ANDAs) for a generic version of Vimovo and we anticipate a launch of generic Vimovo could occur during 2020. This launch would be "at risk", as Nuvo Ireland does own additional valid and enforceable patents (U.S. Patent Nos. 8,858,996 (the '996 patent) and 9,161,920 (the '920 patent) that protect Vimovo. In November 2019, the United States District Court for the District of New Jersey denied a motion for summary judgment filed by Dr. Reddy's. As a result, the patent infringement litigation against Dr. Reddy's, involving the '996 patent and the '920 patent, will continue. We anticipate this infringement litigation to go to trial in mid-2021.

The other generic Vimovo applicants, except the most recent ANDA filer, which is subject to a 30-month stay, have entered into settlement agreements with Nuvo Ireland and our U.S. partner, which currently restricts them from entering the U.S. market until after Dr. Reddy's launches. If Dr. Reddy's launches a generic version of Vimovo in the U.S., then other generic companies may also be able to obtain final FDA approval to launch. Nuvo Ireland and its U.S. partner will continue to consider all legal strategies and opportunities to protect this revenue stream as long as possible.

While the future of the Vimovo U.S. royalty is somewhat uncertain, it is important to note that the Vimovo royalty we receive for sales outside of the U.S. are not impacted by the U.S. litigation. In addition, through the organizational changes implemented in the second quarter of 2019, the amendment to our Facility Agreement with Deerfield and the continued growth of our other business segments - in particular Blexten, Cambia, and the anticipated launch of Suvexx™ in Canada (upon approval from Health Canada), as well as new global launches for Resultz® and Pennsaid® 2%, we are well positioned to adapt to the Vimovo U.S. royalty uncertainty.

\*Adjusted EBITDA and Adjusted Total Revenue are Non-IFRS measures. See "Non-IFRS Measures" in the Company's MD&A dated February 24, 2020 for a reconciliation of non-IFRS measures to IFRS

## **Pipeline and Business Development Update**

We have been successful in 2019 and early in 2020, in advancing our pipeline with new regulatory approvals and planned entry into new territories.

During the third quarter of 2019, our Indian partner, Sayre Therapeutics PVT Ltd. received approval from the Drug Controller General of India to market Pennsaid 2% as a prescription drug in India for the treatment of the pain of osteoarthritis of the knee. The Company anticipates the commercial launch of Pennsaid 2% in India during the second half of 2020.

The Company was notified by its licensee in Switzerland, Gebro Pharma AG (Gebro Pharma) that the marketing authorization for Pennsaid 2% was issued by Swissmedic in January 2020. The Company and Gebro Pharma are finalizing commercialization plans and anticipate the commercial launch of Pennsaid 2% in Switzerland before the end of 2020, once pricing has been established with Swiss authorities.

In April 2019, the Company announced the marketing authorization application for Pennsaid 2% had been accepted for review by the Austrian Agency for Health and Food Safety (AGES) acting as the reference member state. This decentralized extension procedure also included the local health authorities in Greece and Portugal. We anticipate that a review decision will be made in the first half 2020.

In January 2020, Nuvo closed a licensing transaction bringing a new line extension to the NeoVisc Canadian business. NeoVisc is an injectable viscosupplement used by orthopedic surgeons, sports medicine physicians and healthcare practitioners to replenish synovial fluid in the joints of patients with osteoarthritis. Aralez Canada has been selling NeoVisc in Canada for over a decade and we are excited to bring an innovative format of NeoVisc to the market - NeoVisc One, our new, reduced injection volume, single-dose format. Through our exclusive license, we will bring to market NeoVisc One which contains the lowest injection volume (only 4ml) available for single-dose viscosupplements in Canada. The reduction of injection volume makes administration of NeoVisc One easier for healthcare professionals and more comfortable for patients. Subject to receiving Health Canada approval, we anticipate launching the new and improved NeoVisc format during Q2 2020.

We remain focused on enhanced growth through business development activities and will continue to evaluate new and synergistic opportunities to leverage our existing commercial infrastructure and established customer and healthcare provider relationships. As always, timing on business development transactions is difficult to predict and we will update you on new and significant developments as appropriate.

## **Continued Momentum through Q4**

I would like to thank our employees for their commitment and hard work during this transformative year at Nuvo. I would also like to thank shareholders for your continued support at this time of tremendous growth and opportunity. I believe we are well positioned to continue to execute on our business strategy and look forward to the year ahead.

Sincerely,

Jesse Ledger  
President & CEO

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

February 24, 2020 / The following information should be read in conjunction with Nuvo Pharmaceuticals® Inc. (Nuvo or the Company) Consolidated Financial Statements for the year ended December 31, 2019, which were prepared in accordance with International Financial Reporting Standards (IFRS). Additional information about the Company, including the Consolidated Financial Statements and Annual Information Form (AIF), can be found on SEDAR at [www.sedar.com](http://www.sedar.com).

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

This MD&A contains "forward-looking information". Please see the discussion under "Forward-looking Statements" below.

The Company uses non-IFRS financial performance measures in this MD&A. For a detailed reconciliation of the non-IFRS measures used in this MD&A, please see the discussion under "Non-IFRS Measures" below.

### 2019 Highlights

Key developments for the Company during the year ended December 31, 2019 and up to the date of this MD&A, include the following:

- Adjusted total revenue<sup>(1)</sup> was \$74.7 million for the year ended December 31, 2019 compared to \$20.5 million for the year ended December 31, 2018. Adjusted total revenue for the three months ended December 31, 2019 was \$19.6 million compared to \$4.8 million for the three months ended December 31, 2018.
- Adjusted EBITDA<sup>(1)</sup> was \$27.2 million for the year ended December 31, 2019 compared to \$(3.1) million for the year ended December 31, 2018. Adjusted EBITDA for the three months ended December 31, 2019 was \$8.6 million compared to \$(4.5) million for the three months ended December 31, 2018.
- Canadian prescriptions of Blexten® increased by 61% for the year ended December 31, 2019 compared to the year ended December 31, 2018. For the three months ended December 31, 2019, Canadian prescriptions of Blexten increased by 51% compared to the comparative period in 2018.
- Canadian prescriptions of Cambia® increased by 28% for the year ended December 31, 2019 compared to the year ended December 31, 2018. For the three months ended December 31, 2019, Canadian prescriptions of Cambia increased by 23% compared to the comparative period in 2018.

<sup>(1)</sup> Non-International Financial Reporting Standards (IFRS) financial measure defined by the Company below.

### Business Update

- In January 2020, the Company was informed by its licensee in Switzerland and Lichtenstein, Gebro Pharma AG (Gebro Pharma) that the marketing authorization for Pennsaid® 2% was issued by Swissmedic. The Company and Gebro Pharma are finalizing commercialization plans and anticipate the commercial launch of Pennsaid 2% in Switzerland before the end of 2020.
- In January 2020, the Company repaid the US\$6.0 million Bridge Loan (12.5% per annum) to Deerfield Management Company, L.P. (Deerfield), ahead of its June 2020 maturity date. The Bridge Loan was one component of the financing provided by Deerfield in support of the acquisition of Aralez Canada, the U.S. and International rights to Vimovo and other related assets. The Company's remaining loans, US\$52.5 million and US\$60.0 million carry coupon interest rates of 3.5% per annum.
- In November 2019, the United States District Court for the District of New Jersey denied a motion for summary judgment filed by Dr. Reddy's Laboratories Inc. (Dr. Reddy's). As a result, the patent infringement

litigation against Dr. Reddy's, involving Nuvo Pharmaceuticals (Ireland) DAC (Nuvo Ireland) U.S. Patent Nos. 8,858,996 (the '996 patent) and 9,161,920 (the '920 patent), will continue.

- In October 2019, the United States Court of Appeals for the Federal Circuit (Court of Appeals) issued a ruling affirming the New Jersey court's decision upholding the validity of a certain claim of U.S. Patent No. 9,066,913 (the '913 patent) which covers Pennsaid 2%. Pursuant to this decision, but subject to any appeal rights, Actavis Laboratories UT, Inc., formerly known as Watson Laboratories, Inc., Actavis, Inc. and Actavis plc (collectively Actavis) is blocked from launching its generic version of Pennsaid 2% in the U.S. until the '913 patent expires on October 17, 2027. Nuvo is the exclusive manufacturer of Pennsaid 2% for our licensing partner, who owns the Pennsaid 2% intellectual property rights in the U.S.

## Non-IFRS Financial Measures

The Company discloses non-IFRS measures (such as adjusted total revenue, adjusted EBITDA and adjusted EBITDA per share) that do not have standardized meanings prescribed by IFRS. The Company believes that shareholders, investment analysts and other readers find such measures helpful in understanding the Company's financial performance and in interpreting the effect of the Aralez Transaction and the Deerfield Financing (described below) on the Company. Non-IFRS financial measures do not have any standardized meaning prescribed by IFRS and may not have been calculated in the same way as similarly named financial measures presented by other companies.

### Adjusted Total Revenue

The Company defines adjusted total revenue as total revenue, plus amounts billed to customers for existing contract assets, less revenue recognized upon recognition of a contract asset. Management believes adjusted total revenue is a useful supplemental measure to determine the Company's ability to generate cash from its customer contracts used to fund its operations.

The following is a summary of how adjusted total revenue is calculated:

	Three months ended December 31		Year ended December 31	
	2019	2018	2019	2018
in thousands	\$	\$	\$	\$
<b>Total revenue</b>	<b>19,593</b>	4,607	<b>69,546</b>	19,998
Add:				
Amounts billed to customers for existing contract assets	<b>51</b>	146	<b>5,178</b>	475
<b>Adjusted total revenue</b>	<b>19,644</b>	4,753	<b>74,724</b>	20,473

Adjusted total revenue increased to \$74.7 million for the year ended December 31, 2019 compared to \$20.5 million for the year ended December 31, 2018. The \$54.3 million increase in adjusted total revenue in the current year was primarily attributable to the addition of revenue related to the Aralez Transaction, which provided an incremental \$35.6 million of total revenue contributed from the Commercial Business segment and \$18.8 million attributable to earned Vimovo royalties. Adjusted total revenue for the three months ended December 31, 2019 increased to \$19.6 million compared to \$4.8 million for the three months ended December 31, 2018.

### Adjusted EBITDA

EBITDA refers to net income (loss) determined in accordance with IFRS, before depreciation and amortization, net interest expense (income) and income tax expense (recovery). The Company defines adjusted EBITDA as net income before net interest expense (income), depreciation and amortization and income tax expense (recovery) (EBITDA), plus amounts billed to customers for existing contract assets, inventory step-up expense, stock-based compensation expense, Other Expenses (Income), less revenue recognized upon recognition of a contract asset and other income. Management believes adjusted EBITDA is a useful supplemental measure to determine the Company's ability to generate cash available for working capital, capital expenditures, debt repayments, interest expense and income taxes.

The following is a summary of how EBITDA and adjusted EBITDA are calculated:

	Three months ended December 31		Year ended December 31	
	2019	2018	2019	2018
in thousands	\$	\$	\$	\$
<b>Net income (loss)</b>	<b>(456)</b>	<b>(4,631)</b>	<b>3,361</b>	<b>(6,153)</b>
Add back:				
Income tax expense (recovery)	29	(64)	28	(187)
Net interest expense (income)	3,142	5	10,305	(32)
Depreciation and amortization	2,312	633	9,546	2,493
<b>EBITDA</b>	<b>5,027</b>	<b>(4,057)</b>	<b>23,240</b>	<b>(3,879)</b>
Add back:				
Amounts billed to customers for existing contract assets	51	146	5,178	475
Stock-based compensation	114	184	457	795
<i>Other Expenses (Income):</i>				
Loss on disposal of contract assets	-	452	-	452
Change in fair value of derivative liabilities <sup>(1)</sup>	401	-	(31,070)	-
Change in fair value of contingent and variable consideration	1,856	(775)	1,216	(518)
Impairment <sup>(2)</sup>	159	-	23,780	-
Foreign currency loss (gain)	(1,081)	(478)	(2,598)	(429)
Inventory step-up	875	-	4,979	-
Other losses (gains)	1,168	-	2,060	-
<b>Adjusted EBITDA</b>	<b>8,570</b>	<b>(4,528)</b>	<b>27,242</b>	<b>(3,104)</b>

<sup>(1)</sup> As a result of the decrease in the share price in the current year, combined with a reduction in the risk-free interest rate, the value of the Company's derivative liabilities decreased and the Company recognized a net non-cash \$31.1 million gain on the change in fair value of derivative liabilities for the year ended December 31, 2019.

<sup>(2)</sup> In the year ended December 31, 2019, the Company recognized a \$22.4 million impairment charge related to the Vimovo contract asset. In July 2019, the Company received notice that the Court of Appeals had denied the Company's and Horizon Therapeutic pl's (Horizon) request to reconsider the May 2019 decision with respect to the validity of the Vimovo '907 patent and the '285 patent in the U.S. In October, a petition to the Supreme Court of the United States was filed to request to have the decision of the Court of Appeals reconsidered. The Supreme Court denied that petition on January 13, 2020. On February 18, 2020, Dr. Reddy's second-filed Abbreviated New Drug Application (ANDA) for Vimovo in the U.S. received FDA approval and the Company anticipates a generic version of Vimovo could launch in the U.S. during 2020. It is the Company's understanding that Dr. Reddy's does not have the benefit of 180-days of exclusivity, and, consequently, other generic companies may obtain final FDA approval for a generic version of Vimovo and be able to market the product in the U.S. If, and when, a competitor generic version of Vimovo enters the U.S. market, Nuvo will continue to receive a 10% royalty on net sales of Vimovo by its U.S. partner, subject to a step-down provision in the event that generic competition achieves a certain market share. Nuvo's US\$7.5 million minimum annual royalty due for Vimovo net sales in the U.S. will cease with the launch of a generic Vimovo in the U.S. In the year, the Company also recorded impairment of \$1.4 million of certain intangible assets in the commercial and licensing and royalty segment.

Adjusted EBITDA increased to \$27.2 million for the year ended December 31, 2019 compared to \$(3.1) million for the year ended December 31, 2018. The increase in adjusted EBITDA for the current year was primarily attributable to the increase in gross profit of \$36.7 million (net of inventory step-up expense of \$5.0 million) as a result of the Aralez Transaction, offset by an increase in general and administrative (G&A) expenses of \$1.5 million and an increase in sales and marketing expenses of \$9.8 million due to expenses incurred for the Commercial Business segment due to the Aralez Transaction. Adjusted EBITDA for the three months ended December 31, 2019 increased to \$8.6 million compared to \$(4.5) million for the three months ended December 31, 2018.

### Adjusted EBITDA Per Common Share

The Company defines adjusted EBITDA per share as adjusted EBITDA divided by the average number of issued and outstanding common shares of the Company as follows:

	Three months ended December 31		Year ended December 31	
	2019	2018	2019	2018
in thousands	\$	\$	\$	\$
Adjusted EBITDA	8,570	(4,528)	27,242	(3,104)
Adjusted EBITDA per common share	0.75	(0.40)	2.39	(0.27)
Average number of common shares outstanding (in thousands) - basic	11,388	11,443	11,388	11,443

Adjusted EBITDA per common share was \$2.39 for the year ended December 31, 2019 compared to adjusted EBITDA per common share of \$(0.27) for the year ended December 31, 2018. Adjusted EBITDA per common share was \$0.75 for the three months ended December 31, 2019 compared to adjusted EBITDA per common share of \$(0.40) for the three months ended December 31, 2018.

## Significant Transactions

### The Aralez Transaction

On December 31, 2018, the Company announced the acquisition of a portfolio of more than 20 revenue-generating products from Aralez Pharmaceuticals Inc. (Aralez) (the Aralez Transaction). The Aralez Transaction included the acquisition of Aralez Canada, a growing business that includes the products Cambia, Blexten, as well as the Canadian distribution rights to Resultz and provides a platform for the Company to acquire and launch additional commercial products in Canada. The Company also acquired the worldwide rights and royalties from licensees for Vimovo, Yosprala™ and the ex-U.S. product rights to Suvexx™.

The aggregate purchase price paid by the Company to Aralez for the Aralez Transaction was \$146.4 million (US\$110 million, subject to certain working capital and indebtedness adjustments). The Company satisfied the purchase price through funding provided by certain funds managed by Deerfield Management Company, L.P. (Deerfield), a global, healthcare-specialized investor (the Deerfield Financing).

### The Deerfield Financing

On December 31, 2018, the Company and Nuvo Ireland, as borrowers, and Aralez Canada, as guarantor, entered into the Deerfield Financing. The Deerfield Financing includes three loans: the Bridge Loan, the Amortization Loan and the Convertible Loan each with coupon interest rates of 12.5%, 3.5% and 3.5% respectively. The Company issued 25.6 million warrants (the Warrants) attached to the Amortization Loan at a \$3.53 strike price. The facility agreement with Deerfield (Deerfield Facility Agreement) contains customary representations and warranties and affirmative and negative covenants, including, among other things, limitations on asset sales, mergers and acquisitions, indebtedness, liens and dividends. In addition, the Company is subject to an annual financial covenant based on minimum levels of trailing twelve month net sales per fiscal year and a mandatory quarterly principal repayment requirement under the Amortization Loan and the Bridge Loan equal to the greater of (i) 50% of excess cash flow (as defined in the Deerfield Facility Agreement) for such quarter, and (ii) US\$2.5 million, which commenced with the quarter ended March 31, 2019, provided that, solely with respect to the first four fiscal quarters after the closing date, the US\$2.5 million quarterly minimum is not applicable as long as US\$10.0 million in principal repayments have been made over such four fiscal quarters. The mandatory quarterly principal repayments are first applied to the Bridge Loan, which is at a higher interest rate than the Amortization Loan. In January 2020, the Company repaid its US\$6.0 million Bridge Loan.



The Company agreed to an amendment to the financing agreement dated June 25, 2019, to provide, among other things, for a payment deferral mechanism in the event that Vimovo U.S. market exclusivity is lost. The amendment allows the Company to defer a portion of the mandatory minimum quarterly principal repayments by the difference between one quarter of the existing US\$7.5 million minimum annual royalty due from Vimovo sales in the U.S. and the actual amount of royalties received in the applicable quarter in the event Vimovo U.S. market exclusivity is lost earlier than had been expected (2022) prior to the Court of Appeals decision. The amount of any principal repayment deferred would, until repaid in accordance with the amendment, be subject to an interest rate of 12.5% per annum.

### **Acquisition of U.S. Rights to Resultz**

In January 2018, the Company's wholly owned subsidiary, Nuvo Ireland acquired the U.S. product and intellectual property rights to Resultz (50% isopropyl myristate, 50% cyclomethicone D5 topical solution lice and egg removal kit) from Piedmont Pharmaceuticals LLC (Piedmont). Resultz was cleared as a Class 1 medical device by the FDA in May 2017 and has not yet been commercially launched in the U.S. Nuvo anticipates commercializing Resultz in the U.S. through a licensing partner and is in active discussions with potential licensees. Under the terms of the agreement, US\$1.5 million (\$1.9 million) was paid to Piedmont. The transaction included a single-digit royalty payable to Piedmont on net sales through 2034. Nuvo, through Nuvo Ireland, has also obtained a right of first refusal to license or acquire certain related assets from Piedmont targeting other human indications.

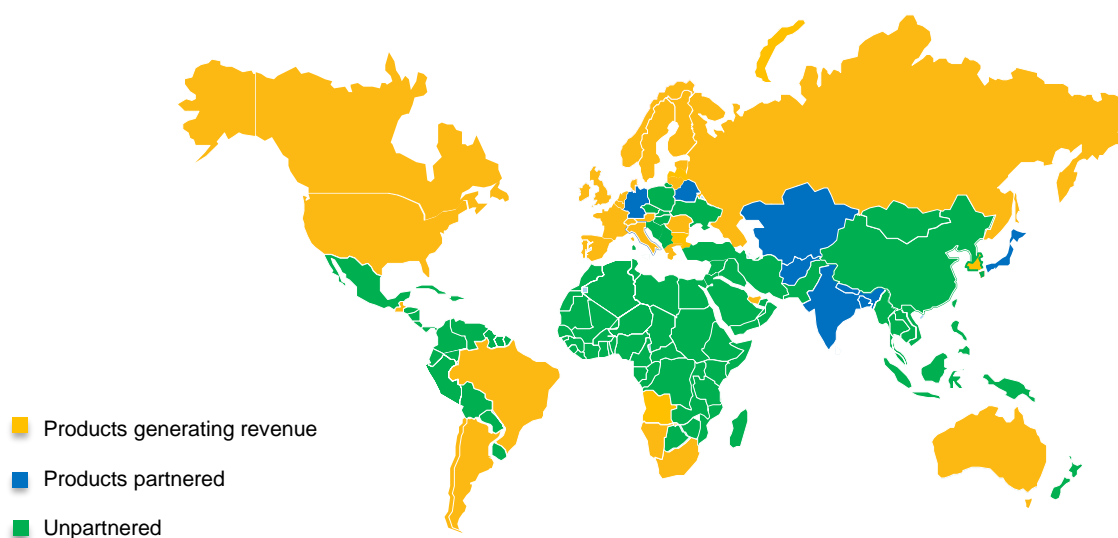
## **Our Business**

Nuvo is a publicly traded, Canadian healthcare company with global reach and a diversified portfolio of prescription and non-prescription products.

Nuvo's head office is located in Mississauga, Ontario, Canada, its international operations are headquartered in Dublin, Ireland and its manufacturing facility is located in Varennes, Québec, Canada. The Varennes facility operates in a Good Manufacturing Practices (GMP) environment respecting the U.S., Canada and E.U. GMP regulations and is regularly inspected by Health Canada and the FDA.

As at December 31, 2019, the Company employed a total of 91 full-time employees across its manufacturing facility in Varennes, Québec, corporate office, Commercial Business in Mississauga, Ontario and international headquarters in Dublin, Ireland.

### **Global Presence**



## Intellectual Property

The Company protects its intellectual property by means of a combination of patents, rights, licenses, non-disclosure agreements and contractual provisions. Nuvo currently holds 125 patents in a number of jurisdictions and has 7 patent applications pending. Additionally, the Company holds commercial licenses and cross-licenses to access third-party intellectual property.

## Operating Segments

The Company has three operating segments: Commercial Business, Production and Service Business and Licensing and Royalty Business.

## Commercial Business

The Commercial Business segment is comprised of products commercialized by the Company in Canada. This segment includes the Company's promoted products - Blexten, Cambia, the Canadian business for Resultz and Suvexx, which the Company anticipates receiving Health Canada approval in the first quarter of 2020 with an expected commercial launch in Q3 2020, as well as a number of mature assets. The Company sells its products to wholesalers who in turn supply retail and hospital pharmacies across Canada.

The Company's promoted products are primarily prescribed by Canadian Health Care Professionals, including neurologists, pain and migraine specialists, dermatologists, allergists, primary care physicians, prescribing pharmacists and nurse practitioners, which the Company's in-house commercial team calls on and supports through various educational and product detailing activities. The mature assets are used to treat patients across a broad range of therapeutic areas, including pain management, cardiology, gastroenterology, antihyperlipidemic/metabolic agents, dermatology and various non-prescription medicines. These mature assets receive no or minimal promotional support, and in some many cases, have lost market exclusivity and now compete with generic alternatives.

The Company's approved products related to the Commercial Business segment are as follows:

Distributed by Aralez Pharmaceuticals Canada Inc. In Canada			
Product	Description	Product	Description
<b>BLEXTEN<sup>®</sup></b>	Second-generation antihistamine for the treatment of seasonal allergies and urticaria (hives)	<b>CAMBIA<sup>®</sup></b>	Treatment of acute migraine
<b>Resultz<sup>®</sup></b>	Pesticide-free topical treatment of head lice infestations.	<b>Suvexx<sup>™</sup></b>	Treatment of acute migraine with or without aura in adults.
<b>Bezalip<sup>®</sup> SR</b>	Once daily treatment for patients with high cholesterol or high levels of triglycerides.	<b>Durela<sup>®</sup></b>	Sustained release oral capsule for the management of moderate to moderately severe pain.
<b>Fiorinal<sup>®</sup> Fiorinal<sup>®</sup>-c</b>	Relief for tension-type headaches.	<b>Visken<sup>®</sup> Viskazide<sup>®</sup></b>	Antihypertensive agent
<b>NeoVisc<sup>®</sup></b>	Replacement or replenishment for synovial fluid in joints following arthrocentesis.	<b>URACYST<sup>®</sup></b>	Instillation for the treatment of mild to severe GAG layer damage of the urinary bladder.
<b>PegaLAX<sup>®</sup></b>	Laxative for the treatment of occasional constipation and irregularity.	<b>MOVI<b>PREP</b><sup>®</sup></b>	Indicated for the cleansing of the colon in preparation for colonoscopy.
<b>Mutaflor<sup>®</sup></b>	Probiotic for the management and relief of chronic constipation and associated abdominal pain and cramps	<b>COLLATAMP<sup>®</sup> G</b>	Fully resorbable, antibiotic, collagen "haemostat" for surgical implantation during surgery to reduce the risk of surgical site infections.
<b>Proferrin<sup>®</sup></b>	Iron supplement for the prevention and treatment of iron deficiency.	<b>Soriatane<sup>®</sup></b>	Once daily treatment for psoriasis and other keratinization disorders.

### **Production and Service Business**

The Production and Service Business segment includes revenue from the sale of products manufactured by Nuvo from its manufacturing facility in Varennes, Québec or contracted by Nuvo Ireland from its international headquarters in Dublin, Ireland, as well as service revenue for testing, development and related quality assurance and quality control services provided by the Company. Key revenue streams in this segment include: Pennsaid 2%, Pennsaid and the bulk drug product for the Heated Lidocaine/Tetracaine (HLT) Patch, as well as ad hoc service agreements for testing, development and related quality assurance/quality control services.

The Company currently supplies Pennsaid 2% to Horizon for the U.S. market and is actively engaged in ongoing partnering efforts for Pennsaid 2% across Europe and the rest of the world. The Company will continue to focus on identifying license partners for Resultz in key unpartnered territories around the world, including the U.S. Nuvo believes its Production and Service Business segment has continued growth potential, as Nuvo has the in-house capabilities and capacity to produce Pennsaid 2% and Resultz for new license partners.









### **Licensing and Royalty Business**

The Licensing and Royalty Business segment includes the revenue generated from the licensing of the intellectual property and the ongoing royalties received under these exclusive licensing agreements. The Company's Licensing and Royalty revenue is primarily generated from:

- Net sales of Vimovo in the U.S. through the Company's partner Horizon (See *Risk Factors* below);
- Net sales of Vimovo in various ex-U.S. markets, including Europe, Canada and South America by the Company's partner Grunenthal GmbH (Grunenthal); and
- Net sales of Resultz in select European markets by the Company's various European license partners (see table below for full details).

The Company's out-licensing efforts for Pennsaid 2%, Resultz, Suvexx and Yosprala are targeted on all markets that remain unlicensed with a particular focus on Europe, the U.S., the Middle East and Asia. The Company enters into exclusive, long-term licensing agreements with strategic partners in specific geographies. Nuvo believes its Licensing and Royalty Business segment has continued growth potential, as Pennsaid 2%, Resultz and Suvexx products are protected by patents that provide licensees with market exclusivity and protection from generic competition, as well as favourable product profiles (See *Commercial Products* below).

The Company's approved products related to the Production and Service Business and Licensing and Royalty Business are segmented as follows:

Product	Description	Segments	Licensee or Distributor	Territories
<b>Resultz</b>	Pesticide-free topical treatment of head lice infestations.	Production and Service Business Licensing and Royalty Business	Fagron Belgium NV Heumann Pharma GmbH & Co. Generica KG Reckitt Benckiser (Brands) Limited Sato Pharmaceutical Co., Ltd.	
<b>Treximet</b> <small>sumatriptan / naproxen sodium</small>	Treatment of acute migraine	Licensing and Royalty Business	Currax Holdings USA LLC <sup>(1)</sup>	
<b>PENNSAID</b> <sup>®</sup> <small>(diclofenac sodium topical solution) 2% w/w</small>	Topical treatment of osteoarthritic pain in a more convenient format.	Production and Service Business Licensing and Royalty Business	Horizon Therapeutics plc Paladin Labs Inc. Sayre Therapeutics PVT Ltd Gebro Pharma AG	
<b>PENNSAID</b>	Topical treatment of osteoarthritic pain.	Production and Service Business Licensing and Royalty Business	Paladin Labs Inc. Vianex S.A. Recordati S.p.A.	
<b>VIMOVO</b> <sup>®</sup>	Oral treatment for relief of arthritis symptoms with a reduced risk of developing gastric ulcers.	Licensing and Royalty Business	Horizon Therapeutics plc Grunenthal GmbH	
<b>SYNERA</b> <sup>™</sup> <small>(lidocaine and tetracaine) Topical Patch</small> <b>RAPYDAN</b>	Topical patch used to help prevent pain associated with needle sticks and other superficial skin procedures.	Licensing and Royalty Business Production and Service Business	Galen US Incorporated Eurocept International B.V.	
<b>Yosprala</b> <sup>™</sup> <small>(aspirin and omeprazole)</small>	Once daily treatment to help in the prevention of heart attacks and strokes with a reduced risk of developing gastric ulcers.	Licensing and Royalty Business	Genus Lifesciences Inc. Takeda Pharmaceutical Company Limited	
<b>URACYST</b> <sup>®</sup>	Instillation for the treatment of mild to severe GAG layer damage of the urinary bladder.	Licensing and Royalty Business	Aspire Pharmaceuticals	

<sup>(1)</sup> Pernix Ireland Ltd. assets were acquired by Currax Holdings USA LLC in April 2019.

## Growth Strategy

The Company intends to further expand its Canadian and international businesses through continued organic growth of existing products, targeted in-licensing and acquisition opportunities, which leverage the Company's in-house commercial, scientific and manufacturing infrastructure and out-licensing of distribution rights for Nuvo's proprietary products - Pennsaid 2%, Resultz, Suvexx and Yosprala in global markets and the launch of Suvexx in Canada. The Company will continue to build on its commercial presence in Canada and will look to utilize a network of license and distribution partners for its products in global markets. The Company targets global and regional pharmaceutical companies that have therapeutic area expertise and established commercial infrastructure as potential license and distribution partners.

To achieve its strategic objectives, the Company will leverage its competitive advantages through its in-house capabilities:

- Attracting, developing, pursuing and consummating transactions to in-license or acquire accretive, growth-oriented products;
- Creating intellectual property portfolios that provide defense against generic threats;
- Launching new products in Canada;
- Managing complex relationships with regulators to register new products in Canada, the U.S., Europe and other global markets; and
- Developing innovative processes to enhance the quality and efficiency of manufacturing operations.

## Commercial Products

### Products Commercialized by Nuvo

#### **Blexten**

Blexten is a second-generation antihistamine drug for the symptomatic relief of allergic rhinitis and chronic spontaneous urticaria. Blexten exerts its effect through its highly selective inhibition of peripheral histamine H1 receptors and has an efficacy comparable to cetirizine and desloratadine. In comparative studies, Blexten demonstrated somnolence rates similar to placebo representing a potentially non-sedating effect at therapeutic doses. It was developed in Spain by Faes Farma, S.A. (Faes). Bilastine, (the active ingredient in Blexten), is approved in Canada and over 100 countries worldwide, including Japan and most European countries. In 2014, Aralez Canada entered into an exclusive license and supply agreement with Faes for the exclusive right to sell bilastine in Canada, which is sold under the brand name Blexten. The exclusive license is inclusive of prescription and non-prescription rights for Blexten, as well as adult and pediatric presentations in Canada.

In April 2016, Health Canada approved Blexten (bilastine 20 mg oral tablet) for the treatment of the symptoms of seasonal allergic rhinitis and chronic spontaneous urticaria (such as itchiness and hives). Blexten was commercially launched in Canada in December 2016. Aralez Canada will owe additional milestone payments of approximately \$1.9 million to Faes if certain sales targets or other milestone events are achieved over the life of the license and supply agreement term.

#### **Cambia**

Cambia, (diclofenac potassium for oral solution), is a patent protected, nonsteroidal anti-inflammatory drug (NSAID) and is currently the only prescription NSAID approved and available in Canada for the acute treatment of migraine with or without aura in adults 18 years of age or older. In 2010, Aralez Canada signed a license agreement with Nautilus Neurosciences, Inc. (Nautilus) for the exclusive rights to develop, register, promote, manufacture, use, distribute, market and sell Cambia in Canada. Since 2011, three separate amendments to the license agreement have been executed. The license was assigned by Nautilus to Depomed, Inc. (Depomed) in December 2013. Depomed has subsequently been renamed Assertio Therapeutics Inc. The Company pays a tiered royalty on net sales of Cambia and future sales-based milestone payments of up to \$6.8 million may be payable over time.

Cambia was approved by Health Canada in March 2012 and was commercially launched to specialists in Canada in October 2012 and broadly to all primary care physicians in February 2013.

#### **Resultz**

Resultz is a patent protected commercial-stage, non-prescription product intended to kill head lice and remove their eggs from hair with as little as a 5-minute treatment. It is a pesticide-free, topical solution that contains only two common cosmetic ingredients - 50% isopropyl myristate and 50% cyclomethicone D5. It is clinically proven to achieve 100% effectiveness when used as directed. Resultz is currently manufactured by the Company's contract manufacturing partner in Europe.

#### Canada

As a result of the acquisition of Aralez Canada, the Company reacquired the exclusive rights to distribute, market and sell Resultz in Canada. Resultz is sold as a non-prescription drug in Canada.

## **Suvexx**

Suvexx, (sumatriptan/naproxen sodium), is a patent protected migraine medicine that was developed by the Aralez Pharmaceuticals Inc. (Aralez) wholly owned subsidiary POZEN, Inc. (POZEN) in collaboration with GSK. The product is formulated with POZEN's patented technology (now owned by Nuvo) of combining a triptan, sumatriptan 85 mg, with an NSAID, naproxen sodium 500 mg and GSK's RT Technology in a single tablet. The Company anticipates receiving Health Canada approval in the first quarter of 2020 with an expected commercial launch in Q3 2020.

## **Other Commercialized Products in Canada**

The Company also markets: Bezalip<sup>®</sup> SR<sup>1</sup>, Durela<sup>®2</sup>, Proferrin<sup>®1</sup>, Fiorinal<sup>®2</sup>, Fiorinal<sup>®</sup> C<sup>2</sup>, Viskazide<sup>®1</sup>, Visken<sup>®1</sup>, Collatamp<sup>®</sup> G<sup>1</sup>, PegaLAX<sup>®1</sup>, Mutaflor<sup>®1</sup>, MoviPrep<sup>®1</sup>, NeoVisc<sup>®1</sup>, Uracyst<sup>®1</sup> and Soriatane<sup>™1</sup>.

1. Promoted products in Canada
2. Products are available in Canada and not promoted in any capacity

## **Fiorinal**

On October 30, 2019, Aralez Canada received an amended application for authorization to institute a class action against a group of 34 defendants, including Aralez Canada, that manufacture, market, and/or distribute opioids in Québec. The claim is for \$30,000, plus interest for compensatory damages for each class member, \$25.0 million from each defendant for punitive damages and pecuniary damages for each class member. The proposed class is all natural persons in Québec who have been prescribed and consumed any one or more of the opioids manufactured, marketed, distributed and/or sold by the defendants between 1996 and the present day and who suffer or have suffered from opioid use disorder. The proposed class includes any direct heirs of any deceased persons who met the above-description and excludes certain persons subject to a prior settlement agreement. The amended application is currently pending before the Superior Court in the Province of Québec. The Company has never promoted or made any claims outside of the approved Health Canada label and believes that the claim is without merit and intends to vigorously defend the matter.

## **Products Out-licensed and/or Manufactured by Nuvo**

### **Pennsaid 2%**

Pennsaid 2% is a follow-on product to original Pennsaid (described below). Pennsaid 2% is a topical pain product that combines a dimethyl sulfoxide (DMSO) based transdermal carrier with 2% diclofenac sodium, a leading NSAID, compared to 1.5% for original Pennsaid. Pennsaid 2% is more viscous, 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 potential advantages over Pennsaid and other competitor products and with patent protection. Nuvo owns the worldwide rights to Pennsaid 2%, excluding the U.S., which is owned by Horizon.

### **Pennsaid 2%**

#### *Pennsaid 2% - United States*

Pennsaid 2% was approved on January 16, 2014 in the U.S. and launched by Mallinckrodt Inc. (Mallinckrodt) in February 2014 for the treatment of pain of osteoarthritis (OA) of the knee. 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. In October 2014, Nuvo sold the U.S. rights to Pennsaid 2% to Horizon for US\$45.0 million. Under the terms of this agreement, the Company earns revenue from the manufacturing and sale of Pennsaid 2% to Horizon.

Nuvo records revenue from Horizon when it ships Pennsaid 2% commercial bottles and product samples to Horizon for the U.S. market. The Company earns product revenue from Horizon pursuant to a long-term, exclusive supply agreement, as well as contract service revenue.

#### *Pennsaid 2% - Rest of World*

Gebro Pharma has the exclusive rights to register, distribute, market and sell Pennsaid 2% in Switzerland and Liechtenstein. In January 2020, Gebro Pharma received marketing authorization for Pennsaid 2% from Swissmedic, the overseeing Swiss regulatory authority. The Company and Gebro Pharma are finalizing commercialization plans and anticipate the commercial launch of Pennsaid 2% in Switzerland before the end of 2020. The Company is eligible to receive milestone payments and royalties on net sales of Pennsaid 2% in Switzerland and Liechtenstein and will earn product revenue from the supply of Pennsaid 2% to Gebro Pharma on an exclusive basis from its manufacturing facility in Varennes, Québec.

Sayre Therapeutics PVT Ltd (Sayre Therapeutics) has the exclusive rights to distribute, market and sell Pennsaid 2% in India, Sri Lanka, Bangladesh and Nepal. Sayre Therapeutics filed their application for regulatory approval with the Drug Controller General of India in December 2017. In September 2019, the Company received notice that the Drug Controller General of India had approved the sale of Pennsaid 2% as a prescription medication. The Company anticipates the commercial launch of Pennsaid 2% in India during the second half of 2020. The Company is eligible to receive milestone payments and royalties on net sales of Pennsaid 2% in India, Sri Lanka, Bangladesh and Nepal and will earn product revenue from the supply of Pennsaid 2% to Sayre Therapeutics on an exclusive basis from its manufacturing facility in Varennes, Québec.

In November 2019, the Company terminated the license agreement with NovaMedica LLC (NovaMedica), due to changing market conditions which made a Pennsaid 2% launch in the territory no longer commercially viable. NovaMedica had exclusive rights to sell and market Pennsaid 2% and Pennsaid in Russia and some of the Commonwealth of Independent States.

Paladin Labs Inc. (Paladin) has exclusive rights to market and sell Pennsaid 2% in Canada. In November 2014, the Company reacquired from Paladin the rights to market Pennsaid 2% in South America, Central America, South Africa and Israel. As consideration for these rights, Nuvo provided its authorization to Paladin to distribute, market and sell an authorized generic version of Pennsaid in Canada. Pennsaid 2% has not been approved or commercially launched in any of these territories.

#### Pennsaid 2% - Unlicensed Territories

The Company intends to pursue Pennsaid 2% registrations in select European territories that will accept the existing clinical and technical data package. The Company has submitted its regulatory dossier for Pennsaid 2% to the Austrian Agency for Health and Food Safety acting as the Reference Member State (RMS). As part of this decentralized procedure, Nuvo has also submitted its Pennsaid 2% dossier to the Concerned Member States (CMS) of Greece and Portugal.

#### **Pennsaid**

Pennsaid, the Company's first commercialized topical pain product, is used to treat the signs and symptoms of OA of the knee. Pennsaid is a combination of a DMSO-based transdermal carrier and 1.5% diclofenac sodium and delivers the active drug through the skin at the site of pain. While conventional oral NSAIDs expose patients to potentially serious systemic side effects such as gastrointestinal bleeding and cardiovascular risks, Nuvo's clinical trials suggest that some of these systemic side effects occur less frequently with topically applied Pennsaid.

#### **Resultz**

##### United States

The Company acquired the U.S. product and intellectual property rights from Piedmont in January 2018. Resultz was cleared as a Class I medical device by the FDA in May 2017 and has not yet been commercially launched in the U.S.

##### Rest of World (excluding the U.S. and Canada)

The Company acquired the global, ex-U.S. product and intellectual property rights from Piedmont in December 2017. Resultz is approved and marketed in France, Spain, Portugal, Belgium, Netherlands, Germany, Ireland, the United Kingdom, Russia and Australia through a network of existing license agreements and global licensees which include Reckitt Benckiser, Fagron Belgium NV (Fagron) and Heumann Pharma GmbH & Co. (Heumann). Resultz is also pending registration in Japan, where the local license is held by Sato Pharmaceutical Co. Ltd. Resultz is a CE marked, Class I medical device, which does not require a prescription. The Company recognized a contingent and variable consideration related to the ex-U.S. acquisition of Resultz for \$2.8 million as at December 31, 2019.

Fagron has the exclusive rights to register, distribute, market and sell Resultz in Belgium, the Netherlands and Luxembourg (BeNeLux) as a Class I medical device for the human treatment of head lice infestation. Resultz is already cleared for marketing in BeNeLux. Nuvo Ireland received upfront consideration, is eligible to receive royalties on net sales of Resultz in BeNeLux and will earn revenue from Fagron pursuant to an exclusive supply agreement. Fagron launched Resultz in BeNeLux in the second half of 2018. Resultz is currently manufactured by the Company's contract manufacturing partner in Europe. Nuvo Ireland immediately began to earn royalty revenue under this agreement with Fagron.

Heumann has the exclusive rights to distribute, market and sell Resultz in Germany. Resultz is considered a Class I medical device in Germany. Nuvo Ireland received upfront consideration, is eligible to receive milestone payments and royalties on net sales of Resultz in Germany and will earn revenue from Heumann pursuant to an exclusive supply agreement. Heumann has now placed orders for commercial quantities of Resultz and will launch Resultz in Germany during the first half of 2020. Resultz is currently manufactured by the Company's contract manufacturing partner in Europe.

### **Vimovo**

Vimovo (naproxen/esomeprazole magnesium) is the brand name for a proprietary fixed-dose combination of enteric-coated naproxen, a pain-relieving NSAID, and immediate-release esomeprazole magnesium, a proton pump inhibitor, in a single delayed-release tablet. POZEN developed Vimovo in collaboration with AstraZeneca. On April 30, 2010, the FDA approved Vimovo for the relief of the signs and symptoms of OA, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers. Vimovo is currently commercialized in the U.S. by Horizon and by Grunenthal in various rest of world territories, including Canada, Europe and select additional countries.

#### Rest of World (excluding the U.S)

Grunenthal holds the rights to commercialize Vimovo outside of the U.S. and Japan and pays Nuvo Ireland a 10% royalty on net sales. Grunenthal's royalty payment obligation with respect to Vimovo expires on a country-by-country basis upon the later of (a) expiration of the last-to-expire of certain patent rights related to Vimovo in that country, and (b) ten years after the first commercial sale of Vimovo in such country. The royalty rate may be reduced to the mid-single digits in the event of a loss of market share as a result of certain competing products. Canada is the only country where a generic naproxen/esomeprazole magnesium product has been approved and commercialized dating back to 2017, prior to the Company purchasing this royalty stream.

#### United States

Under the terms of the license agreement with Horizon, Nuvo Ireland receives a 10% royalty on net sales of Vimovo sold in the U.S., with guaranteed minimum annual royalty payments of US\$7.5 million. The minimum annual royalty payments are applicable for each calendar year that certain patents which cover Vimovo are in effect and certain types of competing products are not on the market in the U.S. Horizon's royalty payment obligation with respect to Vimovo expires on the later of (a) the last to expire of certain patents covering Vimovo, and (b) ten years after the first commercial sale of Vimovo in the U.S. If, and when, a competitor generic version of Vimovo enters the U.S. market, Nuvo will continue to receive a 10% royalty on net sales of Vimovo by its U.S. partner, subject to a step-down provision in the event that generic competition achieves a certain market share. When the Company acquired the Vimovo patents as part of the Aralez Transaction, the Company anticipated that the US\$7.5 million annual minimum royalty payments would cease in 2022.

Currently, there is active patent litigation in the U.S. against Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. (collectively, Dr. Reddy's) and Ajanta Pharma Ltd. and Ajanta Pharma USA, Inc. (collectively, Ajanta). In February 2018, Nuvo Ireland entered into an amendment to its license agreement with Horizon for Vimovo in the U.S. that allows Horizon to settle such litigation without Nuvo Ireland's consent in certain circumstances. Horizon and Nuvo Ireland reached litigation settlements with three other generic companies: (i) Teva Pharmaceuticals Industries Limited (formerly known as Actavis Laboratories FL, Inc., which itself was formerly known as Watson Laboratories, Inc. - Florida) and Actavis Pharma, Inc. (collectively, Actavis Pharma) (ii) Lupin; and (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, Mylan). Under the settlement agreements, the license entry date is August 1, 2024; however, all three may be able to enter the market earlier in certain circumstances.

In May 2019, the Court of Appeals reversed a decision made in June 2017 by the United States District Court for the District of New Jersey (New Jersey District Court). As a result, the '907 and the '285 patent owned by Nuvo Ireland and licensed to Horizon covering Vimovo in the U.S were found to be invalid. On June 15, 2019, Nuvo Ireland and Horizon filed an *en banc* request to the Court of Appeals seeking to have the court reconsider the May 2019 decision. On July 30, 2019, the Court of Appeals denied the request to reconsider their decision invalidating the two patents. Nuvo Ireland and Horizon filed a petition to the Supreme Court of the United States in October 2019 to request to have the decision of the Court of Appeals reconsidered. The Supreme Court denied that petition on January 13, 2020. On February 18, 2020, Dr. Reddy's second-filed ANDA for Vimovo in the U.S. received FDA



approval and the Company anticipates a generic version of Vimovo could launch in the U.S. during 2020. It is the Company's understanding that Dr. Reddy's does not have the benefit of 180-days of exclusivity, and, consequently, other generic companies may obtain final FDA approval for a generic version of Vimovo and be able to market the product in the U.S. If, and when, a competitor generic version of Vimovo enters the U.S. market, Nuvo will continue to receive a 10% royalty on net sales of Vimovo by its U.S. partner, subject to a step-down provision in the event that generic competition achieves a certain market share. Nuvo's US\$7.5 million minimum annual royalty due for Vimovo net sales in the U.S. will cease with the launch of a generic Vimovo in the U.S.

Nuvo Ireland has other valid patents to protect Vimovo in the U.S. and there is ongoing patent litigation against Dr. Reddy's with respect to the '996 patent and the '920 patent. As a result, in the event that Dr. Reddy's launches a generic Vimovo in the U.S. prior to the expiration of these other patents, their launch would be considered an "at risk" launch. If Nuvo Ireland's other patents are found by the New Jersey Court to be valid and infringed as a result of the ongoing litigation, Nuvo Ireland and Horizon could seek damages from Dr. Reddy's.

Dr. Reddy's filed a motion for Summary Judgement in the New Jersey District Court in August 2019 asserting that the '996 patent and the '920 patent are invalid as a result of the decision of the Court of Appeals that invalidated the '907 patent and the '285 patent. The New Jersey District Court denied this motion in November 2019, and the litigation against Dr. Reddy's involving the '996 patent and '920 patent continued.

Nuvo Ireland and its partner filed a motion for a preliminary injunction in the New Jersey District Court in November 2019 requesting that Dr. Reddy's be preliminarily enjoined from infringing the '996 patent and '920 patent. In December 2019, the New Jersey District Court denied this motion. Nuvo and Horizon moved for reconsideration of the decision and the Court denied this motion on February 4, 2020.

Nuvo Ireland's revenues from sales of Vimovo outside of the U.S. are unaffected by any ruling made by the U.S. courts.

#### **Suvexx/Treximet**

Suvexx/Treximet (sumatriptan/naproxen sodium) is a migraine medicine that was developed by the Aralez Pharmaceuticals Inc. (Aralez) wholly owned subsidiary POZEN, Inc. (POZEN) in collaboration with GSK. The product is formulated with POZEN's patented technology (now owned by Nuvo) of combining a triptan, sumatriptan 85 mg, with an NSAID, naproxen sodium 500 mg and GSK's RT Technology in a single tablet. In 2008, the FDA approved Treximet (the U.S. brand name) for the acute treatment of migraine attacks, with or without aura, in adults. Treximet is currently commercialized in the U.S. by Currax Holdings USA LLC.




#### **Yosprala**

Yosprala is currently the only prescription fixed-dose combination of aspirin (acetylsalicylic acid), an anti-platelet agent, and omeprazole, a proton-pump inhibitor, in the U.S. It is indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers. Yosprala is designed to support both cardio- and gastro-protection for at-risk patients through the proprietary Intelli-COAT system, which is formulated to sequentially deliver immediate-release omeprazole (40 mg) followed by a delayed-release, enteric-coated aspirin core in either 81 mg or 325 mg dose strengths. Yosprala was approved by the FDA in September 2016 and was commercially launched in the U.S. in October 2016. Yosprala is currently commercialized in the U.S. by Genus Lifesciences Inc. (Genus). The Company will receive a low single-digit royalty on net sales in the U.S. by Genus until July 2023.

#### **The Heated Lidocaine/Tetracaine Patch**

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

## Product Pipeline

Products	Phase 2	Phase 3	Regulatory Submission Preparation	Regulatory Submission	Marketed
Suvexx					
Blexten Pediatric					
Blexten Ophthalmic					

### Suvexx

Pursuant to the Aralez Transaction, the Company acquired the global rights to Suvexx. On May 3, 2019, the Suvexx registration dossier passed screening with Health Canada and is now under formal review. The Company anticipates receiving Health Canada approval in the first quarter of 2020 with an expected commercial launch in Q3 2020. Suvexx is a patent protected, fixed dose combination of naproxen sodium and sumatriptan. Suvexx was originally developed by GSK and Aralez (POZEN) and is currently sold in the U.S. as Treximet.

### Blexten Pediatric

Aralez Canada's original license agreement for Blexten included Canadian rights for the pediatric dosage formats. Blexten pediatric consists of an oral syrup formulation (2.5mg/ml) and an orally dispersible tablet formulation (10mg tablets). Aralez Canada anticipates filing the pediatric dossier to Health Canada during the first half of 2020 with a regulatory decision anticipated by mid-2021.

### Blexten Ophthalmic

In April 2018, Aralez executed an amendment to add an ophthalmic formulation of Blexten, currently under development, to the portfolio. The ophthalmic version of Blexten provides physicians the ability to treat patients suffering from ocular symptoms such as itchy, watery or red eyes related to seasonal allergies with a highly effective, non-drowsy and long-lasting formulation. The Company is examining the dossier for its suitability for filing a New Drug Submission for Blexten ophthalmic with Health Canada.

### NeoVisc Line Extension

In January 2020, Nuvo closed a licensing transaction bringing a new line extension to the NeoVisc Canadian business. NeoVisc is an injectable viscosupplement used by orthopedic surgeons, sports medicine physicians and healthcare practitioners to replenish synovial fluid in the joints of patients with osteoarthritis. NeoVisc One contains the lowest injection volume (only 4ml) available for single-dose viscosupplements in Canada. The reduction of injection volume makes administration of NeoVisc One easier for healthcare professionals and more comfortable for patients. Subject to receiving Health Canada approval, we anticipate launching the new and improved NeoVisc format during Q2 2020.

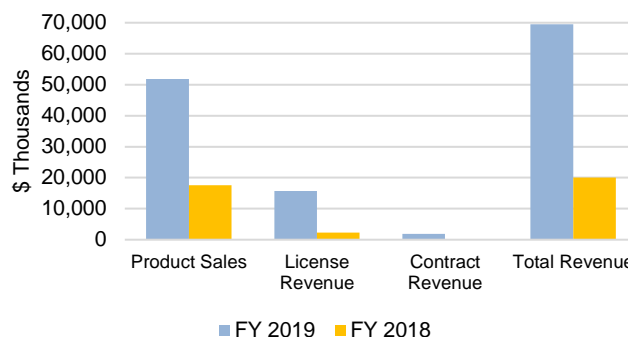
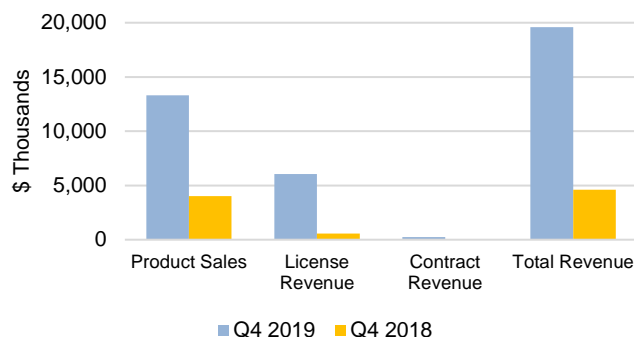
## Selected Financial Information

	Year ended December 31, 2019	Year ended December 31, 2018
in thousands, except per share data	\$	\$
<b>Operations</b>		
Product sales	51,884	17,569
License revenue	15,758	2,262
Contract revenue	1,904	167
<b>Total Revenue</b>	<b>69,546</b>	19,998
Cost of goods sold	26,472	8,638
<b>Gross profit</b>	<b>43,074</b>	11,360
<b>Total operating expenses</b>	<b>46,297</b>	18,195
Other income	(6,612)	(495)
<b>Income (loss) before income taxes</b>	<b>3,389</b>	(6,340)
Income tax expense (recovery)	28	(187)
<b>Net income (loss)</b>	<b>3,361</b>	(6,153)
Other comprehensive income (loss)	(432)	370
<b>Total comprehensive income (loss)</b>	<b>2,929</b>	(5,783)
<b>Share Information</b>		
Net income (loss) per common share		
- basic	0.30	(0.54)
- diluted	(0.51)	(0.54)

<b>Non-IFRS Measures<sup>(1)</sup></b>		
in thousands, except per share data	\$	\$
Adjusted EBITDA per common share	2.39	(0.27)
- basic		
Average number of common shares outstanding		
- basic	11,388	11,443
<b>Adjusted total revenue</b>	<b>74,724</b>	20,473
<b>Adjusted EBITDA</b>	<b>27,242</b>	(3,104)

<sup>(1)</sup> Adjusted EBITDA, adjusted total revenue and adjusted EBITDA per common share are Non-IFRS measures. See *Non-IFRS Measures* above for a reconciliation of non-IFRS measures to IFRS.

## Results of Operations



Total revenue is comprised of product sales, license revenue and contract revenue. Total revenue was \$69.5 million for the year ended December 31, 2019 compared to \$20.0 million for the year ended December 31, 2018. The significant increase in total revenue for the current year was primarily attributable to incremental revenue resulting from the Aralez Transaction.

Product sales, which represent the Company's sales to wholesalers, licensees and distributors, were \$51.9 million for the year ended December 31, 2019 compared to \$17.6 million for the year ended December 31, 2018.

License revenue was \$15.8 million for the year ended December 31, 2019 compared to \$2.3 million for the year ended December 31, 2018. The Company receives license revenue from its exclusive licensing agreements with global partners related to net sales of Vimovo, Resultz, Pennsaid, the HLT Patch, Yosprala and Treximet in certain territories. The Company acquired the Vimovo, Yosprala and Treximet royalty streams as part of the Aralez Transaction.

Contract revenue is mainly derived from ad hoc service agreements for testing, development and related quality assurance/quality control services provided by the Company. During the first half of 2019, the Company's subsidiary, Nuvo Ireland provided transition services to two companies.

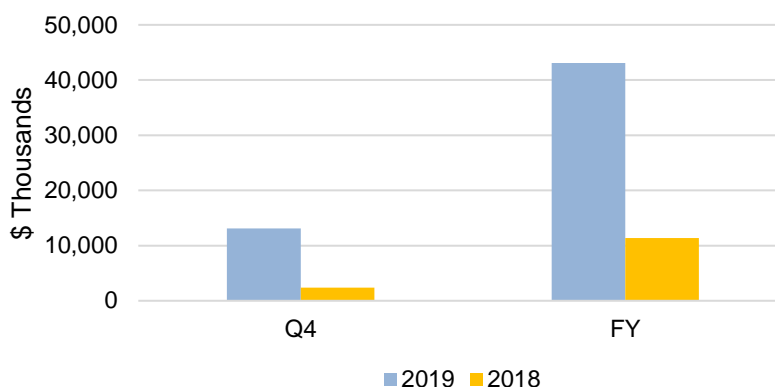
Adjusted total revenue increased to \$74.7 million for the year ended December 31, 2019 compared to \$20.5 million for the year ended December 31, 2018. Adjusted total revenue is a non-IFRS measure (See *Non-IFRS Financial Measures* above).

### Cost of Goods Sold

Cost of goods sold (COGS) for the year ended December 31, 2019 was \$26.5 million compared to \$8.6 million for the year ended December 31, 2018. The increase in COGS in the current year was primarily attributable to the addition of product sales as a result of the Aralez Transaction. COGS for the year ended December 31, 2019, included \$5.0 million of inventory step-up expense for the sale of inventory that was acquired by the Company as part of the Aralez Transaction.

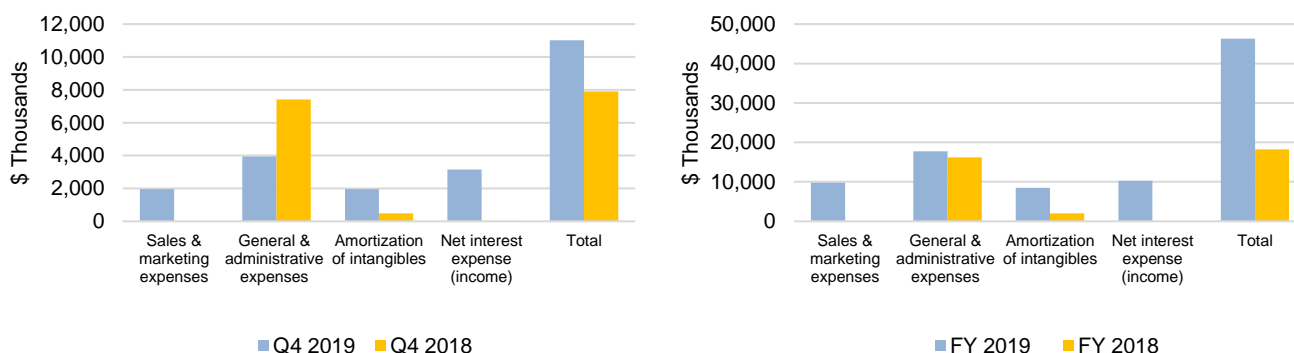
Gross margin on product sales for the year ended December 31, 2019 was \$25.4 million or 49% compared to \$8.9 million or 51% for the year ended December 31, 2018.

## Gross Profit



Gross profit on total revenue was \$43.1 million or 62% for the year ended December 31, 2019 compared to a gross profit of \$11.4 million or 57% for the year ended December 31, 2018. The increase in gross profit for the current year was primarily attributable to an increase in gross margin on product sales and an increase in license revenue as a result of the Aralez Transaction.

## Operating Expenses



Total operating expenses includes sales and marketing expenses, G&A expenses, amortization of intangibles and net interest expense. Total operating expenses for the year ended December 31, 2019 were \$46.3 million, an increase from \$18.2 million for the year ended December 31, 2018. The significant increase in operating expenses for the current year related to incremental operating expenses from the Aralez Transaction. The Company also incurred \$1.5 million of one-time integration expenses and \$1.1 million of one-time restructuring expenses in the current year. As a result of the June 2019 restructuring, the Company reduced its operating expenses by \$7.0 million annually.

### Sales and Marketing

The Company incurred \$9.8 million in expenses for sales and marketing for the year ended December 31, 2019 compared to \$nil for the year ended December 31, 2018. The Company acquired commercial infrastructure as part of the Aralez Transaction. Sales and marketing expenses relate to the Company's dedicated commercial efforts to promote Blexten, Cambia and the Canadian business for Resultz (See *Operating Segments* above).

### General and Administrative

G&A expenses were \$17.8 million for the year ended December 31, 2019 compared to \$16.2 million for the year ended December 31, 2018. In the current year, the G&A expenses increased due to incremental activities related to the Company's Aralez Canada and Nuvo Ireland subsidiaries, as well as an increase in information technology, finance and legal head office costs as a result of the integration of the Aralez Transaction. The Company incurred

\$1.5 million of one-time integration expenses during the year ended December 31, 2019. In the comparative year, the Company incurred \$7.7 million in legal and diligence transaction costs related to the Aralez transaction.

### Amortization of Intangibles

For the year ended December 31, 2019, the Company recognized non-cash costs of \$8.4 million for amortization of intangibles compared to \$2.0 million in the comparative year. In the current year, amortization related to the license and patents acquired in the Aralez Transaction, as well as the Resultz patents. In the comparative year, amortization of intangibles related exclusively to the Company's Resultz patents.

### Net Interest Expense (Income)

Net interest expense for the year ended December 31, 2019 was \$10.3 million compared to net interest income of \$32,000 for the year ended December 31, 2018.

The Company's Bridge Loan, Amortization Loan and Convertible Loan, all components of the Deerfield Financing, are carried at amortized cost with effective interest rates of 9.70%, 10.20% and 10.22%, respectively. For the year ended December 31, 2019, the Company recognized \$12.8 million of interest expense on financial instruments measured at amortized cost, which was partially offset by \$2.3 million of accreted interest income on contract assets and \$0.2 million of interest income on cash held in the Company's bank accounts.

The Deerfield Financing requires the Company to make quarterly interest payments on outstanding loans. The coupon rates for the Company's Bridge Loan, Amortization Loan and Convertible Loan are 12.5%, 3.5% and 3.5%, respectively. During the year ended December 31, 2019, the Company made payments of \$6.2 million to Deerfield for interest due under the Deerfield Financing.

### Other Expenses

	Year ended December 31, 2019	Year ended December 31, 2018
in thousands	\$	\$
Change in fair value of derivative liabilities (gain)	<b>(31,070)</b>	-
Change in fair value of contingent and variable consideration (gain)	<b>1,216</b>	(518)
Impairment	<b>23,780</b>	-
Loss on disposal of contract assets	-	452
Foreign currency gain	<b>(2,598)</b>	(429)
Other losses	<b>2,060</b>	-
<b>Total other income</b>	<b>(6,612)</b>	(495)

The Company holds two derivative liabilities related to the Deerfield Financing - the conversion feature embedded in the Convertible Loan and the Warrants. These derivative liabilities are measured at fair value at each reporting period. As a result of the decrease in the share price in the current year, combined with a reduction in the risk-free interest rate, the value of the Company's derivative liabilities decreased and the Company recognized a net non-cash \$31.1 million recovery on the change in fair value of derivative liabilities for the year ended December 31, 2019. During the year ended December 31, 2019, the Company recognized a \$0.3 million gain on foreign exchange related to the conversion feature [\$nil for the year ended December 31, 2018].

During the year ended December 31, 2019, the Company recognized a loss of \$1.2 million on the change in fair value of contingent and variable consideration compared to a gain of \$0.5 million for the fair value remeasurement of the Company's contingent and variable consideration for the year ended December 31, 2018. The Company reassesses the value of contingent consideration related to Resultz and Yosprala at each reporting period. The ex-U.S. Resultz acquisition included contingent consideration related to meeting certain milestones in partnered markets, payable only if those targets are achieved, as well as variable consideration based on annual royalties earned in the non-partnered markets. The Company recognized a contingent and variable consideration related to the ex-U.S. acquisition of Resultz for \$2.8 million as at December 31, 2019. The Yosprala purchase agreement included contingent consideration in the form of 50% of the lifetime net earnings from monetization of the Yosprala product. In the year ended December 31, 2019, the Yosprala contingent consideration was reduced as the result of a change in estimates.

The Company's contract assets are subject to estimation regarding the likelihood of the minimum guaranteed sales-based royalties. In July 2019, the Company received notice that the Court of Appeals had denied the Company's and Horizon's request to reconsider the May 2019 decision with respect to the validity of the Vimovo '907 patent and the '285 patent in the U.S. In October, a petition to the Supreme Court of the United States was filed to request to have the decision of the Court of Appeals reconsidered. The Supreme Court denied that petition on January 13, 2020. On February 18, 2020, Dr. Reddy's second-filed ANDA for Vimovo in the U.S. received FDA approval and the Company anticipates a generic version of Vimovo could launch in the U.S. during 2020. It is the Company's understanding that Dr. Reddy's does not have the benefit of 180-days of exclusivity, and, consequently, other generic companies may obtain final FDA approval for a generic version of Vimovo and be able to market the product in the U.S. If, and when, a competitor generic version of Vimovo enters the U.S. market, Nuvo will continue to receive a 10% royalty on net sales of Vimovo by its U.S. partner, subject to a step-down provision in the event that generic competition achieves a certain market share. Nuvo's US\$7.5 million minimum annual royalty due for Vimovo net sales in the U.S. will cease with the launch of a generic Vimovo in the U.S. (See *Commercial Products* above). At June 30, 2019, the Company wrote off its contract asset attributable to its Vimovo U.S. royalty and on June 30, 2019 recognized a \$23.6 million impairment charge of which \$22.4 million was reversed from the related contract asset balance with the remainder recorded as an increase in liabilities. This increase in liabilities was subsequently reversed as a generic version of Vimovo did not launch in the U.S. in 2019.

During the year ended December 31, 2019, the Company recognized other losses of \$2.1 million, primarily related to the modification of the long-term debt of \$2.2 million. The Company agreed to an amendment to the financing agreement dated June 25, 2019, to provide, among other things, for a payment deferral mechanism in the event that Vimovo U.S. market exclusivity is lost. The amendment allows the Company to defer a portion of the mandatory minimum quarterly principal repayments by the difference between one quarter of the existing US\$7.5 million minimum annual royalty due from Vimovo sales in the U.S. and the actual amount of royalties received in the applicable quarter in the event Vimovo U.S. market exclusivity is lost earlier than had been expected (2022) prior to the Court of Appeals decision. The amount of any principal repayment deferred would, until repaid in accordance with the amendment, be subject to an interest rate of 12.5% per annum. As a result of this amendment, for the year ended December 31, 2019, the Amortization Loan and Bridge Loan were revalued and a loss of \$2.2 million was recorded due to both modification of debt and changes in the assumptions regarding the timing of the payments.

### Foreign Currency

During the year ended December 31, 2019, the Company recognized a foreign currency gain of \$2.6 million compared to a foreign currency gain of \$0.4 million during the year ended December 31, 2018. In the current year, the strengthening of the Canadian dollar against the U.S. dollar decreased the carrying value of the Company's long-term debt.

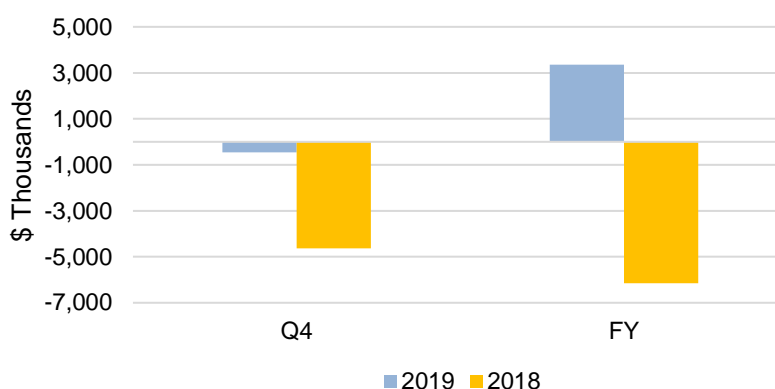
### Net Income (Loss) and Total Comprehensive Income (Loss)

	Year ended December 31, 2019	Year ended December 31, 2018
in thousands	\$	\$
Net income (loss) before income taxes	3,389	(6,340)
Income tax expense (recovery)	28	(187)
Net income (loss)	3,361	(6,153)
Unrealized gain (loss) on translation of foreign operations	(432)	370
<b>Total comprehensive income (loss)</b>	<b>2,929</b>	<b>(5,783)</b>

### Income Tax Expense (Recovery)

For the year ended December 31, 2019, the Company recognized an income tax expense of \$28,000 compared to an income tax recovery of \$0.2 million for the year ended December 31, 2018.

## Net Income (Loss)



Net income for the year ended December 31, 2019 was \$3.4 million compared to a net loss of \$6.2 million for the year ended December 31, 2018. In the current year, the Company's \$31.7 million increase in gross profit and \$6.1 million increase in other income was offset by a \$28.1 million increase in total operating expenses. The increase in other income related primarily to the change in fair value of derivative liabilities as a result of the decrease in the share price in the period, offset by the Vimovo contract asset impairment.

## Total Comprehensive Income (Loss)

Total comprehensive income was \$2.9 million for the year ended December 31, 2019 compared to a total comprehensive loss of \$5.8 million for the year ended December 31, 2018. The current year included unrealized losses of \$0.4 million on the translation of foreign operations compared to \$0.4 million of unrealized gains in the comparative year.

## Net Income (Loss) Per Common Share

	Year ended December 31, 2019	Year ended December 31, 2018
share figures in thousands	\$	\$
<b>Net income (loss) from per common share</b>		
- basic	<b>0.30</b>	(0.54)
- diluted	<b>(0.51)</b>	(0.54)
<b>Average number of common shares outstanding (in thousands)</b>		
- basic	<b>11,388</b>	11,443
- diluted	<b>43,457</b>	11,443

Net income per common share was \$0.30 for the year ended December 31, 2019 compared to a net loss per common share of \$0.54 for the year ended December 31, 2018. On a diluted basis, net loss per common share was \$0.51 for the year ended December 31, 2019 compared to net loss per common share of \$0.54 for the year ended December 31, 2018.

The Company's weighted average number of common shares outstanding on a basic basis was 11.4 million for the years ended December 31, 2019 and December 31, 2018.

The weighted average number of common shares outstanding on a diluted basis was 43.5 million for the year ended December 31, 2019 and 11.4 million for year ended December 31, 2018. As at December 31, 2019, the dilutive impact of the warrants and convertible debt increased the weighted average number of common shares outstanding by 32.1 million. As at December 31, 2018, there were no potentially dilutive instruments in a dilutive position.



## Operating Segments

IFRS 8 - *Operating Segments* (IFRS 8) requires operating segments to be determined based on internal reports that are regularly reviewed by the chief operating decision maker for the purpose of allocating resources to the segment and to assessing its performance. Pursuant to the Aralez Transaction, the Company determined that the operating segments structure reviewed by the chief operating decision maker required adjustment. For the year ended December 31, 2019, the Company had three operating segments: Commercial Business, Production and Service Business and Licensing and Royalty Business. During the year ended December 31, 2018, the Company operated as one segment: pharmaceutical and healthcare products. The Company modified this disclosure on a retrospective basis.

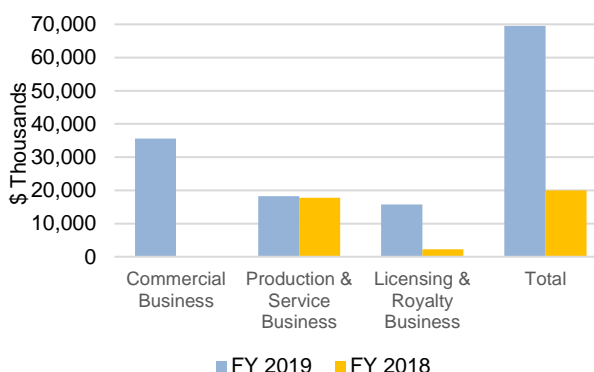
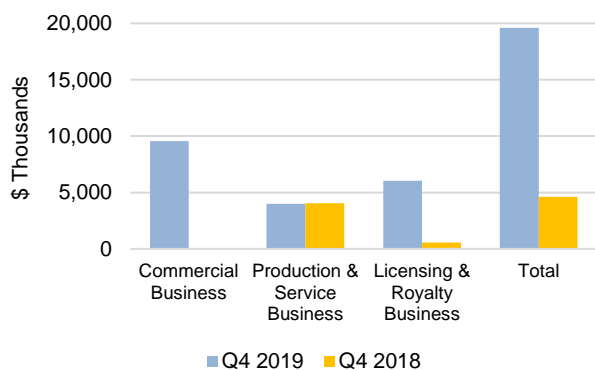
### Operating Segments

The Commercial Business segment is comprised of products commercialized by the Company in Canada. This includes products with dedicated promotional efforts – Blexten, Cambia and the Canadian business for Resultz, as well as 14 mature products sold by Aralez Canada.

The Production and Service Business segment includes: revenue from the sale of products manufactured by or contracted by Nuvo from its manufacturing facility in Varennes, Québec or its international headquarters in Dublin, Ireland, as well as service revenue for testing, development and related quality assurance/quality control services provided by the Company. Key revenue streams in this segment include: Pennsaid 2%, Pennsaid and the bulk drug product for the HLT Patch, as well as transition services provided by Nuvo Ireland to two companies.

The Licensing and Royalty Business segment includes: the revenue generated by the licensing of intellectual property and ongoing royalties from exclusive licensing agreements with global partners. Key revenue streams in this segment include royalties from the Company’s Vimovo, Resultz and HLT Patch license agreements.

**Total Revenue by Operating Segment**



## Selected Segmented Financial Information

### Commercial Business

	Year ended December 31, 2019	Year ended December 31, 2018	Change
in thousands	\$	\$	\$
Revenue	35,578	-	35,578
Cost of Sales	17,860	-	17,860
<b>Gross profit</b>	<b>17,718</b>	-	<b>17,718</b>
<b>Gross profit %</b>	<b>50%</b>	-	<b>50%</b>

During the year ended December 31, 2019, the Company's Commercial Business segment contributed \$35.6 million or 51% of the Company's total revenue [\$nil for the year ended December 31, 2018] and \$17.7 million or 41% of the Company's gross profit [\$nil for the year ended December 31, 2018]. COGS for the year ended December 31, 2019 included \$5.0 million of inventory step-up expense. The products in the Commercial Business segment were acquired pursuant to the Aralez Transaction. As a result, there are no comparable figures for the year ended December 31, 2018.

### Production and Service Business

	Year ended December 31, 2019	Year ended December 31, 2018	Change
in thousands	\$	\$	\$
Revenue	18,210	17,736	474
Cost of Sales	8,612	8,638	(26)
<b>Gross profit</b>	<b>9,598</b>	<b>9,098</b>	<b>500</b>
<b>Gross profit %</b>	<b>53%</b>	<b>51%</b>	<b>2%</b>

During the year ended December 31, 2019, the Company's Production and Service Business segment contributed \$18.2 million or 26% of the Company's total revenue [\$17.7 million or 89% for the year ended December 31, 2018] and \$9.6 million or 22% of the Company's gross profit [\$9.1 million or 80% for the year ended December 31, 2018]. The increase in the Production and Service Business segment revenue during the year ended December 31, 2019 was attributable to an increase in contract revenue for transition services, provided by Nuvo Ireland, to two companies, partially offset by a decrease in the Company's Pennsaid product sales.

### Licensing and Royalty Business

	Year ended December 31, 2019	Year ended December 31, 2018	Change
in thousands	\$	\$	\$
Revenue	15,758	2,262	13,496
Cost of Sales	-	-	-
<b>Gross profit</b>	<b>15,758</b>	<b>2,262</b>	<b>13,496</b>
<b>Gross profit %</b>	<b>-</b>	<b>-</b>	<b>-</b>

During the year ended December 31, 2019, the Company's Licensing and Royalty Business segment contributed \$15.8 million or 23% of the Company's total revenue [\$2.3 million or 11% for the year ended December 31, 2018] and \$15.8 million or 37% of the Company's gross profit [\$2.3 million or 20% for the year ended December 31, 2018]. The increase in the Licensing and Royalty Business segment revenue for the year ended December 31, 2019 was attributable to the Aralez Transaction. During the year ended December 31, 2019, the Company recognized an incremental \$13.8 million related to the Vimovo royalty.

## Financial Position

	As at December 31, 2019	As at December 31, 2018
in thousands	\$	\$
<b>Financial Position</b>		
Working capital	14,423	(2,171)
Contract assets	402	26,752
Long-lived assets	114,988	127,875
Right-of-use assets	573	-
Long-term debt (including current portion)	123,377	124,207
Other obligations (including current portion)	3,408	1,672
Derivative liabilities	2,229	33,646
Total equity	24,092	20,706

### Working Capital

The Company defines the working capital above as total current assets (excluding cash and contract assets), less accounts payable and accrued liabilities and current income tax liabilities. The \$16.6 million increase in working capital during the year ended December 31, 2019 was primarily due to the following factors:

- Accounts receivable increased \$9.4 million, primarily related to new royalties receivable from the Company's Vimovo licensing partners and as a result of timing of revenue.
- Inventory decreased \$5.8 million due to a \$5.0 million release of inventory step-up expense from inventory to COGS as inventory related to the Aralez Transaction was sold, as well as a decrease of \$0.8 million related to timing of purchases.
- Accounts payable and accrued liabilities decreased by \$14.1 million, primarily due to i) \$10.0 million as a result of the Company settling indebtedness acquired with the Aralez Transaction, and ii) \$2.5 million for the settlement of the working capital adjustment related to the purchase price of the Aralez Transaction and the settlement of transaction costs accrued at December 31, 2018.

### Contract Assets

Contract assets represent the present value of current and future guaranteed minimum sales-based royalties, upfront fees and milestone payments that are expected to be received over the life of the licensing agreements. Contract asset balances are reduced as the contractual minimums are realized throughout the life of the agreement. No new agreements were entered into during the year ended December 31, 2019.

The Company's contract assets are subject to estimation regarding the likelihood of the minimum guaranteed sales-based royalties. In July 2019, the Company received notice that the Court of Appeals had denied the Company's and Horizon's request to reconsider the May 2019 decision with respect to the validity of the Vimovo '907 patent and the '285 patent in the U.S. In October, a petition to the Supreme Court of the United States was filed to request to have the decision of the Court of Appeals reconsidered. The Supreme Court denied that petition on January 13, 2020. On February 18, 2020, Dr. Reddy's second-filed ANDA for Vimovo in the U.S. received FDA approval and the Company anticipates a generic version of Vimovo could launch in the U.S. during 2020. It is the Company's understanding that Dr. Reddy's does not have the benefit of 180-days of exclusivity, and, consequently, other generic companies may obtain final FDA approval for a generic version of Vimovo and be able to market the product in the U.S. If, and when, a competitor generic version of Vimovo enters the U.S. market, Nuvo will continue to receive a 10% royalty on net sales of Vimovo by its U.S. partner, subject to a step-down provision in the event that generic competition achieves a certain market share. Nuvo's US\$7.5 million minimum annual royalty due for Vimovo net sales in the U.S. will cease with the launch of a generic Vimovo in the U.S. (See *Commercial Products* above). At June 30, 2019, the Company wrote off its contract asset attributable to its Vimovo U.S. royalty and on June 30, 2019 recognized a \$23.6 million impairment charge of which \$22.4 million was reversed from the related contract asset balance with the remainder recorded as an increase in liabilities. This increase in liabilities was subsequently reversed as a generic version of Vimovo did not launch in 2019.

### **Long-lived Assets**

Long-lived assets consist of property, plant and equipment, intangible assets and goodwill. The \$12.9 million decrease for the year ended December 31, 2019 was primarily related to \$8.4 million of intangible asset amortization, \$1.0 million of property, plant and equipment amortization, \$2.0 million due to foreign exchange translation and \$1.4 million due to impairment charges.

### **Right-of-use Assets**

Right-of-use assets consist of leased assets, which under IFRS 16 - *Leases* (IFRS 16), are accounted for as a right-of-use asset with a corresponding lease liability. The Company adopted IFRS 16 on January 1, 2019.

### **Long-term Debt**

Long-term debt includes the long-term carrying values of the Company's Bridge Loan, Amortization Loan and Convertible Loan. No new loan facilities were entered into during the year ended December 31, 2019. As payments are made, and interest is accreted, the net impact reduces the long-term debt balance over time.

The Company has agreed to an amendment to the financing agreement dated June 25, 2019, to provide, among other things, for a payment deferral mechanism in the event that Vimovo U.S. market exclusivity is lost. The amendment allows the Company to defer a portion of the mandatory minimum quarterly principal repayments by the difference between one quarter of the existing US\$7.5 million minimum annual royalty due from Vimovo sales in the U.S. and the actual amount of royalties received in the applicable quarter in the event Vimovo U.S. market exclusivity is lost earlier than had been expected (2022) prior to the Court of Appeals decision. The amount of any principal repayment deferred would, until repaid in accordance with the amendment, be subject to an interest rate of 12.5% per annum.

During the year ended December 31, 2019, the Company made a \$3.4 million payment towards its Bridge Loan. In January 2020, the Company repaid its US\$6.0 million Bridge Loan.

### **Derivative liabilities**

The Company's derivative liabilities include the conversion feature embedded in the Convertible Loan and the Warrants. No conversions or Warrant exercises occurred during the year ended December 31, 2019. These derivative liabilities are measured at fair value at each reporting period, which increase as the Company's share price increases and interest rates decrease. As a result of the decrease in the share price in the current year, combined with a reduction in the risk-free interest rate and foreign exchange movements, the value of the Company's derivative liabilities decreased by \$31.4 million.

### **Fluctuations in Operating Results**

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 product sales to the Company's customers, licensees and distributors, the timing and amount of royalties, milestones and other payments made or received pursuant to current and future licensing arrangements, interest costs associated with servicing the Deerfield Financing, revaluation of derivative liabilities and fluctuations in foreign exchange rates.

On December 31, 2018, the Company completed the Aralez Transaction including a portfolio of over 20 revenue-generating products, a commercial infrastructure and the Deerfield Financing. There are no comparable figures for this business for the year ended December 31, 2018.

## Liquidity and Capital Resources

	Year ended December 31, 2019	Year ended December 31, 2018
	\$	\$
in thousands		
Net income (loss)	3,361	(6,153)
Items not involving current cash flows	13,071	(1,423)
Cash provided (used in) by operations	16,432	(7,576)
Net change in non-cash working capital	(14,069)	4,061
Cash provided by (used in) operating activities	2,363	(3,515)
Cash used in investing activities	(2,630)	(138,647)
Cash provided by (used in) financing activities	(3,743)	161,031
Effect of exchange rates on cash	(1,045)	807
Net change in cash during the year	(5,055)	19,676
Cash and cash equivalents, beginning of the year	28,074	8,398
<b>Cash and cash equivalents, end of the year</b>	<b>23,019</b>	<b>28,074</b>

### Cash and cash equivalents

Cash and cash equivalents were \$23.0 million as at December 31, 2019 compared to \$28.1 million as at December 31, 2018.

### Cash Provided by (Used in) Operations

Cash provided by operations was \$16.4 million for the year ended December 31, 2019 compared to cash used in operations of \$7.6 million for the year ended December 31, 2018.

### Cash Provided by Operating Activities

Cash provided by operating activities was \$2.4 million for the year ended December 31, 2019 compared to cash used in operating activities of \$3.5 million for the comparative year.

In the current year, the \$14.1 million investment in non-cash working capital was primarily attributable to a \$11.7 million decrease in accounts payable and accrued liabilities, as the Company settled indebtedness acquired with the Aralez Transaction and transaction costs that were accrued at December 31, 2018, a \$9.0 million increase in accounts receivable, primarily due to new royalty receivables from the Company's Vimovo licensing partners, slightly offset by a \$0.1 million decrease in current income tax liabilities, offset by a \$0.5 million decrease in inventories, a \$5.0 million decrease in contract assets and a \$1.2 million decrease in prepaid expenses and other assets.

### Investing Activities

Net cash used in investing activities was \$2.6 million for the year ended December 31, 2019 compared to net cash used in investing activities of \$138.6 million for year ended December 31, 2018. In the current year, the Company paid \$2.5 million to settle the working capital adjustment related to the final purchase price for the Aralez Transaction and \$0.1 million for property, plant and equipment additions at the Company's manufacturing facility.

### Financing Activities

Net cash used in financing activities was \$3.7 million for the year ended December 31, 2019 compared to net cash provided by financing activities of \$161.0 million for the year ended December 31, 2018. During the year ended December 31, 2019, the Company repaid \$3.4 million of debt to Deerfield and paid \$0.4 million as cash payments for lease liabilities. In the current year, the adoption of IFRS 16 resulted in certain leases being recorded as a right-of-use asset and a corresponding lease liability. Previously, these assets were accounted for as operating leases and the expense was included in cash provided by operating activities. In the comparative year, the Company's payments of \$138.5 million and \$1.9 million for the Aralez Transaction and Resultz U.S. Acquisition were slightly offset by \$2.0 million provided from the disposal of the Company's short-term investments.

## Capital Structure

The Company's stated strategy is to expand its Canadian and international business through targeted in-licensing and acquisition opportunities. To execute this strategy, the Company may need to access the additional capacity under its senior secured term loan facility or seek alternate sources of financing.

## Selected Quarterly Information

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

	Q4 2019	Q3 2019	Q2 2019	Q1 2019	Q4 2018	Q3 2018	Q2 2018	Q1 2018
in thousands, except per share data	\$	\$	\$	\$	\$	\$	\$	\$
Product sales	13,317	14,102	13,235	11,230	4,009	4,456	5,349	3,755
License revenue	6,043	4,646	2,655	2,414	558	592	472	640
Contract revenue	233	75	690	906	40	37	54	36
Sales and marketing expenses	1,968	1,955	3,043	2,830	-	-	-	-
General and administrative expenses	3,941	3,584	5,125	5,190	7,441	4,517	1,862	2,418
Net income (loss)	(456)	4,425	6,796	(7,404)	(4,631)	(2,407)	1,054	(169)
Net income (loss) per common share								
- basic	0.30	0.39	0.60	(0.65)	(0.41)	(0.21)	0.09	(0.01)

Non-IFRS Measures	Q4 2019	Q3 2019	Q2 2019	Q1 2019	Q4 2018	Q3 2018	Q2 2018	Q1 2018
Adjusted total revenue	19,644	18,889	19,078	17,112	4,753	5,176	6,034	4,524
Adjusted EBITDA	8,570	7,784	5,663	5,225	(4,528)	(1,276)	2,088	612
Adjusted EBTIDA per common share								
- basic	0.75	0.68	0.50	0.46	(0.39)	(0.11)	0.18	0.05

## Fourth Quarter Results

	Three months ended December 31, 2019	Three months ended December 31, 2018
in thousands	\$	\$
Product sales	13,317	4,009
License revenue	6,043	558
Contract revenue	233	40
<b>Total revenue</b>	<b>19,593</b>	<b>4,607</b>
Cost of goods sold	6,499	2,201
<b>Gross profit</b>	<b>13,094</b>	<b>2,406</b>
Sales and marketing	1,968	-
General and administrative expenses	3,941	7,410
Amortization of intangibles	1,967	488
Net interest expense (income)	3,142	5
<b>Total operating expenses</b>	<b>11,018</b>	<b>7,903</b>
Other income	2,503	(802)
Income tax expense (recovery)	29	(64)
<b>Net loss</b>	<b>(456)</b>	<b>(4,631)</b>
Other comprehensive income (loss)	414	420
<b>Total comprehensive loss</b>	<b>(42)</b>	<b>(4,211)</b>

## Operating Results

Total revenue for the three months ended December 31, 2019 was \$19.6 million compared to \$4.6 million for the three months ended December 31, 2018. The significant increase in revenue for the current quarter was primarily attributable to the addition of revenue as a result of the Aralez Transaction.

Total operating expenses for the three months ended December 31, 2019 increased to \$11.0 million compared to \$7.9 million for the three months ended December 31, 2018. The increase in operating expenses for the current quarter is related to incremental operating expenses from the Aralez Transaction.

COGS for the three months ended December 31, 2019 was \$6.5 million compared to \$2.2 million for the three months ended December 31, 2018. The increase in COGS in the current quarter was primarily attributable to the addition of product sales as a result of the Aralez Transaction and COGS included \$0.9 million of inventory step-up expense for the sale of inventory that was acquired by the Company as part of the Aralez Transaction.

The Company incurred \$2.0 million in expenses for sales and marketing activities during the three months ended December 31, 2019 compared to \$nil for the comparative three-month period. The Company acquired commercial infrastructure as part of the Aralez Transaction. Sales and marketing expenses related to the Company's dedicated commercial efforts to promote Blexten, Cambia and the Canadian business for Resultz (See *Operating Segments* above).

G&A expenses decreased to \$3.9 million for the three months ended December 31, 2019 compared to \$7.4 million for the three months ended December 31, 2018. In the current quarter, G&A expenses increased due to incremental activities related to the Company's Aralez Canada and Nuvo Ireland subsidiaries, as well as an increase in information technology, finance and legal head office costs as a result of the Aralez Transaction. In the comparative three-month period, the Company incurred one-time transaction fees of \$5.0 million related to the Aralez Transaction.

Net interest expense was \$3.1 million for the three months ended December 31, 2019 compared to net interest income of \$5,000 for the three months ended December 31, 2018. The Company's Bridge Loan, Amortization Loan and Convertible Loan, all components of the Deerfield Financing, are carried at amortized cost with effective interest rates of 9.70, 10.20% and 10.22%, respectively. For the three months ended December 31, 2019, the Company recognized \$3.2 million of interest expense on financial instruments measured at amortized cost, which was partially offset by \$0.1 million of interest income for cash held in the Company's bank accounts.

Other expenses (income) primarily consists of the change in fair value of derivative liabilities due to the decrease in the share price in the current quarter, contract asset impairment related to the impairment of the Vimovo minimum annual royalty, intangible asset impairment, change in fair value of contingent and variable consideration and net foreign currency gains or losses in both the current and comparative quarters, which will vary based on fluctuations in foreign currency rates.

Net loss was \$0.5 million for the three months ended December 31, 2019 compared to a net loss of \$4.6 million for the three months ended December 31, 2018. The decrease in net loss was primarily related to an increase in gross profit due to the Aralez Transaction.

## Liquidity

	Three months ended December 31, 2019	Three months ended December 31, 2018
in thousands	\$	\$
Net income (loss)	(456)	(4,631)
Items not involving current cash flows	7,470	(4,005)
Cash provided by operations	7,014	(8,636)
Net change in non-cash working capital	1,275	2,973
Cash provided by (used in) operating activities	8,289	(5,663)
Cash used in investing activities	(7)	(132,795)
Cash (used in) provided by financing activities	(3,356)	161,693
	4,926	23,235
Effect of exchange rates on cash	(378)	751
Net change in cash	4,548	23,986
Cash and cash equivalents, beginning of period	18,471	4,088
<b>Cash and cash equivalents, end of period</b>	<b>23,019</b>	<b>28,074</b>

Cash was \$23.0 million as at December 31, 2019, a decrease of \$5.1 million compared to \$28.1 million as at December 31, 2018. In the current quarter, an increase in cash provided by operating activities was offset by an increase in cash used for financing activities.

Cash provided by operating activities was \$8.3 million for the three months ended December 31, 2019 compared to cash used in operating activities of \$5.7 million for the three months ended December 31, 2018. In the current quarter, \$8.3 million of cash was provided by operating activities and a \$1.3 million recovery in non-cash working capital.

Net cash used in investing activities was \$7,000 for the three months ended December 31, 2019 compared to net cash used in investing activities of \$132.8 million for the three months ended December 31, 2018. In the comparative quarter, the Company paid \$138.5 million for the Aralez Transaction.

Net cash used in financing activities was \$3.4 million for the three months ended December 31, 2019 compared to net cash provided by financing activities of \$161.7 million for the three months ended December 31, 2018. In the current quarter, the Company made a \$3.4 million principal repayment towards its Bridge Loan and paid \$0.1 million of cash to settle lease liabilities.

## FINANCIAL INSTRUMENTS

IFRS 7 - *Financial Instruments: Disclosures* requires disclosure of a three-level hierarchy that reflects the significance of the inputs used in making fair value measurements. All assets and liabilities for which fair value is measured or disclosed in the Consolidated Financial Statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 - Unadjusted quoted prices at the measurement date for identical assets or liabilities in active markets
- Level 2 - Observable inputs other than quoted prices in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data
- Level 3 - Significant unobservable inputs that are supported by little or no market activity

The Company reviews the fair value hierarchy classification on a quarterly basis. Changes to the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy. The



Company did not have any transfer of assets and liabilities between Level 1, Level 2 and Level 3 of the fair value hierarchy during the year ended December 31, 2019.

As at December 31, 2019, the Company's financial instruments consisted of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities, contingent and variable consideration, long-term debt and derivative liabilities. The Company has determined the estimated fair values of its financial instruments based on appropriate valuation methodologies. However, considerable judgment is required to develop these estimates. Accordingly, these estimated values are not necessarily indicative of the amounts the Company could realize in a current market exchange. The estimated fair value amounts can be materially affected by the use of different assumptions or methodologies.

The Company's cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities are measured at amortized cost and their fair values approximate carrying values. Cash and cash equivalents are Level 1, while the other short-term financial instruments are Level 3.

The fair values of the Company's Amortization Loan, Bridge Loan and host liability of the Convertible Loan are Level 3 measurements determined using a discounted cash flow model that considers the present value of the contractual cash flows using a risk-adjusted discount rate. The Company recognized \$123.4 million for the Amortization Loan, Bridge Loan and host liability of the Convertible Loan as at December 31, 2019 [December 31, 2018 - \$124.2 million].

The conversion feature that accompanies the Company's Convertible Loan is considered a Level 3 liability. The value is determined as the difference between the fair value of the hybrid Convertible Loan contract, determined using an income approach with a binomial lattice model and the fair value of the host liability contract, determined using a discounted cash flow model. The Company recognized \$0.8 million for the conversion feature as at December 31, 2019 [December 31, 2018 - \$14.5 million].

The fair values of the prepayment option that allows the Company to make prepayments against the Bridge Loan or Amortization Loan at any time is considered a Level 3 financial instrument. The fair value of the prepayment option bifurcated from the term loan was a derivative asset with a nominal value as at December 31, 2019 and is presented net of the non-current portion of the long-term debt. The fair value of this option was determined using a binomial-lattice model.

The fair value of the Company's Warrants is revalued at each reporting period using the Black-Scholes option pricing model. As at December 31, 2019, the Company recognized a \$1.4 million derivative liability related to outstanding Warrants [December 31, 2018 - \$19.1 million]. These Warrants are Level 3.

Level 3 liabilities include the fair value of contingent and variable consideration related to the acquisition of the ex-U.S. rights to Resultz and the Aralez Transaction.

## **FINANCIAL RISK MANAGEMENT**

### **Financial Instruments at Amortized Cost**

For year ended December 31, 2019, the Company recognized \$0.2 million in interest income from financial assets held at amortized cost [December 31, 2018 - \$39].

For year ended December 31, 2019, the Company recognized \$12.8 million in interest expense from financial liabilities held at amortized cost [December 31, 2018 - \$nil].

### **Credit Risk**

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 and contract assets are subject to normal industry risks in each geographic region in which the Company operates. 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.

Pursuant to the Aralez Transaction, the Company has expanded its customer base primarily in Canada with well-established wholesale and retail pharmacy chains. Management does not expect the expanded customer base will have a significant impact on the Company's credit risk assessment.

As at December 31, 2019, the Company's largest customer represented 49% [December 31, 2018 - 47%] of accounts receivable. Pursuant to their collective terms, accounts receivable, net of allowance, were aged as follows:

n thousands	December 31, 2019 \$	December 31, 2018 \$
Current	9,064	4,052
0 - 30 days past due	777	571
31 - 60 days past due	60	84
Over 60 days past due <sup>(i)</sup>	4,486	250
	<b>14,387</b>	<b>4,957</b>

<sup>(i)</sup> The Company collected \$3.7 million of receivables over 60 days past due subsequent to December 31, 2019. The remainder is withholding tax receivable.

The loss allowance provision for the Production and Service Business segment as at December 31, 2019 was determined using reference to expected loss rates and management judgment as follows:

in thousands		Current	Less than 181 days past due	181 to 270 days past due	271 to 365 days past due	More than 365 days past due	Total
Expected loss rate	%	0%	0%	25%	50%	100%	
Gross carrying amount	\$	2,099	281	-	-	-	2,380

The loss allowance provision for the Licensing and Royalty Business and Commercial Business segment as at December 31, 2019 was determined using reference to expected loss rates and management judgment as follows:

n thousands		Current	Less than 61 days past due	61 to 120 days past due	121 to 180 days past due	More than 181 days past due	Total
Expected loss rate	%	0%	0%	25%	50%	100%	
Gross carrying amount	\$	7,040	5,166	47	-	77	12,330
Loss allowance provision	\$	(74)	(144)	(46)	-	(59)	(323)

During the year ended December 31, 2019, the Company recorded bad debt reversal of \$0.1 million in total comprehensive income (loss) [December 31, 2018 - \$nil]. For the year ended December 31, 2019, the impairment of accounts receivable was assessed based on the incurred loss model. Individual receivables that were known to be uncollectible were written off by reducing the carrying amount directly.

For contract assets within the scope of IFRS 15, the Company recognizes an asset to the extent contractual minimums established in certain customer licensing agreements are deemed fixed consideration. After analysis of historical default rates and forward-looking estimates, the Company's contract assets were considered to have low credit risk, and as a result, the Company has not recognized a loss allowance as at December 31, 2019 [December 31, 2018 - \$nil].

The Company's cash and cash equivalents subject the Company to a concentration of credit risk. As at December 31, 2019, the Company had \$23.0 million deposited with three financial institutions in various bank accounts. These financial institutions are major banks, including one in Canada, one in the U.S. and one in Ireland, which the Company believes lessens the degree of credit risk. All of these financial institutions are considered to have low credit risk and, therefore, the provision recognized during the current period was limited to 12 months of expected losses. The Company has not recognized a loss allowance as at December 31, 2019 [December 31, 2018 - \$nil].

## Risk Factors

The following is a discussion of liquidity risk and market risk and related mitigation strategies that have been identified. Credit risk has been discussed in the Company's assessment of impairment under IFRS 9. This is not an exhaustive list of all risks nor will the mitigation strategies eliminate all risks listed.

## Liquidity Risk

Liquidity risk is the risk that the Company will encounter difficulties in meeting its financial obligations as they become due.

As at December 31, 2019, the Company's financial liabilities had undiscounted contractual maturities (including interest payments where applicable) as summarized below:

in thousands	Total \$	Current	Non-current		
		Within 12 Months \$	1 to 2 Years \$	2 to 5 Years \$	> 5 years \$
Accounts payable and accrued liabilities	9,678	9,678	-	-	-
Other obligations	5,160	398	2,898	1,864	-
Senior secured Amortization Loan	93,925	14,548	23,899	55,478	-
Senior secured Bridge Loan <sup>(i)</sup>	4,504	4,504	-	-	-
Senior secured Convertible Loan	80,120	2,387	4,773	72,960	-
	<b>193,387</b>	<b>31,515</b>	<b>31,570</b>	<b>130,302</b>	<b>-</b>

<sup>(i)</sup> Subsequent to December 31, 2019, the Bridge Loan was repaid in its entirety.

The Company's ability to satisfy its debt obligations will depend principally upon its future operating performance. The Company's inability to generate sufficient cash flows to satisfy its debt service obligations or to refinance its obligations on commercially reasonable terms could have a materially adverse impact on the Company's business, financial condition or operating results.

The Deerfield Facility Agreement contains customary representations and warranties and affirmative and negative covenants, including, among other things, an annual financial covenant based on minimum levels of net sales per fiscal year and a mandatory quarterly repayment requirement under the Amortization Loan and the Bridge Loan equal to the greater of (i) 50% of excess cash flows (as defined in the Deerfield Facility Agreement) for such quarter, and (ii) US\$2.5 million, commencing with the quarter ended March 31, 2019, provided that, solely with respect to the first four fiscal quarters after the closing date, the US\$2.5 million quarterly minimum is not applicable as long as US\$10.0 million in principal repayments have been made over such four fiscal quarters. The Company agreed to an amendment to the financing agreement dated June 25, 2019, to provide, among other things, for a payment deferral mechanism in the event that Vimovo U.S. market exclusivity is lost. The amendment allows the Company to defer a portion of the mandatory minimum quarterly principal repayments by the difference between one quarter of the existing US\$7.5 million minimum annual royalty due from Vimovo sales in the U.S. and the actual amount of royalties received in the applicable quarter in the event Vimovo U.S. market exclusivity is lost earlier than had been expected (2022) prior to the Court of Appeals decision. The amount of any deferred principal repayment would, until repaid in accordance with the amendment, be subject to an interest rate of 12.5% per annum. As a result of this amendment, for the year ended December 31, 2019, the Amortization Loan and Bridge Loan were revalued and a loss of \$2.2 million was recorded due to both modification of debt and changes in the assumptions regarding the timing of the payments.

The Company anticipates that its current cash of \$23.0 million as at December 31, 2019, together with the cash flows generated from operations, will be sufficient to execute its current business plan for the next 12 months and will meet its current debt obligations.

## Interest Rate Risk

The Company's policy is to minimize interest rate cash flow risk exposures on its long-term financing. The Company's loans and borrowings and lease obligations are at fixed interest rates.

The fair value of the Company's prepayment option on the Amortization Loan and Bridge Loan and the Company's derivative liabilities are impacted by market rate changes.

## Currency Risk

The Company operates globally, which gives rise to a risk that income and cash flows may be adversely affected by fluctuations in foreign currency exchange rates. The Company is primarily exposed to the U.S. dollar, euro and British Pound (GBP), 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:

	U.S. Dollar		Euro		British Pound	
	December 31, 2019	December 31, 2018	December 31, 2019	December 31, 2018	December 31, 2019	December 31, 2018
in thousands	\$	\$	€	€	£	£
Cash	7,565	15,051	630	755	619	-
Accounts receivable	8,960	1,332	319	581	37	-
Contract assets	-	19,170	-	-	234	-
Loans and borrowings	(94,976)	(93,869)	-	-	-	-
Derivative liabilities	(644)	(10,654)	-	-	-	-
Accounts payable and accrued liabilities	(405)	(6,063)	(785)	(405)	(22)	-
Other obligations	(1,456)	(942)	(1,010)	(244)	-	-
	<b>(80,956)</b>	<b>(75,975)</b>	<b>(846)</b>	687	<b>868</b>	-

Based on the aforementioned net exposure as at December 31, 2019, 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 \$10.5 million on total comprehensive income (loss), a 10% appreciation or depreciation of the Canadian dollar against the euro would have an effect of \$123 on total comprehensive income (loss) and a 10% appreciation or depreciation of the Canadian dollar against the GBP would have an effect of \$149 on total comprehensive income (loss).

In terms of the U.S. dollar, the Company has five significant exposures: its U.S. dollar-denominated cash held in its Canadian operations, its U.S. dollar-denominated loans and borrowings and derivative liabilities held in its Canadian and European operations, its net investment and net cash flows in its European operations, the cost of purchasing raw materials either priced in U.S. dollars or sourced from U.S. suppliers and payments made to the Company under its U.S. dollar-denominated licensing arrangements.

The Company does not currently hedge its U.S. dollar cash flows. The Company funds its U.S. dollar-denominated interest expense and loan obligations using the Company's U.S. dollar-denominated cash and cash equivalents and payments received under the terms of the licensing and supply agreements. 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.

In terms of the euro, the Company has three significant exposures: its euro-denominated cash held in its Canadian operations, sales of Pennsaid by the Canadian operations to European distributors and the cost of purchasing raw materials priced in euros.

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 day-to-day expenses of the Nuvo Ireland 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.

In terms of the GBP, the Company has three significant exposures: its euro-denominated cash held in its Canadian operations and euro operations, the cost of purchasing raw materials or services priced in GBP and payments

made to the Company under its GBP-denominated licensing arrangements, and minimum royalties received and accounted for as a contract asset in GBP.

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

### Market Risk

The Company's derivative liabilities - the Warrants and conversion feature that accompanies the Company's Convertible Loan, are impacted by a variety of valuation inputs, including changes in the Company's share price. As at December 31, 2019, a \$1.00 increase in the Company's share price would increase the value of the Warrants by \$9.0 million and an increase to the conversion feature of \$5.7 million, with a corresponding loss of \$14.7 million recognized in income for the change in fair value of derivative liabilities. As at December 31, 2019, a \$2.00 increase in the Company's share price would increase the value of the Warrants by \$14.8 million and increase the value of the conversion feature by \$9.3 million, with a corresponding loss of \$24.1 million recognized in income for change in fair value of derivative liabilities.

## Contractual Obligations

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

	2020	2021	2022	2023	2024	2025 and thereafter	Total
in thousands	\$	\$	\$	\$	\$	\$	\$
Finance lease obligations	268	195	116	116	--	-	<b>696</b>
Deerfield Financing <sup>(1)</sup>	21,439	12,887	15,786	18,790	109,648	-	<b>178,549</b>
Purchase commitments	3,064	2,583	3,975	3,504	4,252	-	<b>17,377</b>
Other obligations <sup>(2)</sup>	619	1,391	2,265	1,200	1,299	-	<b>6,774</b>
	<b>25,389</b>	<b>17,056</b>	<b>22,142</b>	<b>23,610</b>	<b>115,199</b>	-	<b>203,396</b>

<sup>(1)</sup> Included in the Deerfield Financing is the Convertible Loan in the principal amount of US\$52.5 million, initially convertible into 19,444,444 common shares of the Company at a conversion price of US\$2.70.

<sup>(2)</sup> Other obligations include accounts payable and accrued liabilities and contingent and variable consideration.

### The Deerfield Financing

On December 31, 2018, the Company and Nuvo Ireland, as borrowers, and Aralez Canada, as guarantor, entered into the Deerfield Financing. The Deerfield Facility Agreement contains a quarterly repayment requirement under the Amortization Loan and the Bridge Loan equal to the greater of (i) 50% of excess cash flow (as defined in the Deerfield Facility Agreement) for such quarter, and (ii) US\$2.5 million, commencing with the quarter ended March 31, 2019, provided that, solely with respect to the first four fiscal quarters after the closing date, the US\$2.5 million quarterly minimum is not applicable so long as US\$10.0 million in principal repayments have been made over such four fiscal quarters. The mandatory quarterly principal repayments are first applied to the Bridge Loan, which is at a higher interest rate than the Amortization Loan.

On June 25, 2019, the Company agreed to an amendment to the Deerfield Facility Agreement, to provide, among other things, for a payment deferral mechanism in the event that Vimovo U.S. market exclusivity is lost (See *Commercial Products* above) and an extension of the maturity date in respect of the Company's US\$6.0 million Bridge Loan by 6 months to December 31, 2020. The amendment allows the Company to defer a portion of the mandatory minimum quarterly principal repayments by the difference between one quarter of the existing US\$7.5 million minimum annual royalty due from Vimovo sales in the U.S. and the actual amount of royalties received in the applicable quarter in the event Vimovo U.S. market exclusivity is lost. The amount of any prepayment deferred would, until repaid in accordance with the amendment, be subject to an interest rate of 12.5% per annum. As a result of this amendment, for the year ended December 31, 2019, the Amortization Loan and Bridge Loan were

revalued and a loss of \$2.2 million was recorded due to both modification of debt and changes in the assumptions regarding the timing of the payments.

## Litigation

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

On October 30, 2019, the Company received an application for an industry-wide class action in the Superior Court of Québec. In the application, the Company was named as a defendant, along with 33 other defendants, which includes a group of companies that manufacture, market, and/or distribute opioids in Québec. The claim is for \$30,000, plus interest for compensatory damages for each class member, \$25.0 million from each defendant for punitive damages and pecuniary damages for each class member. The Company is in the process of assessing this application with counsel and intends to vigorously defend itself.

## Off-Balance Sheet Arrangements

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

## Related Party Transactions

For the year ended December 31, 2019, there were no related party transactions.

## Outstanding Share Data

The number of common shares outstanding as at December 31, 2019 was 11.4 million, consistent with December 31, 2018.

As at December 31, 2019, there were 1.4 million options outstanding of which 1.0 million have vested.

## Critical Accounting Policies and Estimates

The preparation of the Consolidated Financial Statements in conformity with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the Consolidated Financial Statements and the reported amounts of revenue and expenses during the reporting periods. Management has identified accounting estimates that it believes are most critical to understanding the Consolidated Financial Statements and those that require the application of management's most subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. The Company's actual results could differ from these estimates and such differences could be material. All significant accounting policies are disclosed in Note 2, *Basis of Preparation* and Note 3, *Summary of Significant Accounting Policies* of the Company's Consolidated Financial Statements for the year ended December 31, 2019, including the adoption of IFRS 16 – *Leases*.

## Recent Accounting Pronouncements

### Accounting Standards Issued But Not Yet Applied

Certain new standards, interpretations, amendments and improvements to existing standards were issued by the IASB or IFRS Interpretations Committee that are mandatory for fiscal periods beginning on or after January 1, 2020.

(a) *Amendments to IFRS 3: Definition of a Business*

In October 2018, the IASB issued amendments to the definition of a business in IFRS 3 - *Business Combinations* to help entities determine whether an acquired set of activities and assets is a business or not. They clarify the minimum requirements for a business, remove the assessment of whether market

participants are capable of replacing any missing elements, add guidance to help entities assess whether an acquired process is substantive, narrow the definitions of a business and of outputs, and introduce an optional fair value concentration test. New illustrative examples were provided along with the amendments. Since the amendments apply prospectively to transactions or other events that occur on or after the date of first application, the Company will not be affected by these amendments on the date of transition.

(b) *Amendments to IAS 1 and IAS 8: Definition of Material*

In October 2018, the IASB issued amendments to IAS 1 - *Presentation of Financial Statements* and IAS 8 - *Accounting Policies, Changes in Accounting Estimates and Errors* to align the definition of 'material' across the standards and to clarify certain aspects of the definition. The new definition states that, "Information is material if omitting, misstating or obscuring it could reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements, which provide financial information about a specific reporting entity." The amendments to the definition of material is not expected to have a significant impact on the Company's Consolidated Financial Statements.

## Management's Responsibility for Financial Reporting

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.

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, DCP and ICFR may not prevent or detect all misstatements, errors and fraud. 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 DCP and ICFR can only provide reasonable, not absolute, assurance of achieving the control objectives for financial and other reporting.

There were no material changes to the Company's ICFR that occurred during the year ended December 31, 2019.

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

## Risks Related to the Business of the Company

### *Inability to Meet Debt Commitments*

As of December 31, 2019, the Company had total liabilities of \$139.0 million, including \$123.4 million of debt outstanding under the Deerfield Facility Agreement.

The Company has significant debt commitments to Deerfield, which may have adverse consequences, including:

- requiring a substantial portion of cash flow from operations to be dedicated to servicing the Company's indebtedness, thereby reducing the ability to use cash flow from its operations to fund operations, capital expenditures, and future business opportunities;
- the Deerfield Facility Agreement is secured by the assets of the Company and its subsidiaries;
- limiting the ability to obtain additional financing for working capital, capital expenditures, product and service development, debt service requirements, acquisitions, and general corporate or other purposes at reasonable rates, which is vital to the Company's business;
- increasing the risks of adverse consequences resulting from a breach of any indebtedness agreement, including, for example, a failure to make required payments of principal or interest due to failure of the Company's business to perform as expected;
- increasing vulnerability to general economic and industry conditions;
- restricting the ability to make strategic acquisitions or requiring non-strategic divestitures;
- subjecting the Company's operations to restrictive covenants that may limit operating flexibility; and
- placing the Company's operations at a competitive disadvantage compared to competitors that are less highly leveraged.

The Company's ability to satisfy its debt obligations will depend principally upon its future operating performance. As a result, prevailing economic conditions and financial, business and other factors, many of which are beyond the Company's control, may affect the Company's ability to make payments on its debt. If the Company does not generate sufficient cash flow to satisfy its debt service obligations, the Company may have to undertake alternative financing plans, such as refinancing or restructuring its debt, cost savings initiatives, proceeds-generating transactions, reducing or delaying capital investments or seeking to raise additional capital. The Company's ability to restructure or refinance its debt will depend on the capital markets and the Company's financial condition at such time. Any refinancing of the Company's debt could be at higher interest rates and may require it to comply with more onerous covenants, which could further restrict the Company's business operations. The Company's inability to generate sufficient cash flow to satisfy its debt service obligations or to refinance its obligations on commercially reasonable terms could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

The Deerfield Facility Agreement imposes various covenants that limit the Company's ability and/or its subsidiaries' ability to, among other things:

- consolidate or merge with or into another person;
- enter into certain transactions with affiliates;
- pay dividends or distributions;
- create, incur or suffer to exist liens;
- create, incur, assume, guarantee or be liable with respect to indebtedness;
- acquire assets or transfer products or material assets; and
- issue equity securities senior to its Common Shares or convertible or exercisable for equity securities senior to its Common Shares.
- The covenants imposed by the Deerfield Facility Agreement and the Company's obligations to service its outstanding debt:
- limit the Company's ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;
- limit the Company's ability to use its cash flow or obtain additional financing for future working capital, capital expenditures, acquisitions or other general business purposes;



- may require the Company to use a substantial portion of its cash flow from operations to make debt service payments;
- limit the Company's flexibility to plan for, or react to, changes in its business and industry;
- place the Company at a competitive disadvantage compared to its less leveraged competitors; and
- increase the Company's vulnerability to the impact of adverse economic and industry conditions.

If the Company is unable to successfully manage the limitations and decreased flexibility on its business due to its debt obligations, the Company may not be able to capitalize on strategic opportunities or grow its business to the extent the Company would be able to without these limitations. The Company's failure to comply with any of the covenants could result in a default under the Deerfield Facility Agreement, which could permit the lenders to declare all or part of any outstanding loans to be immediately due and payable. If the Company is unable to pay the outstanding loans when due, then Deerfield could realize on its security, which encompasses the assets of Company and its subsidiaries.

In addition, pursuant to the Deerfield Financing, if a Major Transaction (as defined in the Deerfield Facility Agreement) occurs, such as a change of control transaction involving the Company, Deerfield is entitled, subject to the terms of the Deerfield Financing, to convert or exercise its Convertible Notes or Warrants, as applicable, such that Deerfield ultimately receives the cash, securities or other assets, as applicable, in exchange for such Common Shares on the same terms as other holders of Common Shares. This could materially adversely impact the anticipated results, or deter the entering into, of such a Major Transaction. In addition, Deerfield, in relation to certain Major Transactions or events of default, is entitled to be issued additional Common Shares. See the Deerfield Facility Agreement and the forms of Convertible Notes and Warrants filed under the Company's profile on SEDAR [www.sedar.com](http://www.sedar.com).

### ***Potential Product Liability***

The Company may be subject to product liability claims associated with the use of certain of its products either after their approval or during clinical trials and there can be no assurance that the Company's liability insurance will continue to be available on commercially reasonable terms or at all. Product liability claims might also exceed the amounts or fall outside of such coverage. Product liability claims against the Company, regardless of their merit or potential outcome, could be costly and divert management's attention from other business matters or adversely affect the Company's reputation and the demand for its products. There can be no assurance that a product liability claim or series of claims brought against the Company would not materially adversely impact the Company's business, financial condition or operating results.

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

### ***Unexpected Product Safety or Efficacy Concerns***

Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales, as well as potential product liability, consumer fraud or other claims. Any of such occurrences could materially adversely impact the Company's business, financial condition or operating results.

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

There can be no assurance as to the breadth or degree of protection that existing or future patents or patent applications may afford the Company or that any patent applications will result in issued patents or that the Company's patents or trademarks will be upheld if challenged. It is possible that the Company's existing patent or trademark rights may be deemed invalid. Although the Company believes that its products do not, and will not, infringe valid patents or trademarks or violate the proprietary rights of others, it is possible that use, sale or manufacture of its products may infringe on existing or future patent, trademark or proprietary rights of others. If the Company's products infringe the patent, trademark or proprietary rights of others, the Company may be required to stop selling or making certain of its products, may be required to modify or rename certain of its products or may

have to obtain licenses to continue using, making or selling such products. There can be no assurance that the Company will be able to do so in a timely manner, upon acceptable terms and conditions, or at all. The failure to do any of the foregoing could materially adversely impact the Company. Moreover, if the Company's products infringe patents, trademarks or proprietary rights of others, the Company could, under certain circumstances, become liable for substantial damages which could materially adversely impact the Company.

Patent litigation is very complex and expensive. Further, the discovery, trial and appeals process in patent litigation can take several years. Should the Company commence a lawsuit against a third party for patent infringement or should there be a lawsuit commenced against the Company with respect to the validity of its patents or any alleged patent infringement by the Company, the cost of such litigation, as well as the ultimate outcome of such litigation, whether or not the Company is successful, could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline. Moreover, there can be no assurance that the Company will have sufficient financial or other resources to enforce or defend a patent infringement or proprietary rights violation action.

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

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

Further, the strength of patents in the pharmaceutical field involves complex legal and scientific questions and, in the U.S., Canada and many foreign jurisdictions, patent policy also continues to evolve, and the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. This uncertainty is also a result of possible changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of granted patents, or both. Particularly in recent years in the U.S., there have been several major legislative developments and court decisions that have affected patent laws in significant ways and there may be more developments in the future that may weaken or undermine our ability to obtain new patents or to enforce existing and future patents owned or licensed.

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

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

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

There can be no assurance that any of the Company's product candidates will be successfully developed in a timely manner or that they will prove to be more effective than products based on existing or new technologies or that a sufficient number of medical professionals will recommend their use. The risk that a product candidate may fail clinical trials, the Company may be unable to successfully complete development or a decision for financial or other reasons to halt development of any product candidate, particularly in instances where significant capital expenditures have already been made, could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

There can be no assurance that preclinical or clinical testing of the Company's product candidates will yield sufficiently positive results to enable progress toward commercialization and any such trials will take significant time to complete. Unsatisfactory results may prompt the Company to reduce or abandon future testing or commercialization of particular product candidates and this could materially adversely impact the Company.

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

## ***Personnel***

The Company's success depends upon certain key members of its sales and marketing, legal, business development, scientific, technical, manufacturing and management teams. The loss of any of these individuals could materially adversely impact the Company. The Company does not maintain key-man insurance coverage with respect to any of its employees.

The Company's success also depends, in large part, on its ability to continue to attract and retain qualified sales and marketing, legal, business development, scientific, technical, manufacturing and management personnel. The Company faces intense competition for such personnel. Highly skilled employees with the education and training required, especially employees with significant experience and expertise in drug delivery systems, are in high demand and may be hired by the Company's competitors. The Company may not be able to attract and retain such personnel in the future which could have a material adverse impact on the success of the Company.

The Company must also provide significant training for its employees due to the highly specialized nature of pharmaceutical products. With respect to its sales force, the Company is required to expend significant time and resources on training to establish credible, compliant and persuasive individuals in educating physicians to prescribe and pharmacists to dispense the Company's products. In addition, the Company must train its sales force to ensure that a consistent and appropriate message about its products is being delivered to its potential customers. If the Company is unable to effectively train its sales force and equip them with effective materials its efforts to successfully commercialize its products could be put in jeopardy, which could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

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

### ***Dependence on a Small Number of Customers***

The Company sells certain of its products in Canada, the U.S. and E.U. to a limited number of distributors. Under this distribution model, the distributors generally take physical delivery of the product and generally sell the product directly to pharmacies or patients. In addition, certain of the Company's products may be highly dependent on a small number of customers. The Company expects this significant distributor/customer concentration to continue for the foreseeable future. The Company's ability to generate and grow sales of its products will depend, in part, on the extent to which its distributors are able to provide adequate distribution of its products on pricing terms that are favorable to it. Although the Company believes it can find additional or replacement distributors, if necessary, the pricing terms of such arrangements may not be as favourable to the Company, its revenue during any period of disruption could suffer and the Company might incur additional costs. In addition, these distributors/customers are responsible for a significant portion of the Company's net trade accounts receivable balances. The loss of any large distributor/customer, a significant reduction in sales the Company make to them, any cancellation of orders they have made with the Company, or any failure to pay for the products the Company has shipped to them could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

### ***Dependence on Third-Party Partnerships for Sales, Marketing, Customer Service, Distribution, Warehousing, Logistics, Invoicing and Accounts Receivables and Regulatory Services***

Regarding products commercialized by Nuvo, the Company relies on third-party arrangements, to provide customer service, distribution, warehousing, logistics, invoicing, accounts receivables and some regulatory services where it lacks the necessary resources or expertise. If the third parties cease to be able to provide the Company with these services or do not provide these services in a timely or professional manner, or in accordance with the applicable regulatory requirements or if contracts with such third parties are terminated for any reason, the Company may not be able to successfully manage the logistics associated with distributing and selling its products.

Regarding products out-licensed by the Company, or products manufactured for third parties under contract, the Company relies on marketing arrangements, including licensing or other third-party arrangements, to provide sales, marketing, distribution, logistics, invoicing and regulatory services including warehousing of finished products, accounts receivable management, billing, collection, record keeping and processing of invoices (including with insurance companies) for its products in jurisdictions where it lacks the necessary resources or expertise. If the third parties cease to be able to provide the Company with these services or do not provide these services in a timely or professional manner, or in accordance with the applicable regulatory requirements or if contracts with such third parties are terminated for any reason, the Company may not be able to successfully manage the logistics associated with distributing and selling its products.

In either case, this could result in a delay or interruption in delivering products to customers and could impact product sales and revenues or the Company's ability to integrate new products into its business, any of which could materially adversely impact the Company's business, financial condition, operating results or royalties earned. In addition, under these arrangements, disputes may arise with respect to payments that the Company or its partners believe are due, a partner or distributor may develop or distribute products that compete with the Company's products or they may terminate the relationship. Further, disagreements with the Company's third-party partners could require or result in litigation or arbitration, which could be time consuming and expensive for the Company.

The Company has no influence in sales and marketing activities for products that are sold by third parties in the markets in which they are currently available. Decisions impacting sales and marketing efforts are made by the Company's partners in their respective territories. If one of the Company's partners is unable to successfully sell or stops selling its respective product, for any reason, it could have an adverse effect on the Company's product sales and cash resources, as well as royalties earned.

### ***Loss of Licenses***

The Company has licensed certain assets used in a substantial part of the Company's business, including certain intellectual property, marketing authorizations and related data, and commercial and technical medical information. The Company believes it is currently in material compliance with all requirements of such licenses. In certain cases, the Company does not control the filing, prosecution or maintenance of the patent rights underlying

a license and may rely upon the Company's licensors to prosecute infringement of those rights. Such license agreements may be terminated by the licensor if the Company is in breach of its obligations thereunder and fails to cure that breach. If a license agreement is terminated, then the Company may lose its rights to utilize the intellectual property and other assets covered by such agreement in order to manufacture, market, promote, distribute and sell the licensed products, which may prevent the Company from continuing a substantial part of the Company's business. This could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

### ***Timing of Milestone and Royalty Payments***

The Company is party to various agreements pursuant to which the Company is obligated to make milestone payments or pay royalties to third parties. The Company may become obligated to make a milestone or other payment at a time when the Company does not have sufficient funds to make such payment, or at a time that would otherwise require it to use funds needed to continue to operate its business, which could curtail its operations, necessitate a scaling back of its commercialization and marketing efforts or cause the Company to seek funds to meet these obligations on terms unfavorable to it.

### ***Manufacturing, Warehousing and Supply Risks***

The Company's current internal manufacturing capabilities are limited to its site in Varennes, Québec, which is the sole manufacturing site of Pennsaid 2%, Pennsaid and the bulk drug product for the HLT Patch for all markets. The Company has never achieved full capacity utilization in this facility. The Company is exposed to the following manufacturing and supply risks, any of which could delay or prevent the commercialization of certain of its products, result in higher costs or deprive it of potential product revenues:

- The Company may encounter difficulties in achieving volume production, quality control and quality assurance, as well as relating to shortages of qualified personnel, which may lead to insufficient quantities to commercialize certain of its customer needs;
- The Company's manufacturing facilities are required to undergo satisfactory current GMP inspections prior to regulatory approval and are obliged to operate in accordance with FDA, E.U. and other nationally mandated GMP, which govern manufacturing processes, stability testing, record keeping and quality standards. Failure to establish and follow GMPs and to document adherence to such practices, may lead to significant delays in the availability of material for customer orders; and
- Changing manufacturing locations would be difficult and the number of potential manufacturers is limited. Changing manufacturers generally requires re-validation of the manufacturing processes and procedures in accordance with FDA, E.U. and other nationally mandated GMPs. Such re-validation may be costly and would be time consuming. It would be difficult or impossible to quickly find replacement manufacturers on acceptable terms, if at all.

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

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

With the exception of Pennsaid 2%, Pennsaid and the bulk drug product for the HLT Patch, the Company relies on several contract manufacturers for the supply of products. There are risks that could affect the ability of the Company's contract manufacturers to meet the Company's delivery time requirements or provide adequate amounts of material to meet the Company's needs. In addition to the manufacture of certain of the Company's products, the Company may have additional manufacturing requirements related to the technology required for any of the Company's products. In some cases, the delivery technology the Company utilizes is highly specialized or proprietary and for technical and legal reasons, the Company may have access to only one or a limited number of potential manufacturers for such delivery technology. Failure by these manufacturers to properly formulate the Company's products or licensed products for delivery could also result in unusable product and cause delays in the Company's discovery and development process, as well as additional expense to the Company.

The manufacturing process for products where the Company uses a contract manufacturer are based on technologies that the Company or its partners may develop and are subject to regulatory approvals from regulatory authorities, including the FDA, Health Canada, EMA, state and local regulations and other regulatory agencies as well as compliance with ongoing regulatory requirements. Together with the Company's partners, the Company needs to contract with manufacturers who can meet all applicable regulatory guidelines and requirements. In addition, if the Company receives the necessary regulatory approval for any product candidate, it also expects to rely on third parties, including its commercial partners, to produce materials required for commercial supply. The Company may experience difficulty in obtaining adequate manufacturing capacity for its needs. If the Company is unable to obtain or maintain contract manufacturing for its product candidates, products or licensed products, or to do so on commercially reasonable terms, the Company may not be able to successfully develop and commercialize its products or licensed products. If a third-party manufacturer with whom the Company contracts fails to perform its obligations, the Company may be forced to manufacture the materials itself, which the Company may not have the necessary capabilities or resources for, or enter into an agreement with a different third-party manufacturer, which the Company may not be able to do on equally favourable terms, within acceptable timelines or that complies with quality standards and with all applicable regulations and guidelines.

In the case of many of the Company's products, there is a single supplier for raw materials used in such products. If the relationships with any of the single-sourced suppliers is discontinued or if any manufacturer is unable to supply or produce required quantities of product on a timely basis, or at all, or if a supplier ceases production of an ingredient or component, the Company's operations would be negatively impacted and the business would be harmed.

In addition, the FDA and other regulatory agencies require that raw material manufacturers comply with all applicable regulations and standards pertaining to the manufacture, control, testing and use of the raw materials as appropriate. For the active pharmaceutical ingredients (API) or critical raw materials depending on the drug product, this means compliance with current GMPs for APIs and submission of all data related to the manufacture, control and testing of the API for quality, purity, identity and stability, as well as a complete description of the process, equipment, controls and standards used for the production of the API. This is usually submitted to the FDA in the form of a Drug Master File (DMF) by the manufacturer and referenced by the sponsor of the NDA. The DMF information and data is reviewed by the FDA as a critical component of the approvability of the NDA. As a result, in the case where only one supplier of a particular API or critical raw material meets all of the FDA's (or other regulatory agencies) requirements and has a DMF (or similar filing) on file with the FDA, the Company is at risk should a supplier violate GMP, fail an FDA inspection, terminate access to its DMF, be unable to manufacture product, choose not to supply the Company or decide to increase prices.

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

### ***Failure to Achieve Anticipated Benefits From Strategic Acquisitions***

A significant part of the Company's business strategy includes acquiring and integrating complementary businesses, products, technologies or other assets, and forming strategic alliances and other business combinations, to help drive future growth. The Company may also in-license new products or compounds. Acquisitions or similar arrangements may be complex, time-consuming and expensive, and the process of

negotiating the acquisition and integrating an acquired product, drug candidate, technology, business or company might result in operating difficulties and expenditures and might require significant management attention that would otherwise be available for ongoing development of the Company's business, whether or not any such transaction is ever completed. Moreover, the Company may never realize the anticipated benefits of any acquisition or forecasted sales may not materialize.

In addition, the Company may explore, pursue and/or negotiate transactions that are not ultimately completed and there are a number of risks, costs and uncertainties relating thereto. For example, the market price of the Company's Common Shares may reflect a market assumption that such transactions will occur, and a failure to complete such transactions could result in a negative perception by the market of the Company generally and a decline in the price of its Common Shares. In addition, many costs relating to such transactions may be payable by the Company whether or not such transactions are completed.

If an acquisition is completed, the integration of the acquired business, product or other assets into the Company may also be complex and time-consuming and, if such businesses, products and assets are not successfully integrated, the Company may not achieve the anticipated benefits, cost-savings or growth opportunities. Potential difficulties that may be encountered in the integration process include the following:

- disruption of the Company's business and diversion of management's and employees' time and attention from operations;
- integrating personnel, operations, manufacturing technology and systems, while maintaining focus on selling and promoting existing and newly-acquired products;
- coordinating geographically dispersed organizations;
- motivating key employees of the acquired businesses;
- retaining existing customers and attracting new customers;
- maintaining the business relationships of the acquired company or that the company that previously owned such product has established, including with healthcare providers, third-party payers and distributors; and
- managing inefficiencies associated with integrating the operations of the Company.

The Company has incurred, and may incur in the future, restructuring and integration costs and a number of non-recurring transaction costs associated with these acquisitions. Non-recurring transaction costs include, but are not limited to, fees paid to legal, financial, regulatory, manufacturing and accounting advisors, filing fees, transfer and other transaction-related taxes and printing costs. Additional unanticipated costs may be incurred in the integration of the businesses of the Company and the acquired business. There can be no assurance that the elimination of certain duplicative costs, as well as the realization of other efficiencies related to the integration of the acquired business, will offset the incremental transaction-related costs over time. Therefore, any net benefit may not be achieved in the near term, the long term or at all.

Finally, these acquisitions and other arrangements, even if successfully integrated, may fail to further the Company's business strategy as anticipated or to achieve anticipated benefits and success, expose it to increased competition or challenges with respect to its products or geographic markets, and expose it to additional or unexpected liabilities associated with an acquired business, product, technology or other asset or arrangement. Any one of these challenges or risks could impair the Company's ability to realize any benefit from an acquisition or arrangement after the Company has expended resources on them.

#### ***Failure to Acquire, License, Develop and Market Additional Product Candidates or Approved Products***

As part of its strategy, the Company may acquire, license or develop and market additional products and product candidates. The product candidates where the Company allocates its resources may not be successful. In addition, because its internal research capabilities are limited, the Company may depend upon pharmaceutical,

biotechnology and other researchers to sell or license products or technology. The success of this strategy depends partly upon the Company's ability to identify, select, license and/or acquire promising pharmaceutical or other healthcare product candidates and approved products for Canada, the U.S. and the rest of the world. Failure of this strategy could impair the Company's ability to grow. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with the Company for the license or acquisition of product candidates and approved products. The Company may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or the Company may fail to realize the anticipated benefits of such efforts. The Company may not be able to acquire the rights to additional product candidates or approved products on terms that the Company find acceptable, or at all.

Further, any unapproved product candidate that the Company acquires may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by applicable regulatory authorities. With all product candidates there are risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by applicable regulatory authorities and thus will never make it to market. If such risks were to materialize, they could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

### ***Hazardous Materials and the Environment***

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

### ***Losses Due to Foreign Currency Fluctuations***

The Company anticipates that a high percentage of the revenue from commercialization of its product candidates may be in currencies other than Canadian dollars. Fluctuation in the exchange rate of the Canadian dollar relative to these other currencies could result in the Company realizing a lower profit margin on sales of its product candidates than anticipated at the time of entering into such commercial agreements. Adverse movements in exchange rates could materially adversely impact the Company's business, financial condition or operating results.

### ***Taxes***

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

The Company and its subsidiaries have operations in various countries that have differing tax laws and rates. The Company's and its subsidiaries' tax reporting is subject to current domestic tax laws in the countries in which the Company and its subsidiaries operate, including transfer pricing laws and regulations between many of these jurisdictions, and the application of tax treaties between the various countries in which the Company and its subsidiaries operate. The Company's and its subsidiaries' income tax reporting is subject to audit by domestic and foreign authorities. Tax laws, regulations, and administrative practices in various jurisdictions may be subject to significant change, with or without notice, due to economic, political, and other conditions.



The amount of income tax and withholding tax required to be paid by the Company and/or its subsidiaries will be affected by many factors, including the amount of net income earned in the relevant operating jurisdictions, the structure of its operations, the availability of benefits under tax treaties, and the rates of taxes payable in respect of that income. The Company must make estimates and judgments, as well as take tax filing positions, based on its knowledge and understanding of applicable tax laws and tax treaties, and the application of those tax laws and tax treaties to its business. The final outcome of any audits by taxation authorities may differ from the estimates, assumptions and filing positions used in determining the tax treatment by the Company and/or its subsidiaries, and such outcome could lead to additional taxes, penalties and interest.

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

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

### ***International Scope of Operations***

The Company's international operations and any future international operations may expose it to risks that could negatively impact its future results. The risks that the Company may be exposed to in these cases include, but are not limited to:

- tariffs and trade barriers;
- currency fluctuations, which could decrease the Company's revenues or increase its costs;
- regulations related to customs and import/export matters;
- tax issues, such as tax law changes, variations in tax laws, withholding tax obligations and claims by foreign tax authorities;
- limited access to qualified staff;
- inadequate infrastructure;
- cultural and language differences;
- inadequate banking systems;
- different and/or more stringent environmental laws and regulations;
- restrictions on the repatriation of profits or payment of dividends;
- crime, strikes, riots, civil disturbances, terrorist attacks or wars;
- nationalization or expropriation of property;
- law enforcement authorities and courts that are weak or inexperienced in commercial matters; and
- deterioration of political relations among countries.

Similarly, adverse economic conditions impacting the Company's customers in international countries or uncertainty about global economic conditions could cause purchases of its products to decline, which would adversely affect the Company's revenues and operating results. Any of these factors, or any other international factors, could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

### ***Information Technology Infrastructure***

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

### ***Security and Cyber Security Breaches***

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

### **Risks Related to the Industry in which the Company Operates**

#### ***Products May Fail to Achieve Market Acceptance***

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

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

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

#### ***Laws and Regulations***

Pharmaceutical and biotechnology companies have faced lawsuits and investigations pertaining to violations of healthcare "fraud and abuse" laws, such as the federal *False Claims Act*, the federal *Anti-Kickback Statute*, the United States *Foreign Corrupt Practices Act* (the FCPA) and other federal, state, territorial and

provincial laws and regulations. The Company also faces increasingly strict data privacy and security laws in the United States, Canada, the E.U. and other countries, the violation of which could result in fines and other sanctions. The United States Department of Health and Human Services Office of Inspector General recommends that pharmaceutical companies have comprehensive compliance programs and disclose certain payments made to healthcare providers or funds spent on the marketing and promotion of drug products. While the Company has developed a corporate compliance program, there can be no assurance it, or its employees or agents, are or will be in compliance with all applicable federal, state, provincial, territorial or foreign regulations and laws. If the Company is in violation of any of these requirements or any such actions are instituted against it, and the Company is not successful in defending or asserting its rights, those actions could have a significant impact on the Company's business, including the imposition of significant fines, exclusion from federal healthcare programs or other sanctions.

The FCPA, the Canadian *Corruption of Foreign Public Officials Act* (the CFPOA) and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to officials for the purpose of obtaining or retaining business. Although the Company requires its employees to consult with its legal department prior to making any payment or gift thought to be exempt under applicable law, there is no assurance that such policies or procedures will work effectively all of the time or protect the Company against liability under the FCPA and/or the CFPOA for actions taken by its employees and other intermediaries with respect to the Company's business or any businesses that the Company may acquire. The Company may operate in parts of the world that have experienced governmental corruption to some degree and, in certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices or may require the Company to interact with doctors and hospitals, some of which may be state controlled, in a manner that is different from the U.S. and Canada. The Company cannot assure that its internal control policies and procedures will protect it from reckless or criminal acts committed by its employees or agents. Violations of these laws, or allegations of such violations, could disrupt the Company's business and result in criminal or civil penalties or remedial measures, any of which could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

The Company is also subject to various privacy and security regulations. In the U.S., the Company is subject to the *Health Insurance Portability and Accountability Act of 1996*, as amended by the *Health Information Technology for Economic and Clinical Health Act of 2009* (as amended, HIPAA). HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions (e.g., healthcare claims information and plan eligibility, referral certification and authorization, claims status, plan enrollment, coordination of benefits and related information), as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. Failure to comply with these laws can result in the imposition of significant civil and criminal penalties.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. Canada has adopted the *Personal Information Protection and Electronic Documents Act* (PIPEDA) which governs how private sector organizations collect, use and disclose personal information in the course of commercial business and which imposes significant compliance obligations. The E.U. and other jurisdictions have adopted data protection laws and regulations which also impose significant compliance obligations, including the E.U. Data Protection Directive, as implemented into national laws by the E.U. member states, which imposes strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from different E.U. member states have interpreted the privacy laws differently, which adds to the complexity of processing personal data in the E.U. and guidance on implementation and compliance practices are often updated or otherwise revised. Any failure to comply with applicable information privacy laws could lead to supervisory authority enforcement actions, reputational damage and significant penalties adversely impacting Company operating results.

The E.U. General Data Protection Regulation (GDPR), came into effect on May 25, 2018 to expand data protection obligations, including by imposing more stringent conditions for consent from data subjects, strengthening the rights of individuals, including the right to have personal data deleted upon request, continuing to restrict the trans-border flow of such data, requiring mandatory data breach reporting and notification, increasing penalties for non-compliance and increasing the enforcement powers of the national data protection authorities. The GDPR mandate harmonizes E.U. data protection laws and is intended to make it easier for

multinational companies operating across the E.U. to comply with their data protection obligations. Therefore, GDPR increases the Company's responsibility and liability in relation to processing personal data internationally. Along with the Company's existing controls, it is in the process of putting in place additional mechanisms to ensure compliance with GDPR. The costs of compliance with these laws and the potential liability associated with the failure to comply with these laws could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

### ***Legislative or Regulatory Reform of the Healthcare System***

In the U.S. and certain state and foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact the ability of certain of the Company's products to be sold profitably. The *Patient Protection and Affordable Care Act* (the ACA) may affect the operational results of companies in the pharmaceutical industry, including the Company, and other healthcare-related industries by imposing additional costs and compliance burdens.

The Company is unable to predict the future course of federal or state healthcare legislation. A variety of federal and state agencies are in the process of implementing the ACA, including through the issuance of rules, regulations or guidance that materially affect the Company's business. The risk of the Company being found in violation of these rules and regulations is increased by the fact that many of them have not been fully interpreted by applicable regulatory authorities or the courts, and their provisions are open to a variety of interpretations. In addition, there is substantial uncertainty regarding the future of the ACA as there is continued interest to repeal and/or replace all or certain aspects of such laws. The outcome of such efforts could have a substantial impact on the Company's business. Further changes to healthcare laws or regulatory framework that reduce the Company's revenues or increase its compliance or other costs could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

In addition, pharmaceutical product pricing is subject to enhanced government and public scrutiny and calls for reform. Efforts by government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products could adversely affect the Company's business if implemented.

In Canada, patented drug products are subjected to regulation by the Patented Medicine Prices Review Board (the PMPRB) pursuant to the Patent Act (Canada) and the Patented Medicines Regulations. The PMPRB does not approve prices for drug products in advance of their introduction to the market, and therefore, there may be risk involved in the determination of an allowable price selected by the Company for a patented drug product at the time of introduction to the market. If the PMPRB does not agree with the pricing assumptions chosen by the Company at any time during the patent life of a product, the price chosen could be challenged by the PMPRB, and if it is determined that the price charged is excessive, the price of the product may be reduced and a fine may be levied against the Company. Drug products that have no valid patents are not subject to the PMPRB's jurisdiction. Aralez Canada currently has three patent protected products in Canada (Blexten, Cambia, Suvexx and Durela) that could be affected by changes to PMPRB regulations. Changes to the PMPRB regulations are anticipated to come into effect on July 1, 2020, with enforcement anticipated to begin on January 1, 2021 and these changes could materially adversely impact the Company's business (Blexten, Cambi, Suvexx and Durela), financial condition or operating results and could cause the market value of its Common Shares to decline. To-date, there are no final guidelines on how these changes will be implemented or how these changes may or may not impact our business.

### ***Formularies***

Third-party payers try to negotiate the pricing of medical services and products to control their costs. Pharmacy benefit managers typically develop formularies to reduce their cost for medications. Due to their lower costs, generic products are often favoured. The breadth of the products covered by formularies varies considerably from one managed care organization to another, and many formularies include alternative and competitive products for treatment of particular medical conditions. Failure to be included on such formularies, failure to achieve favourable formulary status, restrictions on drugs included on formularies such as prior authorizations, step edits or other limitations, or delays in implementing changes to formulary status, may negatively impact the utilization of the Company's products. If the Company's products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favour generic products, its market share which could materially adversely impact the Company's business, financial condition or operating results.

## **Competition**

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

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

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

## **Generic Drug Manufacturers and Litigation**

Regulatory approval for competing generic drugs can be obtained without investing in the same level of costly and time-consuming clinical trials that the Company has conducted or might conduct in the future. Due to the substantially reduced development costs, generic drug manufacturers are often able to charge much lower prices for their products than the original developer. Where available, generic versions may be required or encouraged in preference to branded version under third-party reimbursement programs or substituted by pharmacies for branded versions by law. The Company faces competition from manufacturers of generic drug versions of some of its products that are commercial, since a number of the Company's patents have expired, or if not yet expired, may be ignored by generic drug manufacturers who choose to launch their products "at risk" of a possible patent infringement lawsuit brought by the Company or its licensing partners. Generic competition may impact the prices at which the Company's products are sold, the royalty rates the Company receives and the volume of product sold which may substantially reduce the Company's overall revenues and market share. Such competition could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

In the U.S., under the *Hatch-Waxman Act*, the FDA can approve an Abbreviated New Drug Application (ANDA) for a generic version of a branded drug or a variation of an existing branded drug, without undertaking the clinical testing necessary to obtain approval to market a new drug. This is referred to as the "ANDA process". In place of such clinical studies, an ANDA applicant usually needs to submit data and information demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product, in addition to, for example, any data necessary to establish that any difference in inactive ingredients does not result in different safety or efficacy profiles, as compared to the reference drug. The Hatch-Waxman Act, in addition to providing brand-name drug manufacturers with periods of marketing exclusivity, such as three-year "new clinical investigation" exclusivity, requires an applicant for a drug that relies, at least in part, on the FDA's findings of safety or effectiveness for a branded drug, to notify the sponsor of the branded drug of their application and potential infringement of any patents listed in the FDA Orange Book. Upon receipt of this notice, the sponsor of the branded drug has 45 days to bring a patent infringement suit in federal district court against the applicant seeking approval of a product covered by the patent. If such a suit is commenced and the ANDA was filed after the patent had been listed in the FDA Orange Book, then the FDA is generally prohibited from granting approval of the ANDA or Section 505(b)(2) NDA, a type

of NDA that relies on information for which the applicant does not have a right of reference, until the earliest of 30 months from the date the FDA accepted the application for filing (the 30-Month Stay), or the conclusion of patent infringement litigation in the generic's favour or expiration of the patent. If an ANDA was filed before the patent had been listed in the FDA Orange Book, the 30-Month Stay does not apply and it is possible that the ANDA holder may launch its generic product "at risk" of patent infringement proceedings initiated by the innovator drug company. If the litigation is resolved in favour of the applicant or the challenged patent expires during the 30-month stay period, the stay is terminated and the FDA may thereafter approve the application based on the standards for approval of ANDAs and Section 505(b)(2) NDAs. Frequently, the unpredictable nature and significant costs of patent litigation leads the parties to settle out of court. Settlement agreements between branded companies and generic applicants may allow, among other things, a generic product to enter the market prior to the expiration of any or all of the applicable patents covering the branded product, either through the introduction of an authorized generic or by providing a license to the patents in suit. Comparable procedures exist in Canada under the Patented Medicines (Notice of Compliance) Regulations.

In the U.S., Pennsaid 2% and Vimovo are protected by multiple patents listed in the FDA Orange Book. The approval or launch of generic versions of Pennsaid 2% or Vimovo in the U.S. market, or timely and expensive litigation costs associated with protecting the patents for these products, could materially adversely impact the Company's future revenue from product sales.

### ***General Litigation and Class Action Litigation***

The Company operates in a highly litigious environment. From time-to-time, the Company is or may be threatened with, or is or could be named as a defendant in, various legal proceedings, including lawsuits based upon product liability, patent infringement, personal injury, breach of contract and lost profits or other consequential damage claims. Such actions can include class action based on drugs with unanticipated side effects. In addition, the Company may be forced to litigate to enforce or defend its intellectual property rights, to protect its trade secrets or to determine the validity and scope of other parties' proprietary rights.

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

As more particularly described herein, the Company, along with other defendants, is currently defending a class action filed in the Superior Court of Québec with respect to the manufacturing, marketing, and/or distribution of opioids in Québec. The claim is for \$30,000, plus interest for compensatory damages for each class member, \$25.0 million from each defendant for punitive damages and pecuniary damages for each class member. The Company believes that the claim against the Company is without merit, and intends to vigorously defend itself. However, there can be no assurance about the outcome of this litigation, including the amount of any judgment or settlement against the Company or possible reputational damage. Even if the Company is successful in defending this claim, the Company could incur significant costs in defending itself. The amount of any judgement or settlement and/or the cost of defending the claim could have a significant adverse impact on the financial and operational results of the Company. See "Legal Proceedings and Regulatory Actions".

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

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

The process of completing a drug development program and obtaining regulatory approval for a drug can be long and may involve significant delays, despite the Company's best efforts, and can require substantial cash and resources. Even after initial approval has been obtained, further research, including post-marketing studies, may be required to expand indications covered under the product approvals and labelling. Also, regulatory agencies

require post-marketing surveillance programs to monitor side effects. Results of post-marketing programs may limit or expand additional marketing of the drug. Moreover, regulations are rigorous, time consuming and costly and the Company cannot predict the extent to which it may be affected by changes in regulatory developments and its ability to meet such regulations. There is also a risk that the Company's products may be withdrawn from the market and the required approvals suspended as a result of non-compliance with regulatory requirements. Furthermore, there can be no assurance that the regulators will not require modification to any submissions, which may result in delays or failure to obtain regulatory approvals. There can also be no assurance that the Company's products will prove to be safe and effective in clinical trials.

In addition to the regulatory approval process, pharmaceutical companies are subject to regulations under local, provincial, state and federal law, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control and may be subject to other present and future local, provincial, state, federal and foreign regulations, including possible future regulations of the pharmaceutical industry.

Failure to obtain or a delay in obtaining necessary regulatory approvals, the restriction, suspension or revocation of existing approvals or any other failure to comply with regulatory requirements, could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

### United States Regulation

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

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

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

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

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

### Canadian Regulation

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

## Additional Regulatory Considerations

There is no assurance that problems will not arise that could delay or prevent the commercialization of the Company's products currently under development or that the TPD, FDA or other foreign regulatory agencies will be satisfied with the information submitted by the Company, including results of clinical trials, to approve the marketing of such products. The Company cannot predict the time required for regulatory approval or the extent of clinical testing and documentation that is required by regulatory authorities. Any delays in obtaining, or failure to obtain regulatory approvals in Canada, the U.S., the E.U. or other foreign countries, would significantly delay the development of the Company's markets and the receipt of revenues from the sale of its products.

### ***Demand Fluctuations***

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

### ***Natural Disasters, Climate-Change or Other Events That Disrupt Business Operations***

The Company's manufacturing facility is located in Varennes, Québec, where natural disasters or similar events, like blizzards, fires or explosions or large-scale accidents or power outages, could severely disrupt the Company's operations, and materially adversely impact its business, results of operations, financial condition and prospects. If a disaster, power outage or other event occurred that prevented the Company from using all or a significant portion of this facility, that damaged critical infrastructure or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for the Company to continue its business for a substantial period of time, which could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

Additionally, the Company and its manufacturers or suppliers may be exposed to climate change risk from natural disasters, changes in weather patterns and severe weather, that may result in physical damage to the Company's manufacturing facility or those of the Company's manufacturers and suppliers. Such damage may result in disrupted operations, and it may be difficult for the Company to continue its business for a substantial period of time, which could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

In addition, climate change has continued to attract the focus of governments, the scientific community and the general public as an important threat, given the emission of greenhouse gases and other activities continue to negatively impact the planet. The Company faces the risk that its operations or those of the Company's manufacturers and suppliers will be subject to government initiatives aimed at countering climate change, which could impose constraints on its operational flexibility.

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

The publication of negative results of studies or clinical trials related to the Company's products, or the therapeutic areas in which its products compete, may adversely affect sales, the prescription trends for the products, the reputation of the products and the market value of the Company's Common Shares. From time-to-time, studies or clinical trials on various aspects of pharmaceutical products are conducted by the Company, academics or others, including government agencies. The results of these studies or trials, when published, may have a dramatic



effect on the market for the pharmaceutical product that is the subject of the study. In the event of the publication of negative results of studies or clinical trials related to the Company's marketed products or the therapeutic areas in which these products compete, there could be a material adverse impact on the Company's business, financial condition or operating results and the market value of its Common Shares could decline.

## **Risks Related to the Ownership of Securities of the Company**

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

Market prices for pharmaceutical related securities, including those of the Company, have been historically volatile and subject to substantial fluctuations. The stock market, from time-to-time, experiences significant price and volume fluctuations unrelated to the underlying value of the Company's business or its operating performance. The market price of Common Shares cannot be predicted. Future announcements concerning the Company or its competitors, including announcements regarding the results of testing, technological innovations, new commercial products, marketing arrangements, government regulations, developments concerning regulatory actions affecting the Company's products and its competitors' products in any jurisdiction, developments concerning proprietary rights, litigation, additions or departures of key personnel, cash flow, public concerns about the safety of the Company's products and economic conditions and political factors in the U.S., E.U., Canada or other jurisdictions may have a significant impact on the market price of the Common Shares. To the extent that other companies within the Company's industry experience declines in their stock price, the share price of the Common Shares may decline as well. In addition, there can be no assurance that the Common Shares will continue to be listed on the TSX or OTCQX.

In addition, when the market price of a company's shares drops significantly, shareholders may institute securities class action against the company. A lawsuit against the Company could result in substantial costs and could divert the time and attention of the Company's management and other resources.

### ***Potential Dilution***

As a result of the Deerfield Financing, Deerfield now holds the Warrants initially exercisable for 25,555,556 fully paid and non-assessable Common Shares, and the Convertible Notes, initially convertible into 19,444,444 fully paid and non-assessable Common Shares. The Common Shares underlying the Warrants and the Convertible Notes represent approximately 395.14% of the Company's 11,388,282 issued and outstanding Common Shares on a non-diluted basis as of December 31, 2019. If the Warrants and Convertible Notes were to be fully exercised, Deerfield would own approximately 79.8% of the issued and outstanding Common Shares. However, Deerfield does not have the right to convert or exercise such securities if doing so would result in Deerfield and its affiliates and joint actors beneficially owning more than 4.985% of the number of Common Shares (on a non-diluted basis) outstanding immediately after giving effect to such conversion or exercise (the 4.985% Cap). Accordingly, Deerfield is unable to exercise a sufficient number of Warrants or Convertible Notes to materially affect control of the Company.

Deerfield may seek to sell some of their Common Shares upon exercise or conversion of the Warrants and Convertible Notes pursuant to the Registration Rights Agreement. No prediction can be made as to the effect, if any, a future sale of Common Shares by Deerfield will have on the market value of the Common Shares prevailing from time to time. However, the future sale of a substantial number of Common Shares by Deerfield, or the perception that such sale could occur, could adversely affect the market value of the Common Shares.

The potential concentration of the Company's issued and outstanding Common Shares in the hands of one shareholder may discourage an unsolicited bid for the Common Shares, and this may adversely impact the value and trading price of the Common Shares.

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

increase its leverage relative to its earnings or to its equity capitalization, requiring the Company to pay interest expenses. The Company may not be able to market such issuances on favourable terms, or at all, in which case, the Company may not be able to execute its business plan.

### ***Active Trading Market for Common Shares***

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

### ***Securities Industry Analyst Research Reports***

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

### ***Quarterly Fluctuations***

The Company's quarterly and annual operating results are likely to fluctuate in the future. These fluctuations could cause the market value of the Company's Common Shares to decline. The nature of the Company's business involves variable factors, such as the timing of launch and market acceptance of the Company's products, the timing and costs associated with the research, development and regulatory submissions of the Company's products in development, the costs of maintaining manufacturing facilities operating below capacity and the costs associated with public company and other regulatory compliance. As a result, in some future quarters or years, the Company's clinical, financial or operating results may not meet the expectations of securities analysts and investors which could result in a decline in the price of the Company's Common Shares.

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

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

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

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

and Chief Financial Officer are required to report on the effectiveness of the Company's internal control over financial reporting.

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

If the Company fails to maintain effective internal controls over its financial reporting, there is the possibility of errors or omissions occurring or misrepresentations in the Company's disclosures which could materially adversely impact the Company's business, its financial statements and the market value of the Common Shares.

### ***Public Company Requirements May Strain Resources***

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

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

## **Forward-looking Statements**

This MD&A contains "forward-looking information" as defined under Canadian securities laws (collectively, "forward-looking statements"). This document should be read in conjunction with material contained in the Company's current consolidated financial statements for the year ended December 31, 2019 along with the Company's other publicly filed documents. Forward-looking statements appear in this MD&A and include, but are not limited to, statements which reflect management's expectations regarding objectives, plans, goals, strategies, future growth, results of operations, performance, business prospects, opportunities and macroeconomic and industry trends.

The words "plans", "expects", "does not expect", "goals", "seek", "strategy", "future", "estimates", "intends", "anticipates", "does not anticipate", "projected", "believes" or variations of such words and phrases or statements to the effect that certain actions, events or results "may", "will", "could", "would", "should", "might", "likely", "occur", "be achieved" or "continue" and similar expressions identify forward-looking statements. In addition, any statements that refer to expectations, intentions, projections or other characterizations of future events or circumstances contain forward-looking statements. Forward-looking statements are not historical facts but instead represent management's expectations, estimates and projections regarding future events or circumstances. Such forward-looking statements are qualified in their entirety by the inherent risks, uncertainties and changes in circumstances surrounding future expectations which are difficult to predict and many of which are beyond the control of the Company.

Forward-looking statements are necessarily based on a number of estimates and assumptions that, while considered reasonable by management of the Company as of the date of this MD&A, are inherently subject to significant business, economic and competitive uncertainties and contingencies. The Company's estimates, beliefs and assumptions, which may prove to be incorrect, include the various assumptions set forth herein, including, but

not limited to, the Company's future growth potential, results of operations, future prospects and opportunities, the competitive landscape, industry trends, legislative or regulatory matters, future levels of indebtedness, availability of capital and current economic conditions.

The Company cautions readers not to place undue reliance on these statements, as forward-looking statements involve significant risks and uncertainties. Forward-looking statements should not be read as guarantees of future performance or results and will not necessarily be accurate indications of whether or not the times at or by which such performance or results will be achieved. A number of factors could cause actual results to differ materially from the results discussed in the forward-looking statements, including, but not limited to: the Company's ability to execute its growth strategies; the impact of changing conditions in the regulatory environment and drug development processes; increasing competition in the industries in which Nuvo operates; the Company's ability to meet its debt commitments; the impact of unexpected product liability matters; the impact of changes in relationships with customers and suppliers; the degree of intellectual property protection currently afforded to the Company's products; including the invalidation of any of the Company's current patents and the outcome of any litigation or other proceedings seeking to challenge or protect such patents; the scope of the impact of patent litigation or other proceedings involving the Company's products; the timing of any launch of generic products that compete with the Company's products and the scope of their impact on the Company's product sales and royalty payments; the degree of market acceptance of the Company's products; changes in prevailing economic conditions; developments and changes in applicable laws and regulations; and such other factors discussed under "Risk Factors" in the Company's most recent AIF.

If any risks or uncertainties described above or otherwise materialize, or if the opinions, estimates or assumptions underlying the forward-looking statements prove incorrect, actual results or future events might vary materially from those anticipated in the forward-looking statements. The opinions, estimates or assumptions referred to above and described in greater detail under "Risk Factors" in the AIF should be considered carefully by readers. Although management has attempted to identify important risk factors that could cause actual results to differ materially from those contained in forward-looking statements, there may be other risk factors not presently known that management believes are not material that could also cause actual results or future events to differ materially from those expressed in such forward-looking statements.

All forward-looking statements are based only on information currently available to the Company and are made as of the date of this MD&A. Except as expressly required by applicable Canadian securities law, the Company assumes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All forward-looking statements in this MD&A are qualified by these cautionary statements.

## **Additional Information**

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

# Management's Report

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

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

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

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

*/s/ Jesse F. Ledger*

*/s/ Mary-Jane E. Burkett*

Jesse F. Ledger  
President & Chief Executive Officer  
February 24, 2020

Mary-Jane E. Burkett  
Vice President & Chief Financial Officer  
February 24, 2020

## **INDEPENDENT AUDITOR'S REPORT**

**To the Shareholders of Nuvo Pharmaceuticals Inc.**

### **Opinion**

We have audited the consolidated financial statements of Nuvo Pharmaceuticals Inc. and its subsidiaries (the "Group"), which comprise the consolidated statements of financial position as at December 31, 2019 and 2018 and the consolidated statements of income (loss) and comprehensive income (loss), consolidated statements of changes in equity and consolidated statements of cash flows for the years then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies.

In our opinion, the accompanying consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Group as at December 31, 2019 and 2018, and its consolidated financial performance and its consolidated cash flows for the years then ended in accordance with International Financial Reporting Standards (IFRS).

### **Basis for opinion**

We conducted our audit in accordance with Canadian generally accepted auditing standards. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Consolidated Financial Statements* section of our report. We are independent of the Group in accordance with the ethical requirements that are relevant to our audit of the consolidated financial statements in Canada, and we have fulfilled our ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### **Other information**

Management is responsible for the other information. The other information comprises:

- Management's Discussion and Analysis
- The information, other than the consolidated financial statements and our auditor's report thereon, in the Annual Report

Our opinion on the consolidated financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the consolidated financial statements, our responsibility is to read the other information, and in doing so, consider whether the other information is materially inconsistent with the consolidated financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

We obtained Management's Discussion & Analysis prior to the date of this auditor's report. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

The Annual Report is expected to be made available to us after the date of the auditor's report. If based on the work we will perform on this other information, we conclude there is a material misstatement of other information, we are required to report that fact to those charged with governance.

### **Responsibilities of Management and Those Charged with Governance for the Consolidated Financial Statements**

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

In preparing the consolidated financial statements, management is responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the Group's financial reporting process.

### **Auditor's Responsibilities for the Audit of the Consolidated Financial Statements**

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Canadian generally accepted auditing standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As part of an audit in accordance with Canadian generally accepted auditing standards, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure, and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide those charged with governance with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

The engagement partner on the audit resulting in this independent auditor's report is Kwan-Ho Song, CPA, CA.

The logo for Ernst & Young LLP is written in a black, cursive script font. The letters are fluid and connected, with a prominent 'E' and 'Y'.

Chartered Professional Accountants  
Licensed Public Accountants

February 24, 2020  
Toronto, Canada

**NUVO PHARMACEUTICALS INC.**  
**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**

<i>(Canadian dollars in thousands)</i>	<i>Notes</i>	<b>As at December 31, 2019</b>	<b>As at December 31, 2018 RESTATED Note 5</b>
		<b>\$</b>	<b>\$</b>
<b>ASSETS</b>			
<b>CURRENT</b>			
Cash and cash equivalents	25	23,019	28,074
Accounts receivable	25	14,387	4,957
Inventories	6	7,927	13,747
Other current assets	7	1,795	3,007
Contract assets	3, 5, 25, 26	90	8,642
<b>TOTAL CURRENT ASSETS</b>		<b>47,218</b>	<b>58,427</b>
<b>NON-CURRENT</b>			
Contract assets	3, 5, 25, 26	312	18,110
Right-of-use assets	4, 8	573	-
Property, plant and equipment	9	3,850	4,659
Intangible assets	5, 10	83,558	95,234
Goodwill	5, 11	27,580	27,982
<b>TOTAL ASSETS</b>		<b>163,091</b>	<b>204,412</b>
<b>LIABILITIES AND EQUITY</b>			
<b>CURRENT</b>			
Accounts payable and accrued liabilities	15, 17	9,678	23,800
Current portion of long-term debt	5, 12	18,385	6,821
Current portion of other obligations	14	372	408
Current income tax liabilities	23	8	82
<b>TOTAL CURRENT LIABILITIES</b>		<b>28,443</b>	<b>31,111</b>
Long-term debt	5, 12	104,992	117,386
Other obligations	5, 14	3,036	1,264
Derivative liabilities	13	2,229	33,646
Deferred income tax liabilities	23	299	299
<b>TOTAL LIABILITIES</b>		<b>138,999</b>	<b>183,706</b>
<b>EQUITY</b>			
Common shares	16	184,764	184,764
Contributed surplus	16, 17	15,892	15,435
Accumulated other comprehensive income (loss) (AOCI)		(63)	369
Deficit		(176,501)	(179,862)
<b>TOTAL EQUITY</b>		<b>24,092</b>	<b>20,706</b>
<b>TOTAL LIABILITIES AND EQUITY</b>		<b>163,091</b>	<b>204,412</b>

Note 24, *Commitments and Contingencies*  
See accompanying Notes.

On behalf of the Nuvo Board of Directors:

*/s/ Anthony E. Dobranowski*

Anthony E. Dobranowski  
Director

*/s/ Daniel N. Chicoine*

Daniel N. Chicoine  
Director



**NUVO PHARMACEUTICALS INC.  
CONSOLIDATED STATEMENTS OF INCOME (LOSS) AND  
COMPREHENSIVE INCOME (LOSS)**

		Year ended December 31, 2019	Year ended December 31, 2018
<i>(Canadian dollars in thousands, except per share and share figures)</i>	<i>Notes</i>	<i>\$</i>	<i>\$</i>
<b>REVENUE</b>			
Product sales	3, 26	51,884	17,569
License revenue	3, 26	15,758	2,262
Contract revenue	3, 26	1,904	167
<b>Total revenue</b>		<b>69,546</b>	<b>19,998</b>
Cost of goods sold	6, 17, 21	26,472	8,638
<b>Gross profit</b>		<b>43,074</b>	<b>11,360</b>
<b>OPERATING EXPENSES</b>			
Sales and marketing	21	9,796	-
General and administrative expenses	17, 21	17,840	16,238
Amortization of intangibles	10	8,356	1,989
Net interest expense (income)	18	10,305	(32)
<b>Total operating expenses</b>		<b>46,297</b>	<b>18,195</b>
<b>OTHER EXPENSES (INCOME)</b>			
Change in fair value of derivative liabilities	13	(31,070)	-
Change in fair value of contingent and variable consideration (gain)	14	1,216	(518)
Impairment	5, 10	23,780	-
Loss on disposal of contract assets		-	452
Foreign currency gain		(2,598)	(429)
Other losses	19	2,060	-
<b>Net income (loss) before income taxes</b>		<b>3,389</b>	<b>(6,340)</b>
Income tax expense (recovery)	3, 23	28	(187)
<b>NET INCOME (LOSS)</b>		<b>3,361</b>	<b>(6,153)</b>
<b>Other comprehensive income (loss) to be reclassified to net income (loss) in subsequent periods</b>			
Unrealized gain (loss) on translation of foreign operations		(432)	370
<b>TOTAL COMPREHENSIVE INCOME (LOSS)</b>		<b>2,929</b>	<b>(5,783)</b>
<b>Net income (loss) per common share</b>			
- basic	20	0.30	(0.54)
- diluted	20	(0.51)	(0.54)
<b>Average number of common shares outstanding (in thousands)</b>			
- basic	20	11,388	11,443
- diluted	20	43,457	11,443

See accompanying Notes.

**NUVO PHARMACEUTICALS INC.  
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

	Common Shares		Contributed	AOCI	Deficit	Total	
	000s	\$	\$	\$	\$	\$	
<i>(Canadian dollars in thousands, except for number of shares)</i>	<i>Notes</i>	<i>16, 17</i>	<i>16, 17</i>	<i>16, 17</i>			
Balance, December 31, 2017		11,551	185,266	14,763	(1)	(174,877)	25,151
Balance, January 1, 2018, as previously reported		11,551	185,266	14,763	(1)	(174,877)	25,151
Impact of change in accounting policy (See Note 3)		-	-	-	-	1,168	1,168
Adjusted balance, January 1, 2018		11,551	185,266	14,763	(1)	(173,709)	26,319
Employee contribution to Share Purchase Plan		36	123	-	-	-	123
Employer's portion of Share Purchase Plan		36	123	-	-	-	123
Stock option compensation expense		-	-	672	-	-	672
Unrealized loss on translation of foreign operations		-	-	-	370	-	370
Normal course issuer bid		(235)	(748)	-	-	-	(748)
Net loss		-	-	-	-	(6,153)	(6,153)
Balance, December 31, 2018		11,388	184,764	15,435	369	(179,862)	20,706
Stock option compensation expense		-	-	457	-	-	457
Unrealized loss on translation of foreign operations		-	-	-	(432)	-	(432)
Net income		-	-	-	-	3,361	3,361
<b>Balance, December 31, 2019</b>		<b>11,388</b>	<b>184,764</b>	<b>15,892</b>	<b>(63)</b>	<b>(176,501)</b>	<b>24,092</b>

See accompanying Notes.

**NUVO PHARMACEUTICALS INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

<i>(Canadian dollars in thousands)</i>	<i>Notes</i>	Year ended December 31, 2019	Year ended December 31, 2018
		\$	\$
<b>OPERATING ACTIVITIES</b>			
Net income (loss)		3,361	(6,153)
Items not involving current cash flows:			
Depreciation and amortization	21	9,546	2,493
Impairment	3, 5, 10	23,780	-
Accreted non-cash interest, net and amortization of deferred financing fees	12	4,228	-
Modification of debt	12	2,166	-
Change in fair value of derivative liabilities	13	(31,070)	-
Capitalization of deferred financing fees		-	(3,804)
Equity-settled stock-based compensation	17	457	795
Unrealized foreign exchange gain		(2,457)	(663)
Change in fair value of contingent and variable consideration	14	1,216	(518)
Change in allowance for doubtful accounts		(107)	-
Inventory write-down	6	333	31
Inventory step-up expense	6	4,979	-
Disposal of fixed assets	9	38	-
Lease disposal		(38)	-
Disposal of contract assets		-	452
Disposal of development costs		-	16
Benefit for deferred income taxes		-	(225)
		16,432	(7,576)
Net change in non-cash working capital	22	(14,069)	4,061
<b>CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES</b>		<b>2,363</b>	<b>(3,515)</b>
<b>INVESTING ACTIVITIES</b>			
Aralez Transaction	5	(2,547)	(138,471)
Acquisition of property, plant and equipment	9	(83)	(300)
Resultz U.S. asset purchase		-	(1,876)
Disposal of short-term investments		-	2,000
<b>CASH USED IN INVESTING ACTIVITIES</b>		<b>(2,630)</b>	<b>(138,647)</b>
<b>FINANCING ACTIVITIES</b>			
Principal payment on debt	12	(3,354)	-
Cash payment of lease liabilities		(389)	-
Deerfield Financing		-	161,658
Normal course issuer bid		-	(748)
Issuance of common shares		-	123
Repayment of capital lease and other obligations		-	(2)
<b>CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES</b>		<b>(3,743)</b>	<b>161,031</b>
Effect of exchange rate changes on cash		(1,045)	807
Net change in cash during the period		(5,055)	19,676
Cash and cash equivalents, beginning of year		28,074	8,398
<b>CASH AND CASH EQUIVALENTS, END OF YEAR</b>		<b>23,019</b>	<b>28,074</b>

See accompanying Notes.

**Supplemental Cash Flow Information<sup>1</sup>**

Interest received	220	87
Interest paid	5,796	5
Income taxes paid	41	37

<sup>1</sup>. Amounts have been reflected as operating cash flows in the Consolidated Statements of Cash Flows.

# NUVO PHARMACEUTICALS® INC.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Unless noted otherwise, all amounts shown are in thousands of Canadian dollars, except per share amounts.

### 1. NATURE OF BUSINESS

Nuvo Pharmaceuticals Inc. (Nuvo or the Company) is a Canadian focused, healthcare company with global reach and a diversified portfolio of commercial products. The Company targets several therapeutic areas, including pain, allergy and dermatology. The Company's strategy is to in-license and acquire growth-oriented, complementary products for Canadian and international markets. The Company's registered office and principal place of business is located at 6733 Mississauga Road, Suite 610, Mississauga, Ontario, Canada, L5N 6J5, its international operations are located in Dublin, Ireland and its manufacturing facility is located in Varennes, Québec, Canada. The Varennes facility operates in a Good Manufacturing Practices (GMP) environment respecting the U.S., Canada and E.U. GMP regulations and is regularly inspected by Health Canada and the U.S. Food and Drug Administration (FDA).

#### **The Aralez Transaction**

On December 31, 2018, the Company announced the acquisition of a portfolio of more than 20 revenue-generating products from Aralez Pharmaceuticals Inc., (Aralez) (the Aralez Transaction). The Aralez Transaction included the acquisition of Aralez Pharmaceuticals Canada Inc. (Aralez Canada), a growing business that includes the products Cambia®, Blexten®, as well as the Canadian distribution rights to Resultz® and provides a platform for the Company to acquire and launch additional commercial products in Canada. The Company also acquired the worldwide rights and royalties from licensees for Vimovo®, Yosprala and the ex-U.S. product rights to Suvexx™.

#### **The Deerfield Financing**

The aggregate purchase price paid by the Company for the Aralez Transaction was \$146.4 million (US\$110 million, subject to certain working capital and indebtedness adjustments). The Company satisfied the purchase price through funding provided by certain funds managed by Deerfield Management Company, L.P. (Deerfield), a global, healthcare-specialized investor (the Deerfield Financing). (See Note 12, *Loans and Borrowings* and Note 13, *Derivative Liabilities*).

### 2. BASIS OF PREPARATION

#### **Statement of Compliance**

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

The policies applied to these Consolidated Financial Statements are based on IFRS, which have been applied consistently to all periods presented. These Consolidated Financial Statements were issued and effective as at February 24, 2020, the date the Board of Directors approved these Consolidated Financial Statements.

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### **Basis of Measurement**

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

#### **Use of Judgments and Estimates**

##### ***Judgments***

In the process of applying the Company's accounting policies, management has made the following judgments, which have the most significant effect on the amounts recognized in these Consolidated Financial Statements.

(i) *Functional Currency*

The Company and its subsidiary companies use judgment when determining its functional currency. This determination includes an assessment of the indicators as prescribed in International Accounting Standards 21, *The Effects of Changes on Foreign Exchange Rates* (IAS 21). However, applying the factors in IAS 21 does not always result in a clear indication of functional currency. Where IAS 21 factors indicate differing functional currencies, management uses judgment in the ultimate determination of the functional currency.

(ii) *Impairment of Non-financial Assets*

Impairment exists when the carrying value of an asset or cash-generating unit (CGU) exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The value in use calculations are based on discounted cash flow (DCF) models. The cash flows are derived from the budget and do not include restructuring activities that the Company is not yet committed to or significant future investments that will enhance the performance of the assets of the CGU being tested. The recoverable amount is sensitive to the discount rate used for the DCF model, as well as the expected future cash-inflows and outflows and the growth rate used for extrapolation purposes. These estimates are most relevant to goodwill and other intangibles recognized by the Company. The key assumptions used to determine the recoverable amount for the different CGUs, including a sensitivity analysis, are disclosed and further explained in (See Note 10, *Intangible Assets* and Note 11, *Goodwill*).

(iii) *Determination of Groups of CGUs*

The determination of the Company's CGUs, group of CGUs and their associated assets involves judgement and is based on how senior management monitors the operations of the Company. The Company has determined that the lowest aggregation of assets that generate largely independent cash inflows include individual patents, brands and licenses. For purposes of the Company's goodwill impairment testing, the Company has grouped certain CGUs to test at the operating segment level, the lowest level at which management monitors goodwill for internal management purposes. The Company has used significant judgement in determining the groups of CGUs. The Company allocates goodwill to the groups of CGUs that are expected to benefit from the synergies of the business combination (See Note 11, *Goodwill*).

### **Estimates**

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below. The Company based its assumptions and estimates on parameters available when these Consolidated Financial statements were prepared. Existing circumstances and assumptions about future developments; however, may change due to market changes or circumstances arising that are beyond the control of the Company. Such changes are reflected in the assumptions when they occur.

(i) *Revenue Recognition and Returns*

As is typical in the pharmaceutical industry, the Company's royalty streams are subject to a variety of sales deductions including rebates, discounts, incentives and product returns. Sales deductions are typically estimates resulting from judgments about future events and uncertainties and rely on management assumptions. Sales deductions are recorded in the same period that the revenues are recognized.

The provision for sales returns is an estimate used in the recognition of revenue. The Company has a return policy that allows wholesalers to return product within a specified period prior to and subsequent to the expiration date. Provisions for returns are recognized in the period in which the underlying sales are recognized, as a reduction of product sales revenue. The Company estimates provisions for returns based upon historical return data of each product to determine return percentages and current market conditions, representing management's best estimate. As historical experience may not always be an accurate indicator of future returns, the Company continually monitors return provisions and makes adjustments when it believes that actual product returns may differ from established reserves.

(ii) *Determination of Amortized Cost for Debt Liabilities*

The Company's Amortization Loan, Bridge Loan and host liability of the Convertible Loan (the Loans) are initially measured at fair value using a discounted cash flow model that considers the present value of the contractual cash flows using a risk-adjusted discount rate. The discounted cash flow model requires management to estimate the timing of debt repayments and the effective interest rate related to the debts.

For financial liabilities held at amortized cost, when the Company revises its estimates and timing of payments, it will adjust the gross carrying amount of the amortized cost of a financial liability to reflect actual and revised estimated contractual cash flows. The Company recalculates the gross carrying amount of the amortized cost of the financial liability as the present value of the estimated future contractual cash flows that are discounted at the financial instrument's original effective interest rate. The adjustment is recognized in income.

The Company has made assumptions regarding the timing and amount of the payments, which differ significantly depending upon whether the Vimovo U.S. minimum annual royalty is maintained or lost.

(iii) *Determination of Fair Value for Derivative Liabilities*

The fair value of the Company's Warrants are initially recognized and subsequently revalued at each reporting period using the Black-Scholes option pricing model. The conversion feature that accompanies the Company's Convertible Loan is valued by determining the difference between the fair value of the hybrid Convertible Loan contract, determined using an income approach with a binomial lattice model and the fair value of the host liability contract, determined using a discounted cash flow model. The Warrants and conversion feature are measured at fair value through profit and loss at each period end. (See Note 13, *Derivative Liabilities*).

(iv) *Useful Lives of Intangible Assets*

Management estimates the useful lives of intangible assets based on the period during which the assets are expected to be available for use and also estimates their recoverability to assess if there has been an impairment. The amounts and timing of recorded expenses for amortization and impairments of intangible assets for any period are affected by these estimates. The estimates are reviewed at least annually and are updated if expectations change as a result of commercial obsolescence, generic threats and legal or other limits to use. It is possible that changes in these factors may cause significant changes in the estimated useful lives of the Company's intangible assets in the future.

(v) *Valuation of Inventory*

The Company estimates future product sales when establishing appropriate provisions for inventory. In making these estimates, the Company considers the product life of inventory and the profitability of recent sales of inventory. In many cases, products sold by the Company turn quickly and inventory on-hand values are low, which reduces the risk of inventory obsolescence. Management relies on expiry dates in the determination of realizable value of inventory. (See Note 6, *Inventories*).

(vi) *Share-based Payments*

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

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

Several assumptions are used in the underlying calculation of fair values of the Company's stock options and share appreciation rights using the Black-Scholes option pricing model, including the expected life of the option, stock-price volatility and forfeiture rates. (See Note 17, *Stock-based Compensation and Other Stock-based Payments*).

(vii) *Contingent Consideration*

Contingent consideration, resulting from business combinations, is valued at fair value at the acquisition date as part of the business combination. When the contingent consideration meets the definition of a financial liability, it is subsequently remeasured to fair value at each reporting date. The determination of the fair value is based on discounted cash flows. The key assumptions take into consideration the probability of meeting each performance target and the discount factor (see Note 14, *Other Obligations*).

## Basis of Consolidation

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

	<b>% Ownership</b>
Aralez Pharmaceuticals Canada Inc.	<b>100%</b>
Nuvo Pharmaceuticals (Ireland) Designated Activity Company	<b>100%</b>

All significant intercompany balances and transactions have been eliminated upon consolidation.

## Foreign Currency Translation

The Company and its subsidiary companies each determine their functional currency based on the currency of the primary economic environment in which they operate. The Company's functional currency is the Canadian dollar.

(i) *Transactions*

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

(ii) *Translation into Presentation Currency*

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

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

## Cash and Cash Equivalents

Cash includes cash on hand and current balances with banks and cash equivalents include money market mutual funds. These are readily convertible into known amounts of cash and have an insignificant risk of changes in value. The cost basis of cash approximates its fair value.

## Inventories

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

An inventory provision is estimated by management based on expected future sales and expiry dates and is recorded in cost of goods sold (COGs). Subsequent changes to provisions are recorded in COGs in the Consolidated Statements of Income (Loss) and Comprehensive Income (Loss).

## Contract Assets

Contract assets represent the present value of current and future guaranteed minimum sales-based royalties, upfront fees and milestone payments that are expected to be received over the life of the licensing agreements. Contract asset balances are reduced as the contractual minimums are realized throughout the life of the agreement.

The timing of revenue recognition, billings and cash collections results in accounts receivable and unbilled receivables (contract assets). Generally, billing occurs subsequent to revenue recognition, resulting in accounts

receivable. The Company's contract assets relate to license revenue attributable to minimum guaranteed sales-based royalties, upfront fees and milestone payments that have not been billed at the reporting date. Unbilled receivables (contract assets) will be billed (and subsequently transferred to accounts receivable) in accordance with the agreed-upon contractual terms.

### Property, Plant and Equipment

Property, plant and equipment (PP&E) is recorded at cost.

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

Buildings	10 - 25 years	Straight-line
Leasehold improvements	Term of lease	Straight-line
Furniture and fixtures	5 years	Straight-line
Computer equipment and software	1 - 3 years	Straight-line
Production, laboratory and other equipment	3 - 12 years	Straight-line

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

### Intangible Assets

Intangible assets acquired in a business combination are recognized separately from goodwill at their fair value at the date of acquisition, which is considered to be at cost. Following initial recognition, intangible assets are carried at cost, less any accumulated amortization and accumulated impairment losses. Amortization commences when the intangible asset is available for use. For patented assets, amortization is computed on a straight-line basis over the intangible asset's estimated useful life, which cannot exceed the lesser of the remaining patent life and 20 years. For license assets, amortization is computed on a straight-line basis over the intangible asset's estimated useful life, which management estimates based on the license period and opportunity for license renewal. The estimated useful lives are as follows:

Brand	Indefinite life	-
Patents	5 - 20 years	Straight-line
Licenses	4 - 27 years	Straight-line

### Goodwill and Business Combinations

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred, which is measured at the acquisition date fair value and the amount of any non-controlling interest in the acquiree.

When the Company acquires a business, it assesses the classification and designation of financial assets and liabilities assumed in accordance with the contractual terms, economic circumstances and conditions as at the acquisition date. Any contingent consideration to be transferred by the acquirer will be recognized at fair value at the acquisition date. All contingent consideration (unless classified as equity) is subsequently remeasured to fair value at each reporting period end, with the changes in fair value recognized in profit or loss.

Goodwill is initially measured at cost over the net identifiable assets acquired and liabilities assumed. If the fair value of the net assets acquired is in excess of the aggregate consideration transferred, the Company reassesses whether it has correctly identified all of the assets acquired and all of the liabilities assumed and reviews the procedures used to measure the amounts recognized at the acquisition date. If the reassessment still results in an excess of the fair value of net assets acquired over the aggregate consideration transferred, then the gain is recognized in net income (loss).

After initial recognition, goodwill is measured at cost less any accumulated impairment losses. See below for a description of the Company's impairment testing procedures.



## **Impairment of Non-financial Assets**

The Company assesses, at each reporting date, whether there is an indication that an asset may be impaired. If any indication exists, or when annual impairment testing for an asset is required, the Company estimates the asset's recoverable amount. An asset's recoverable amount is the higher of an asset's or CGU's fair value less costs of disposal and its value in use. The recoverable amount is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets. When the carrying amount of an asset or CGU exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pretax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

The Company bases its impairment calculation on the most recent budgets and forecast calculations, which are prepared separately for each of the Company's CGUs to which the individual assets are allocated. A long-term growth rate is calculated and applied to project future cash flows. Impairment losses of continuing operations are recognized in the Consolidated Statements of Income (Loss) and Comprehensive Income (Loss) in expense categories consistent with the function of the impaired asset. For assets excluding goodwill, an assessment is made at each reporting date to determine whether there is an indication that previously recognized impairment losses no longer exist or have decreased. If such indication exists, the Company estimates the asset's or CGU's recoverable amount. A previously recognized impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's recoverable amount since the last impairment loss was recognized. The reversal is limited so that the carrying amount of the asset does not exceed its recoverable amount, nor exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognized for the asset in prior years. Such reversal is recognized in the Consolidated Statements of Income (Loss) and Comprehensive Income (Loss).

Goodwill is tested for impairment annually as at December 31 and when circumstances indicate that the carrying value may be impaired. Impairment is determined for goodwill by assessing the recoverable amount of each CGU (or group of CGUs) to which the goodwill relates. When the recoverable amount of the CGU is less than its carrying amount, an impairment loss is recognized. Impairment losses relating to goodwill cannot be reversed in future periods.

## **Leases**

Effective January 1, 2019, the Company adopted IFRS 16 - Leases (See Note 4, *Changes in Accounting Policies*). The following are policies on leases under IFRS 16.

### *Leased assets*

Leased assets are capitalized at the commencement date of the lease and are comprised of the initial lease liability amount, initial direct costs incurred when entering into the lease, less any lease incentives received.

### *Leased liabilities*

The lease liability is measured at the present value of the fixed and variable lease payments that depend on an index or rate, net of cash lease incentives that are unpaid. Lease payments are apportioned between the finance charges and reduction of the lease liability using the incremental borrowing rate implicit in the lease to achieve a constant rate of interest on the remaining balance of the liability.

Lease modifications are accounted for as either a new lease with an effective date of the modification or as a change in the accounting for the existing lease.

The policy prior to January 1, 2019 was as follows:

### *IAS 17 - Leases*

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

## Financial Instruments

There are three measurement categories in which the Company classifies its financial assets:

- *Amortized cost*: Financial instruments that are held for collection of contractual cash flows, where those cash flows represent solely payments of principal and interest, are measured at amortized cost. Interest income (expense) from these financial instruments is recorded in net income (loss) using the effective interest rate method.
- *Fair value through other comprehensive income (FVOCI)*: Debt instruments that are held for collection of contractual cash flows and for selling the financial instruments, where the financial instruments' cash flows represent solely payments of principal and interest, are measured at FVOCI. Movements in the carrying amount are taken through OCI, except for the recognition of impairment gains or losses, interest income and foreign exchange gains and losses that are recognized in net income (loss). When the financial instrument is derecognized, the cumulative gain or loss previously recognized in OCI is reclassified from equity to net income (loss) and recognized in other gains (losses). Interest income (expense) from these financial instruments is included in interest using the effective interest rate method. Foreign exchange gains (losses) are presented in other gains (losses) and impairment expenses in other expenses (income).
- *Fair value through profit (loss) (FVTPL)*: Financial instruments that do not meet the criteria for amortized cost or FVOCI are measured at FVTPL. A gain or loss on a financial instrument that is subsequently measured at FVTPL and is not part of a hedging relationship is recognized in net income (loss) and presented net in comprehensive income (loss) within other gains (losses) in the period in which it arises.

Financial liabilities are either classified as amortized cost or FVTPL. For financial liabilities held at amortized cost, when the Company revises its estimates of payments, it will adjust the gross carrying amount of the amortized cost of a financial liability to reflect actual and revised estimated contractual cash flows. The Company recalculates the gross carrying amount of the amortized cost of the financial liability as the present value of the estimated future contractual cash flows that are discounted at the financial instrument's original effective interest rate. The adjustment is recognized in income.

The Company classifies its financial instruments as follows:

- Cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, long-term debt and other obligations are measured at amortized cost. Interest income and interest expense are recorded in net income (loss), as applicable.
- Embedded derivatives, including the conversion feature of the Convertible Loan and the prepayment option on the Bridge Loan and Amortization Loan are separated from the host contract and accounted for separately if the host contract is not a financial asset and certain criteria are met. The conversion feature, prepayment option and the Warrants are initially measured at fair value and subsequently measured at FVTPL.

## Impairment of Financial Assets

The Company assesses, on a forward-looking basis, the expected credit losses associated with its financial instruments carried at amortized cost and FVOCI. The impairment methodology applied depends on whether the asset originated from a contract that is in the scope of IFRS 15 - *Revenue from Contracts with Customers* (IFRS 15) or if there have been significant increases in credit risk. The Company was required to revise its impairment methodology under IFRS 9 - Financial Instruments (IFRS 9) for each of the following classes of assets:

- *Accounts receivable and contract assets*: For accounts receivable and contract assets, the Company applies the simplified approach to providing for expected credit losses prescribed by IFRS 9, which requires the use of the lifetime expected loss provision for all accounts receivable and contract assets within the scope of IFRS 15. The Company has established a provision based on the Company's historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.
- *Cash equivalents*: For cash equivalents and short-term investments at amortized cost, the Company applies the general approach to providing for expected credit losses. These instruments are considered to be low credit risk, and therefore, the impairment provision is determined using a 12-month expected credit loss basis.

## Comprehensive Income

Comprehensive income (loss) is the change in equity from transactions and other events and circumstances from non-shareholder sources. Other comprehensive income (loss) refers to items recognized in comprehensive income

(loss), but that are excluded from net income (loss) calculated in accordance with IFRS. The resulting changes from translating the financial statements of foreign operations into Canadian dollars, the Company's presentation currency, are recognized in comprehensive income (loss) for the year.

## **Revenue Recognition**

### *Product Sales*

Revenue from product sales is recognized upon shipment of the product to the customer, provided transfer of title to the customer occurs upon shipment and provided the Company has not retained any significant risks of ownership or future obligations with respect to the product shipped, the price is fixed and determinable and collection is reasonably assured.

Rights of return give rise to variable consideration. The variable consideration is estimated at contract inception using the expected value method, as this best predicts the amount of variable consideration to which the Company is entitled to receive. The variable consideration is constrained to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when any uncertainty is subsequently resolved. For products that are expected to be returned, a sales return provision is recognized as a reduction of revenue at the time control of the products is transferred to the customers.

The Company may provide discounts and rebates, to its customers, which give rise to variable consideration. The variable consideration is constrained to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when any uncertainty is subsequently resolved. The application of the constraint on variable consideration increases the amount of revenue that will be deferred. The Company applies the most likely amount method estimating discounts and rebates provided to customers using contracted rates. Consequently, revenue is recognized net of reserves for estimated sales discounts and rebates.

### *License Revenue*

The Company has tied the sales-based royalties to the distinct performance obligation to which it relates - the license of intellectual property rights to the Company's commercial products. With the application of the sales-based royalties exception, sales-based royalties and milestone payments contingent on sales-based thresholds are recognized when the subsequent sales occur.

The license of intellectual property rights includes minimum guaranteed sales-based royalties and the Company assesses the contractual minimums as fixed consideration (where a significant reversal is remote), the Company recognizes all of the contractual minimums when control of the intellectual property rights is transferred and a contract asset is recognized. Any sales-based royalties earned, in excess of the contractual minimums, would be recognized in accordance with the royalty exception (when the subsequent sales occur). This can result in significant differences in the timing of revenue recognition and the corresponding receipt of cash flows.

### *Contract Revenue*

Revenue from contracted services is generally recognized as the contracted services are performed and the related expenditures are incurred pursuant to the terms of the agreement and provided collectability is reasonably assured.

### *Government Assistance*

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

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

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

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

Diluted net income or loss per common share is calculated assuming the weighted average number of common shares outstanding during the year is increased to include the number of additional common shares that would have been outstanding if the dilutive potential shares had been issued. The dilutive effect of warrants, stock options and convertible debt is determined using the treasury-stock method. The treasury-stock method assumes that the

proceeds from the exercise of warrants and options are used to purchase common shares at the volume weighted average market price during the year. The dilutive effect of convertible securities is determined using the “if-converted” method. The “if-converted” method assumes that the convertible securities are converted into common shares at the beginning of the period and all income charges related to the convertible securities are added back to income.

### **Income Taxes**

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

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

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

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

A deferred tax asset is recognized for unused tax losses, tax credits and deductible temporary differences to the extent it is probable that future taxable income will be available against which they can be utilized. Deferred tax assets are reviewed as at each reporting date and are reduced to the extent it is no longer probable the related tax benefit will be realized. Within the scope of IAS 12, *Income Taxes*, the Company recognizes its investment tax credits as a reduction against current income tax expense.

### **Stock-based Compensation and Other Stock-based Payments**

The Company has three 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 Company’s Share Appreciation Rights Plan was discontinued on March 1, 2016. The last tranche vested January 1, 2019 with nominal value. See Note 17, *Stock-based Compensation and Other Stock-based Payments*.

#### *Share Incentive Plan*

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

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

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

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

#### **Issuance Costs of Debt Instruments**

The Company records issuance costs of debt instruments against the fair value of the debt and will amortize the debt issuance costs over the remaining term of the debt.

#### **Issuance Costs of Equity Instruments**

The Company records issuance costs of equity instruments against the equity instrument that was issued. For derivative instruments, the cost of issuance is expensed immediately.

#### **Operating Segments**

IFRS 8 - *Operating Segments* (IFRS 8) requires operating segments to be determined based on internal reports that are regularly reviewed by the chief operating decision maker for the purpose of allocating resources to the segment and to assessing its performance. Pursuant to the Aralez Transaction, the Company determined that the operating segments' structure reviewed by the chief operating decision maker required adjustment. For the year ended December 31, 2019, the Company had three operating segments: Commercial Business, Production and Service Business and Licensing and Royalty Business (See Note 27, *Segment Reporting*). During the year ended December 31, 2018, the Company operated as one segment: pharmaceutical and healthcare products. The Company modified this disclosure on a retrospective basis.

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

Certain new standards, interpretations, amendments and improvements to existing standards were issued by the IASB or IFRS Interpretations Committee that are mandatory for fiscal periods beginning on or after January 1, 2020.

(a) *Amendments to IFRS 3: Definition of a Business*

In October 2018, the IASB issued amendments to the definition of a business in IFRS 3 - *Business Combinations* to help entities determine whether an acquired set of activities and assets is a business or not. They clarify the minimum requirements for a business, remove the assessment of whether market participants are capable of replacing any missing elements, add guidance to help entities assess whether an acquired process is substantive, narrow the definitions of a business and of outputs, and introduce an optional fair value concentration test. New illustrative examples were provided along with the amendments. Since the amendments apply prospectively to transactions or other events that occur on or after the date of first application, the Company will not be affected by these amendments on the date of transition.

(b) *Amendments to IAS 1 and IAS 8: Definition of Material*

In October 2018, the IASB issued amendments to IAS 1, *Presentation of Financial Statements* and IAS 8, *Accounting Policies, Changes in Accounting Estimates and Errors* to align the definition of 'material' across the standards and to clarify certain aspects of the definition. The new definition states that, "Information is material if omitting, misstating or obscuring it could reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements, which provide financial information about a specific reporting entity." The amendments to the definition of material is not expected to have a significant impact on the Company's Consolidated Financial Statements.

## **4. CHANGES IN ACCOUNTING POLICIES**

### **IFRS 16 - Leases**

In January 2016, the IASB issued IFRS 16 - *Leases* (IFRS 16), which replaced IAS 17 - *Leases* (IAS 17). This standard introduced a single-lessee accounting model and requires a lessee to recognize assets and liabilities for all leases with a term of more than 12 months, unless the underlying asset is of low value. A lessee is required to recognize a right-of-use asset representing its right to use the underlying asset and a lease liability representing its obligation to make lease payments. The standard was effective for annual periods beginning on or after January 1, 2019 and has been adopted by the Company using the modified retrospective approach where comparative figures were not restated.

As a result of adopting IFRS 16, the Company recognized right-of-use assets of \$2.8 million (See Note 8, *Right-of-use Assets*), lease liabilities of \$2.8 million and a \$40 reduction to prepaid expenses as a result of the leasing arrangements in existence at January 1, 2019.

The right to use the leased asset was measured at the amount of the lease liability, using the Company's incremental borrowing rate on January 1, 2019, representing what the Company would have to pay to borrow the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The weighted average interest rate used to measure the lease liabilities as at January 1, 2019 was 8.03%.

The Company elected to use the following practical expedients and accounting policy choices on adoption of IFRS 16 on all its leases:

- (i) In accordance with IFRS 16.C3, the election is being taken to not reassess whether a contract is, or contains, a lease at the date of initial application and instead to only apply IFRS 16 to contracts that were in the scope of IAS 17;
- (ii) In accordance with IFRS 16.C10(b), the election is being taken to rely on the Provisions, Contingent Liabilities and Contingent Assets (IAS 37) assessment of whether leases are onerous instead of performing an impairment review;
- (iii) In accordance with IFRS 16.C10(c), the election is being taken to exclude leases for which the term ends within 12 months from January 1, 2019;
- (iv) In accordance with IFRS 16.C10(d), the election is being taken to exclude initial direct costs from the measurement of the right-of-use asset on January 1, 2019;
- (v) In accordance with IFRS 16.15, the election is being taken, by class of underlying asset, not to separate non-lease components from lease components and instead account for each lease component and any associated non-lease components as a single lease component where the non-lease components are not significant compared to the lease components;
- (vi) In accordance with IFRS 16.5(a), the election is being taken to not recognize a right-of-use asset and lease liability for leases for which the lease has a term less than 12 months; and
- (vii) In accordance with IFRS 16.5(b), the election is being taken to not recognize a right-of-use asset and lease liability for leases for which the underlying asset is of low value when new.

The following is a reconciliation between the Company's commitments disclosed applying IAS 17 as at December 31, 2018 and the lease liabilities as at January 1, 2019:

	\$
Commitments as at December 31, 2018	22,001
Minimum future payments not related to lease payments	(18,302)
Gross lease liabilities as at January 1, 2019	3,699
Discounting	(894)
<b>Present value of finance lease liabilities as at January 1, 2019</b>	<b>2,805</b>

## 5. BUSINESS COMBINATIONS

### Aralez Transaction

On December 31, 2018, the Company acquired 100% of the issued and outstanding shares of Aralez Canada, as well as control of a global portfolio of pharmaceutical products from Aralez. The acquisition included Aralez's Canadian specialty pharmaceutical business, formerly known as Tribute Pharmaceuticals Canada Inc. and worldwide rights and royalties from licensees for Vimovo, Yosprala and the ex-U.S. product rights to Suvexx™ (marketed as Treximet in the U.S.).

In the year ended December 31, 2019, the consideration for the acquisition and preliminary measurement of assets acquired and liabilities assumed was adjusted as additional information was obtained. Measurement period fair value adjustments of \$0.8 million are a result of closing working capital and indebtedness adjustments. In addition, measurement period fair value adjustments as a result of the assessment of the sales return provision, which also required a reclassification of accounts receivable, resulted in an adjustment in the amount of \$2.3 million.

These adjustments have been accounted for retrospectively, as required under IFRS 3 as at December 31, 2018.

The following consolidated accounts are impacted by adjustments:

	December 31, 2018 ORIGINAL	Measurement period - fair value adjustments	December 31, 2018 RESTATED
	\$	\$	\$
Accounts receivable	5,217	(260)	4,957
Accounts payable and accrued liabilities	20,976	2,824	23,800
Goodwill	24,898	3,084	27,982

The Company finalized its measurement of the assets acquired and liabilities assumed as a result of the Aralez Transaction on December 31, 2019. The consideration for the acquisition and measurement of assets acquired and liabilities assumed, in accordance with IFRS 3, is as follows:

#### Fair Value of Consideration

	\$
Amount settled in cash (US\$105,100)	143,379
Fair value of contingent and variable consideration (Note 14)	475
Plus: amounts due for cash, working capital and indebtedness adjustments	1,443
Plus: adjustment made to working capital for the period ended March 31, 2019	1,104
<b>Total consideration transferred<sup>(i)</sup></b>	<b>146,401</b>

(i) The US\$110 million purchase price was reduced for working capital delivered on close that was less than the target working capital, indebtedness assumed and cash assumed upon close.

#### Recognized Amounts of Identifiable Net Assets

	\$
Cash	4,908
Inventory	11,051
Contract asset	26,152
Property, plant and equipment	580
Patents	33,141
License agreements	51,055
Brands	1,578
Deferred tax asset	7,608
<b>Total identifiable net assets</b>	<b>136,073</b>
Other net working capital	(400)
Less liabilities assumed	(6,148)
Plus: adjustment to liabilities assumed for the year	290
Less: adjustment to liabilities and accounts receivable assumed for the year	(2,270)
Deferred tax liability	(7,907)
<b>Goodwill on acquisition</b>	<b>26,763</b>

#### Consideration Transferred

The Company satisfied the purchase price through funding provided by certain funds managed by Deerfield (See Note 1, *Nature of Business - The Deerfield Financing*).

The purchase agreement included contingent consideration in the form of 50% of the lifetime net earnings from monetization of the Yosprala product. The fair value of contingent consideration initially recognized represented the present value of the Company's probability-weighted estimate of cash outflows discounted at 12% (See Note 14, *Other Obligations*). In the year ended December 31, 2019, the liability was reduced and a recovery of \$0.5 million was recorded as a result of a reduction in the estimated future royalties in the Consolidated Statements of Income (Loss) and Comprehensive Income (Loss).

#### Identifiable Net Assets

The identifiable patents, license agreements and brands have been valued on a product-by-product basis using an income approach. Specifically, patents and licenses were valued using a multi-period excess earnings method

discounted at 12% and 20%, respectively. Brands were valued using a relief-from-royalty method incorporating a royalty rate of 3% and discount rates of 13% to 20%, respectively.

Patents and licenses are considered finite-lived intangible assets and will be amortized over their estimated useful lives. Amortization commenced on January 1, 2019. Useful lives are expected to range from 4 to 27 years. Brands were concluded to be indefinite-lived intangible assets, and as a result, are not being amortized.

The contract asset acquired is related to a minimum royalty the Company is entitled to receive from Horizon Therapeutics plc (Horizon), as per its license agreement for Vimovo in the U.S. The fair value of the contract asset initially recognized represents the present value of the Company's then future estimated minimum royalty payments discounted at a rate of 11%. As at June 30, 2019, the Company assessed that the contract asset attributable to the Company's U.S. Vimovo royalty was impaired and a \$23.6 million loss on the contract asset was recorded of which \$22.4 million was reversed from the related contract asset balance with the remainder recorded as an increase in liabilities. This increase in liabilities was subsequently reversed as a generic version of Vimovo did not launch in the U.S. in 2019.

### Reacquired Rights to Resultz

The Company reacquired the Canadian distribution rights to Resultz, which were previously owned by Aralez. Management determined the fair value of these rights to be \$2.5 million and are recognized as license agreements in identifiable net assets acquired.

### Goodwill

Goodwill is primarily related to growth expectations for Blexten, Cambia and Suvexx. Goodwill recognized will not be deductible for income tax purposes going forward.

### Resultz U.S. Asset Purchase

On January 12, 2018, the Company's wholly owned subsidiary, Nuvo Pharmaceuticals (Ireland) DAC (Nuvo Ireland) acquired control of the U.S. product and intellectual property rights to Resultz (the U.S. Patent). Resultz was cleared as a Class 1 medical device by the FDA in May 2017. As the product had not yet been commercially launched in the U.S. market, the transaction did not include any royalty streams. Further, Nuvo has not assumed a licensee agreement to sell and distribute Resultz as part of this transaction. The transaction has been accounted for as an asset acquisition. The cost of the U.S. Patent was US\$1.5 million (\$1.9 million), settled from cash-on-hand. The U.S. Patent will be amortized over the remaining patent life which expires on April 14, 2023. The purchase agreement included variable consideration related to future earnings associated with the U.S. Patent during the period from 2018 to 2034 and will be expensed as incurred.

## 6. INVENTORIES

Inventories consist of the following as at:

	December 31, 2019	December 31, 2018
	\$	\$
Raw materials	2,683	2,759
Work in process	571	833
Finished goods, net of provision <sup>(i)</sup>	4,673	10,155
	<b>7,927</b>	<b>13,747</b>

<sup>(i)</sup> Includes \$1.4 million of inventory step-up value for inventory acquired by the Company as part of the Aralez Transaction (December 31, 2018 - \$6.4 million).

During the year ended December 31, 2019, inventories in the amount of \$24.2 million were recognized as COGS [December 31, 2018 - \$6.9 million]. During the year ended December 31, 2019, inventories in the amount of \$333 were written down [December 31, 2018 - \$31] and there were no reversals of prior year write-downs during the years ended December 31, 2019 and 2018.

COGS for the year ended December 31, 2019 included \$5.0 million of inventory step-up expense [December 31, 2018 - \$nil] for the sale of inventory that was acquired by the Company as part of the Aralez Transaction. In accordance with IFRS 3, inventory was initially recognized at fair value less reasonable selling costs.



## 7. OTHER CURRENT ASSETS

Other current assets consist of the following as at:

	December 31, 2019	December 31, 2018
	\$	\$
Deposits	206	522
Prepaid expenses	999	1,756
Other receivables	590	729
	<b>1,795</b>	<b>3,007</b>

## 8. RIGHT-OF-USE ASSETS

The change in carrying value of the Company's right-of-use assets was as follows:

	\$
As at January 1, 2019	-
Transition to IFRS 16	2,845
Depreciation expense	(338)
Foreign exchange	(91)
Disposal of asset <sup>(i)</sup>	(1,843)
<b>As at December, 2019</b>	<b>573</b>

<sup>(i)</sup> In the year ended December 31, 2019, the right-of-use asset pertaining to a leased property in Ireland was transferred to an outside party resulting in a gain on disposal of \$38. The Company has no further obligations related to the leased property.

## 9. PROPERTY, PLANT AND EQUIPMENT

PP&E consists of the following as at:

Cost	Land	Buildings	Leasehold	Furniture	Computer	Production,	Total
	\$	\$	Improvements	& Fixtures	Equipment & Software	Laboratory & Other Equipment <sup>(ii)</sup>	
	\$	\$	\$	\$	\$	\$	\$
Balance, December 31, 2017	42	1,491	194	132	211	6,052	8,122
Acquired in Aralez Transaction (Note 5) <sup>(i)</sup>	-	-	343	60	27	150	580
Additions	-	139	73	36	24	15	287
Balance, December 31, 2018	42	1,630	610	228	262	6,217	8,989
Additions (disposals)	-	24	-	-	12	(194)	(158)
<b>Balance, December 31, 2019</b>	<b>42</b>	<b>1,654</b>	<b>610</b>	<b>228</b>	<b>274</b>	<b>6,023</b>	<b>8,831</b>
<b>Accumulated depreciation</b>							
Balance, December 31, 2017	-	917	3	59	166	2,694	3,839
Depreciation expense net of disposals	-	70	39	19	10	353	491
Balance, December 31, 2018	-	987	42	78	176	3,047	4,330
Depreciation expense net of disposals	-	82	172	82	52	263	651
<b>Balance, December 31, 2019</b>	<b>-</b>	<b>1,069</b>	<b>214</b>	<b>160</b>	<b>228</b>	<b>3,310</b>	<b>4,981</b>
Net book value as at December 31, 2018 <sup>(i)</sup>	42	643	568	150	86	3,170	4,659
<b>Net book value as at December 31, 2019<sup>(ii)</sup></b>	<b>42</b>	<b>585</b>	<b>396</b>	<b>68</b>	<b>46</b>	<b>2,713</b>	<b>3,850</b>

<sup>(i)</sup> The Company acquired \$0.6 million of PP&E upon close of the Aralez Transaction.

<sup>(ii)</sup> As at December 31, 2019, all of the Company's PP&E was located in Canada.

## 10. INTANGIBLE ASSETS

Intangible assets consist of the following as at:

Cost	Patents	Brand	Licenses	Development	Total
	\$	\$	\$	Costs	
				\$	\$
Balance, December 31, 2017	8,430	790	-	16	9,236
Acquired in Aralez Transaction (Note 5)	33,141	1,578	51,055	-	85,774
Acquired in Resultz U.S. asset purchase	1,876	-	-	-	1,876
Disposal	-	-	-	(16)	(16)
Foreign exchange movements	350	29	-	-	379
Balance, December 31, 2018	43,797	2,397	51,055	-	97,249
Impairment	(1,136)	(8)	(238)	-	(1,382)
Foreign exchange movements	(1,981)	(62)	-	-	(2,043)
<b>Balance, December 31, 2019</b>	<b>40,680</b>	<b>2,327</b>	<b>50,817</b>	<b>-</b>	<b>93,824</b>
<b>Accumulated amortization</b>					
Balance, December 31, 2017	-	-	-	-	-
Amortization expense	1,989	-	-	-	1,989
Foreign exchange movements	26	-	-	-	26
Balance, December 31, 2018	2,015	-	-	-	2,015
Amortization expense	5,449	-	2,907	-	8,356
Foreign exchange movements	(105)	-	-	-	(105)
Balance, December 31, 2019	7,359	-	2,907	-	10,266
Net book value as at December 31, 2018	41,782	2,397	51,055	-	95,234
<b>Net book value as at December 31, 2019</b>	<b>33,321</b>	<b>2,327</b>	<b>47,910</b>	<b>-</b>	<b>83,558</b>

For impairment testing, goodwill acquired through business combinations and intangibles with indefinite useful lives are allocated to the Aralez, Resultz Canada and Resultz Rest of World CGUs.

Carrying amounts of goodwill and intangibles allocated to each CGU as at December 31, 2019:

	Goodwill	Intangibles
	\$	\$
Aralez cash-generating units	26,409	37,914
Resultz Canada cash-generating units	290	2,682
Resultz Rest of World cash-generating units	881	5,648
Remaining cash-generating units	-	37,314
<b>Total</b>	<b>27,580</b>	<b>83,558</b>

In 2019, the impairment loss of \$1.4 million represented the write-down of certain intangible assets in the commercial and licensing and royalty segments to the recoverable amount as a result of a change in commercial expectations. This was recognized in the Consolidated Statement of Income (Loss) and Comprehensive Income (Loss) as impairment. The recoverable amount as at December 31, 2019 was based on value in use and was determined at the level of the CGU.

The value-in-use calculations considered forecasted cash flows of each CGU based on the current commercialization plans for these products. Cash from product sales and royalties, net of labour and infrastructure costs were included in determining the CGUs recoverable value. The Company's approach for discounted cash flow projections included consideration of prior year actuals, current market conditions and planned commercial efforts per product.

The terminal-growth rate in a range of -2% to -10% was used for discounted cash flow projections. An after-tax discount rate in a range of 10.62% to 20.62% was applied, which approximates the Company's current weighted average cost of capital.

### Sensitivity Analysis

The Company's intangible asset impairment test is sensitive to changes in assumptions. An increase of 5 basis points to the discount rates used by the Company to 11.15% - 21.65% for its intangible asset impairment test and assuming all other variables remain constant, would not have resulted in a material change to the value of the Company's intangible assets. A decrease of 5 basis points to the discount rates used by the Company 10.09% - 19.59% for its intangible asset impairment test and assuming all other variables remain constant, would not have resulted in a material change to the value of the Company's intangible assets.

## 11. GOODWILL

	December 31, 2019	December 31, 2018 RESTATED Note 5
Cost	\$	\$
Ex-U.S. Resultz acquisition (Note 5)	1,187	1,187
Aralez Transaction (Note 5)	26,763	26,763
Foreign exchange movements, cumulative	(370)	32
<b>Balance</b>	<b>27,580</b>	<b>27,982</b>

Goodwill continuity for the year ended December 31, 2018:

	\$
Balance, January 1, 2018	1,187
Aralez Transaction (Note 5)	26,763
Foreign exchange movements	32
<b>Balance, December 31, 2018</b>	<b>27,982</b>

Goodwill continuity for the year ended December 31, 2019:

	\$
Balance, January 1, 2019	24,898
Measurement period fair value adjustments (Note 5)	3,084
Revised balance, at January 1	27,982
Foreign exchange movements	(402)
<b>Balance, December 31, 2019</b>	<b>27,580</b>

Goodwill is recognized on the acquisition date when total consideration exceeds the net identifiable assets acquired. Refer to Note 10, *Intangible Assets* for the Company's annual impairment test performed at the CGU level.

### Aralez CGU

The recoverable amount of the Aralez CGU as at December 31, 2019 has been determined based on a value-in-use calculation using cash flow projections and financial budgets approved by the board of directors. An after-tax discount rate in a range of 15.62% to 20.62% was applied along with a terminal-growth rate in a range of -2% to 5%. It was concluded that the carrying value did not exceed the value-in-use. As a result of this analysis, management did not identify an impairment for this CGU.

### Resultz Canada CGU

The recoverable amount of the Resultz Canada CGU as at December 31, 2019 has been determined based on a value-in-use calculation using cash flow projections and financial budgets approved by the board of directors. An after-tax discount rate of 10.62% was applied along with a terminal-growth rate of -5%. It was concluded that the carrying value did not exceed the value-in-use. As a result of this analysis, management did not identify an impairment for this CGU.

### Resultz Rest of World CGU

The recoverable amount of the Resultz Rest of World CGU as at December 31, 2019 has been determined based on a value-in-use calculation using cash flow projections and financial budgets approved by the board of directors. An after-tax discount rate of 15.62% was applied along with a terminal-growth rate of -5%. It was concluded that the carrying value did not exceed the value-in use. As a result of this analysis, management did not identify an impairment for this CGU.

### Sensitivity analysis

The Company's goodwill impairment test is sensitive to changes in assumptions. An increase of 5 basis points to the discount rates used by the Company, assuming all other variables remain constant, for its goodwill impairment test would not have resulted in a material change to the value of the Company's Resultz Canada and Resultz Rest of World CGUs; however, this change would have resulted in a goodwill impairment charge for the Aralez CGU of approximately \$2 million.

## 12. LOANS AND BORROWINGS

The Company financed the Aralez Transaction, as described in Note 1, *Nature of Business - The Deerfield Financing*, through funding provided by Deerfield on December 31, 2018. The Company received total proceeds of \$161.7 million (US\$118.5 million) from Deerfield in exchange for issuing the Amortization Loan, the Bridge Loan, the Convertible Loan and Warrants. In addition to these freestanding instruments, there were two embedded derivatives requiring bifurcation: the conversion feature in the Convertible Loan (See Note 13, *Derivative Liabilities*) and the prepayment option in the Amortization Loan.

The Company's loans and borrowings were measured at amortized cost as follows:

	December 31, 2019	December 31, 2018
	\$	\$
CURRENT		
Bridge Loan (i)	4,493	6,821
Amortization Loan (ii)	13,892	-
	<b>18,385</b>	6,821
NON-CURRENT		
Bridge Loan (i)	-	1,165
Amortization Loan (ii)	54,572	65,985
Convertible Loan – debt host (iii)	50,420	50,236
	<b>104,992</b>	117,386

The Deerfield Loans are guaranteed by Aralez Canada and cross-guaranteed by each of the Company and Nuvo Ireland as to each other's obligations and are secured by a first ranking charge over substantially all property of each of the Company, Nuvo Ireland and Aralez Canada.

The Amortization Loan, Bridge Loan and Convertible Loan were issued on December 31, 2018. Interest on these Loans is accrued and paid on a quarterly basis. Any repayment of principal on the Amortization Loan and Bridge Loan prior to their respective payment terms is considered a prepayment to which a 0.25% prepayment fee applies. Early repayment is not permitted for the Convertible Loan.

Each quarter, the Company shall pay to the lenders the greater of US\$2.5 million and 50% of the Company's excess cash flows (a defined term in the Facility Agreement), which is applied in the following order: (a) any unpaid fees and transaction costs; (b) proportionately to any accrued and unpaid interest related to these Loans; (c) any unpaid principal of the Bridge Loan, including the applicable prepayment fee; (d) any unpaid principal of the Amortization Loan, including the applicable prepayment fee; and (e) any other obligations owing to the lenders, administrative agent or other secured parties (the Waterfall Provisions).

The Company has the right to prepay the Amortization Loan and Bridge Loan at any time. The fair value of the prepayment option bifurcated from the term loan was a derivative asset with a nominal value as at December 31,

2019 and is presented net of the non-current portion of the long-term debt. The prepayment option on the Bridge Loan was deemed to be clearly and closely related to the host and no bifurcation was required.

If the Company does not have sufficient cash flows to make the minimum principal payments during the first four quarters from the issuance date of these Loans, it may delay the payments for those first four quarters, so long as a minimum of US\$10 million in aggregate has been paid by the payment date of the fourth quarter. As a result of the Waterfall Provisions, the first US\$6.0 million paid by the Company will be applied to the Bridge Loan. The remaining US\$4.0 million is required to be paid in March 2020 and applied to the Amortization Loan. Thereafter, quarterly principal payments will commence on the Amortization Loan until December 31, 2024.

The Company agreed to an amendment to the financing agreement dated June 25, 2019, to provide, among other things, for a payment deferral mechanism in the event that Vimovo U.S. market exclusivity is lost. The amendment allows the Company to defer a portion of the mandatory minimum quarterly repayments by the difference between one quarter of the existing US\$7.5 million minimum annual royalty due from Vimovo sales in the U.S. and the actual amount of royalties received in the applicable quarter in the event Vimovo U.S. market exclusivity is lost earlier than had been expected (2022) prior to the Court of Appeals decision. The amount of any principal repayment deferred would, until repaid in accordance with the amendment, be subject to an interest rate of 12.5% per annum. As a result of this amendment, for the year ended December 31, 2019, the Amortization Loan and Bridge Loan were revalued and a loss of \$2.2 million was recorded due to both modification of debt and changes in the assumptions regarding the timing of the payments. (See Note 19, *Other Losses*)

### (i) Bridge Loan

The Bridge Loan was issued on December 31, 2018 in the principal amount of \$8.2 million (US\$6.0 million). The carrying value reflects an allocation of transaction costs, which reduces the carrying value of the respective liability and are reflected in the calculation of interest expense under the effective interest rate method.

The change in the carrying value of this liability was as follows:

	\$
As at January 1, 2019	7,986
Interest accretion during the year	(214)
Principal repayment	(3,354)
Modification on principal repayment and debt amendment	361
Foreign exchange gain	(286)
<b>As at December 31, 2019<sup>(i)</sup></b>	<b>4,493</b>

<sup>(i)</sup> Subsequent to December 31, 2019, the Bridge Loan was repaid in its entirety.

### (ii) Amortization Loan

The Amortization Loan was issued on December 31, 2018 in the principal amount of \$81.9 million (US\$60 million). The carrying value reflects an allocation of transaction costs, which reduces the carrying value of the respective liability and are reflected in the calculation of interest expense under the effective interest rate method.

The change in the carrying value of this liability was as follows:

	\$
As at January 1, 2019	65,985
Interest accretion during the year	3,940
Modification on debt amendment	1,805
Foreign exchange gain	(3,266)
<b>As at December 31, 2019</b>	<b>68,464</b>

### (iii) Convertible Loan

The Convertible Loan was issued on December 31, 2018 in the principal amount of \$71.6 million (US\$52.5 million), convertible at any time at the option of the holder into 19,444,444 common shares of the Company at a conversion price of US\$2.70 per share. Interest is payable on a quarterly basis and any debenture not converted will be repaid on December 31, 2024. The fair value of the conversion feature as at December 31, 2019 in the amount of \$0.8 million has been classified as a derivative financial liability, as described in Note 13, *Derivative Liabilities*. The

carrying value reflects an allocation of transaction costs, which reduces the carrying value of the respective liability and are reflected in the calculation of interest expense under the effective interest rate method.

The change in carrying value of this liability was as follows:

	\$
As at January 1, 2019	50,236
Interest accretion during the year	2,640
Foreign exchange gain	(2,456)
<b>As at December 31, 2019</b>	<b>50,420</b>

### 13. DERIVATIVE LIABILITIES

The Company's derivative liabilities are measured at FVTPL and are summarized below:

	December 31, 2019 \$	December 31, 2018 \$
Conversion feature on Convertible Loan	837	14,534
Warrants	1,392	19,112
	<b>2,229</b>	<b>33,646</b>

During the year ended December 31, 2019, the Company recognized a net non-cash \$31.1 million recovery on the change in fair value of derivative liabilities [December 31, 2018 - \$nil]. During the year ended December 31, 2019, the Company recognized a \$0.3 million gain on foreign exchange related to the conversion feature [December 31, 2018 - \$nil].

#### *Conversion feature*

The conversion feature is embedded in the Convertible Loan described in Note 12, *Loans and Borrowings* and allows the holder to convert the outstanding principal amount of the debentures into common shares of the Company at any time at a conversion price of US\$2.70 per share, subject to a restriction that the holder shall not ultimately hold more than 4.985% of the total number of common shares of the Company at any one time.

#### *Warrants*

On December 31, 2018, the Company issued 25,555,556 Warrants with a total fair value of \$19.1 million (US\$14.0 million). Each Warrant is exercisable at the option of the holder for one common share of the Company at an exercise price of \$3.53 per Warrant and expires December 31, 2024. Any exercise is subject to a restriction that the holder shall not ultimately hold more than 4.985% of the total number of common shares of the Company at any one time. The fair value of the Warrants is determined using the Black-Scholes option pricing model. The Warrants contain contingent settlement provisions that would require the Company to settle the Warrants as a financial liability in certain circumstances, some of which are beyond the control of both the Company and the holder, such as bankruptcy or insolvency, which requires the Warrants to be classified as derivative liabilities.

There are three methods of Warrant settlement, all at the option of the holder. The first method of settlement requires the holder to remit the exercise price of \$3.53 per Warrant and the Company will issue a common share of the Company. The second method results in the \$3.53 per Warrant strike price being applied as a payment against the principal balance of the Amortization Loan outstanding. The third method of exercise applies to those Warrants classified as Flexible Exercise Shares (FES). Warrants considered FES can be exercised without upfront remuneration to the Company. Instead, the Company issues fractional shares equal to the difference between the current share price and the \$3.53 exercise price of the Warrant. As at December 31, 2019, 3,333,334 of the 25,555,556 Warrants outstanding were classified as FES.

Following a Major Transaction (as defined in the Deerfield Facility Agreement), subject to certain conditions, the Warrants will become exercisable for an additional number of common shares determined in accordance with the terms of the Warrants, subject to continued application of the 4.985% Cap, except that in the case of certain Major Transactions involving the conversion of the common shares into the right to receive cash, securities or other assets (either under the Major Transaction or a subsequent liquidation of the Company), a holder of Warrants is permitted to exercise the warrants (without the application of the 4.985% cap) for the additional number of common shares

described above immediately prior to and conditional upon completion of the Major Transaction, such that the holder ultimately receives the cash, securities or other assets, as applicable, in exchange for such common shares on the same terms as other holders of common shares. See the Deerfield Facility Agreement and the forms of Convertible Notes and Warrants filed under the Company's profile on [www.sedar.com](http://www.sedar.com).

#### *Inputs to fair value models*

Key assumptions used in determining the fair values of the Company's derivative liabilities at initial recognition and period end are summarized below as at:

<b>Conversion Feature</b>		
Issue date	<b>December 31, 2018</b>	December 31, 2018
Valuation date	<b>December 31, 2019</b>	December 31, 2018
Share price	<b>\$0.45</b>	\$2.10
Risk-free interest rate	<b>1.69%</b>	2.55%
Discount for lack of marketability	<b>28.00%</b>	8.10%
Dividend yield	<b>0%</b>	0%
Volatility factor	<b>70.00</b>	53.9%
Expected life	<b>5 years</b>	6 years

<b>Warrants</b>		
Issue date	<b>December 31, 2018</b>	December 31, 2018
Valuation date	<b>December 31, 2019</b>	December 31, 2018
Share price	<b>\$0.45</b>	\$2.10
Risk-free interest rate	<b>1.67%</b>	1.90%
Discount for lack of marketability	<b>28.00%</b>	8.10%
Dividend yield	<b>0%</b>	0%
Volatility factor	<b>70.00%</b>	53.9%
Expected life	<b>5 years</b>	6 years

## **14. OTHER OBLIGATIONS**

Other obligations consist of the following as at:

	<b>December 31, 2019</b>	December 31, 2018
	<b>\$</b>	\$
Contingent and variable consideration related to the ex-U.S. acquisition of Resultz <sup>(i)</sup>	<b>2,814</b>	1,192
Contingent and variable consideration related to the acquisition of Aralez <sup>(ii)</sup>	<b>-</b>	475
Lease obligations <sup>(iii)</sup>	<b>594</b>	5
Less amounts due within one year	<b>(372)</b>	(408)
<b>Long-term balance</b>	<b>3,036</b>	1,264

<sup>(i)</sup> During the year ended December 31, 2019, the Resultz contingent consideration increased to \$2.8 million [December 31, 2018 - \$1.2 million] due to a change in estimates.

<sup>(ii)</sup> In the year ended December 31, 2019, the Yosprala contingent consideration was reduced as a result of a change in estimates.

<sup>(iii)</sup> As at December 31, 2019, the Company recognized \$0.6 million [December 31, 2018 - \$nil] of lease obligations related to IFRS 16 using the modified retrospective approach.

For the year ended December 31, 2019, the contingent consideration liability related to the ex-U.S. Resultz acquisition. The ex-U.S. Resultz acquisition included additional contingent consideration based on meeting certain milestones in partnered markets, payable only if those targets are achieved, as well as variable consideration based on annual royalties earned in non-partnered markets. The Aralez Transaction included additional contingent consideration related to profits earned from Yosprala, (See Note 5, *Business Combinations*) which were reduced by \$0.5 million for the year ended December 31, 2019. The Company recognized \$2.8 million in contingent and

variable consideration as at December 31, 2019 [December 31, 2018 - \$1.7 million], which represented the present value of the Company's probability-weighted estimate of the cash outflow related to the ex-U.S. Resultz acquisition and the profits earned from Yosprala.

### Lease Obligations

The change in the carrying value of this liability was as follows:

	\$
As at January 1, 2019	5
Transition to IFRS 16	2,805
Payments during the period	(389)
Interest expense during the period	128
Foreign exchange	(75)
Disposal of obligation <sup>(i)</sup>	(1,880)
<b>As at December 31, 2019</b>	<b>594</b>

<sup>(i)</sup> In the year ended December 31, 2019, the Company transferred the lease obligation for the leased property in Ireland to an outside party resulting in a gain on disposal of \$38.

## 15. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities for the year ended December 31, 2019 included \$3.2 million of accrued royalties, rebates and returns [December 31, 2018 - \$3.9 million].

As at December 31, 2018, the balance included \$10.0 million as a result of the Company acquiring indebtedness with the Aralez Transaction, as well as transaction costs accrued at December 31, 2018.

## 16. 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.

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

The Company has three 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.

### Share Incentive Plan

On May 11, 2017, Nuvo shareholders approved a resolution affirming, ratifying and approving the Share Incentive Plan and approving all of the unallocated common shares issuable pursuant to the Share Incentive Plan. The Toronto Stock Exchange (TSX) requires that the Company's Share Incentive Plan, along with any unallocated options, rights or other entitlements, receive shareholder approval at the Company's annual meeting every three years.

The maximum number of common shares that will be reserved for issuance under the Share Incentive Plan shall be 15% of the total number of common shares outstanding from time-to-time. The allocation of such maximum percentage among the three sub plans comprising the Share Incentive Plan shall be determined by the Board of Directors from time-to-time (provided that the maximum number of common shares that may be issued under the Share Bonus Plan shall not exceed a fixed number of common shares equal to 3% of the number of common shares outstanding immediately following the arrangement, which was 341,648).



As at December 31, 2019, the number of common shares available for issuance under the Share Incentive Plan was 286,621.

### 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.

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

	Options 000s	Range of Exercise Price \$	Weighted Average Exercise Price \$
Balance, December 31, 2017	1,029	1.53 - 11.18	4.88
Granted	204	2.88 - 3.55	3.54
Forfeited	(10)	3.55	3.55
Expired	(34)	4.32 - 6.35	5.52
Balance, December 31, 2018	1,189	1.53 - 11.18	4.64
Granted	328	0.63 - 2.30	2.14
Forfeited	(53)	2.30 - 3.80	2.51
Expired	(42)	3.80 - 11.18	6.09
<b>Balance, December 31, 2019</b>	<b>1,422</b>	<b>0.63 - 11.18</b>	<b>4.10</b>

The fair value of each tranche is measured at the date of grant using the Black-Scholes option pricing model. Options are valued with a calculated forfeiture rate of 7% [December 31, 2018 - 7%] and the remaining model inputs for options granted during the year ended December 31, 2019 were as follows:

Options 000s	Grant Date	Share Price \$	Exercise Price \$	Risk-free Interest Rate %	Expected Life (years)	Volatility Factor %	Fair Values \$
120	January 10, 2019	2.30	2.30	1.96	5 - 7	58 - 65	1.22 - 1.46
180	April 5, 2019	2.26	2.26	1.49	5 - 7	58 - 63	1.18 - 1.60
28	August 19, 2019	0.63	0.63	1.48	5 - 7	60 - 63	0.32 - 0.36

The following table summarizes the outstanding and exercisable options held by directors, officers, employees and consultants as at December 31, 2019:

Exercise Price Range \$	Options 000s	<u>Outstanding</u> Remaining Contractual Life years	Weighted Average Exercise Price \$	<u>Exercisable</u> Vested Options 000s	Weighted Average Exercise Price \$
0.63 - 3.55	722	7.08	2.56	412	2.52
3.80 - 4.45	81	4.84	4.22	70	4.28
5.08 - 5.75	582	6.08	5.54	469	5.50
11.18	37	0.46	11.18	37	11.18
	<b>1,422</b>	<b>6.37</b>	<b>4.10</b>	<b>988</b>	<b>4.38</b>

### Share Purchase Plan

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

During the year ended December 31, 2019, there was no issuance of shares under the Share Purchase Plan. In the comparative year, employees contributed \$0.1 million to the plan and the Company matched these contributions by issuing 23,478 common shares with a fair value of \$0.1 million that was recorded as compensation expense. The total number of shares issued under this plan during the year ended December 31, 2019 was nil [December 31, 2018 - 72,928].

### Summary of Stock-based Compensation

Stock-based compensation was as follows:

	Year ended December 31, 2019	Year ended December 31, 2018
	\$	\$
Stock option compensation expense under the Share Option Plan	457	672
Shares issued to employees under the Share Purchase Plan	-	123
Share Appreciation Rights compensation expense	-	(4)
<b>Stock-based compensation expense</b>	<b>457</b>	<b>791</b>

*Recorded in the Consolidated Statements of Income (Loss) and Comprehensive Income (Loss) as follows:*

Cost of goods sold	41	73
General and administrative expenses	416	718
<b>Stock-based compensation expense</b>	<b>457</b>	<b>791</b>

### 18. NET INTEREST EXPENSE (INCOME)

	Year ended December 31, 2019	Year ended December 31, 2018
	\$	\$
Interest expense on financial liabilities measured at amortized cost <sup>(i)</sup>	12,756	7
Interest income on contract assets	(2,265)	-
Interest income on cash and cash equivalents	(186)	(39)
<b>Net interest expense (income)</b>	<b>10,305</b>	<b>(32)</b>

<sup>(i)</sup> The Deerfield Financing requires the Company to make quarterly interest payments on outstanding loans. The coupon rates for the Company's Bridge Loan, Amortization Loan and Convertible Loan are 12.5%, 3.5% and 3.5%, respectively. During the year ended December 31, 2019, the Company made interest payments of \$5.8 million to Deerfield.

### 19. OTHER LOSSES

	Year ended December 31, 2019	Year ended December 31, 2018
	\$	\$
Modification of long-term debt	2,165	-
Other	(105)	-
<b>Other losses</b>	<b>2,060</b>	<b>-</b>

The Company agreed to an amendment to the financing agreement dated June 25, 2019, to provide, among other things, for a payment deferral mechanism in the event that Vimovo U.S. market exclusivity is lost. The amendment allows the Company to defer a portion of the mandatory minimum quarterly principal repayments by the difference between one quarter of the existing US\$7.5 million minimum annual royalty due from Vimovo sales in the U.S. and the actual amount of royalties received in the applicable quarter in the event Vimovo U.S. market exclusivity is lost earlier than had been expected (2022) prior to the Court of Appeals decision. The amount of any principal repayment deferred would, until repaid in accordance with the amendment, be subject to an interest rate of 12.5%

per annum. As a result of this amendment, for the year ended December 31, 2019, the Amortization Loan and Bridge Loan were revalued and a loss of \$2.2 million was recorded due to both modification of debt and changes in the assumptions regarding the timing of the payments.

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

Net income (loss) per common share is computed as follows:

	Year ended December 31, 2019	Year ended December 31, 2018
	\$	\$
<b>Basic income (loss) per share:</b>		
Net income (loss)	3,361	(6,153)
Average number of shares outstanding during the year	11,388	11,443
<b>Basic income (loss) per share</b>	<b>0.30</b>	<b>(0.54)</b>
<b>Net income (loss)</b>	<b>3,361</b>	<b>(6,153)</b>
Dilutive effect of:		
Stock Options	-	-
Warrants	(15,415)	-
Convertible Loan	(9,965)	-
<b>Net income (loss), assuming dilution</b>	<b>(22,019)</b>	<b>(6,153)</b>
Average number of shares outstanding during the year	11,388	11,443
Dilutive effect of:		
Warrants	12,625	-
Convertible Loan	19,444	-
Stock options	-	-
<b>Weighted average common shares outstanding, assuming dilution</b>	<b>43,457</b>	<b>11,443</b>
<b>Diluted loss per share</b>	<b>(0.51)</b>	<b>(0.54)</b>

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:

	Year ended December 31, 2019		Year ended December 31, 2018	
	Weighted Average Exercise Price	Units Outstanding	Weighted Average Exercise Price	Units Outstanding
	\$	000s	\$	000s
Common shares issued and outstanding	n/a	11,388	n/a	11,388
Stock options outstanding (Note 17)	4.10	1,422	4.64	1,189
Share appreciation rights outstanding	n/a	-	n/a	52
Warrants (Note 13)	3.53	25,556	3.53	25,556
Convertible Loan (Note 12)	US2.70	19,444	US2.70	19,444
		<b>57,810</b>		<b>57,629</b>

## 21. EXPENSES BY NATURE

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

(a) Employee costs:

	Year ended December 31, 2019	Year ended December 31, 2018
	\$	\$
Short-term wages, bonuses and benefits	15,666	6,222
Share-based payments	339	702
Termination benefits	753	384
<b>Total employee costs</b>	<b>16,758</b>	<b>7,308</b>
<b>Included in:</b>		
Cost of goods sold	3,087	2,859
Sales and marketing	5,073	-
General and administrative expenses	8,598	4,449
<b>Total employee costs</b>	<b>16,758</b>	<b>7,308</b>

(b) Depreciation and amortization:

	Year ended December 31, 2019	Year ended December 31, 2018
	\$	\$
Amortization of intangibles	8,356	1,989
Cost of goods sold	470	429
General and administrative expenses	720	75
<b>Total depreciation and amortization</b>	<b>9,546</b>	<b>2,493</b>

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

Net change in non-cash working capital consists of:

	Year ended December 31, 2019	Year ended December 31, 2018
	\$	\$
Accounts receivable <sup>(i)</sup>	(8,971)	(1,393)
Inventories	508	(224)
Contract assets	4,990	419
Other current assets	1,176	(826)
Accounts payable and accrued liabilities <sup>(ii)</sup>	(11,698)	6,085
Current income taxes payable	(74)	-
<b>Net change in non-cash working capital</b>	<b>(14,069)</b>	<b>4,061</b>

<sup>(i)</sup> For the year ended December 31, 2019, the increase in accounts receivable primarily related to accrued royalties from licensing contracts acquired as part of the Aralez Transaction.

<sup>(ii)</sup> For the year ended December 31, 2019, the decrease in accounts payable and accrued liabilities primarily related to the Company settling final consideration associated with the Aralez Transaction, indebtedness acquired with the Aralez Transaction and the settlement of transaction costs accrued at December 31, 2018.

## 23. INCOME TAXES

### Deferred Tax Assets and Liabilities

Deferred income taxes represent the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. A significant component of deferred tax assets (liabilities) is the accounting value of indefinite lived intangible assets in excess of tax basis for the year ended December 31, 2019 of \$(0.3) million [December 31, 2018 - \$(0.3) million].

A deferred income tax asset has not been recognized for certain temporary differences that may be available to reduce income subject to tax in a taxation period subsequent to the period covered by these Consolidated Financial Statements. The tax effected amounts of such temporary differences that have not been recognized in the Consolidated Statements of Financial Position or Consolidated Statements of Income (Loss) and Comprehensive Income (Loss) are as follows:

	Year ended December 31, 2019	Year ended December 31, 2018
	\$	\$
Investment tax credits	1,730	1,371
Accounting value of PP&E and intangibles in excess of tax basis	(2,453)	(3,898)
Financing costs, deferred revenue and other	812	343
Capital losses	12,664	12,740
Non-capital and operating losses	8,804	9,024
Inventory	(383)	(1,703)
Other	414	511
	<b>21,588</b>	<b>18,388</b>

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

	Year ended December 31, 2019	Year ended December 31, 2018
	%	%
Statutory rate	26.64	26.64
Items not deducted for tax	(206.02)	(25.30)
Utilization of previously unrecognized deferred tax assets	85.04	5.93
Foreign rate differences	95.71	(4.09)
Other	(0.57)	(0.18)
	<b>0.80</b>	<b>3.00</b>

The Company has net capital losses of \$47.8 million in Canada available to offset net taxable capital gains in future years that have not been recognized [December 31, 2018 - \$48.1 million].

### Government Assistance

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

Year of Credit	Amount \$	Year of Expiry
2004	149	2024
2005	130	2025
2006	110	2026
2007	340	2027
2008	237	2028
2009	142	2029
2010	395	2030
2011	208	2031
2012	43	2032
2014	80	2034
2015	494	2035
2016	27	2036
	<b>2,355</b>	

The benefits of these non-refundable Canadian federal investment tax credits have not been recognized in these Consolidated Financial Statements.

### Non-capital Losses

Year of Losses	Amount \$	Year of Expiry
2011	2,040	2031
2012	-	2032
2013	1,515	2033
2014	1,601	2034
2015	11,414	2035
2016	7,523	2036
2017	978	2037
2018	126	2038
2019	2,952	2039
2019	17,757	Indefinite
	<b>45,906</b>	

As at December 31, 2019, the Company has not recognized the benefits of Canadian and foreign non-capital losses of \$28.1 million and \$17.8 million, respectively [December 31, 2018 – 34.4 million and \$1.7 million, respectively].

## 24. COMMITMENTS AND CONTINGENCIES

The Company has minimum future payments under variable lease payment obligations, purchase commitments, minimum royalties and anticipated milestones for the 12 months ending December 31 as follows:

	\$
2020	3,798
2021	3,303
2022	5,695
2023	4,104
2024	5,551
2025 and thereafter	-
	<b>22,451</b>

For the year ended December 31, 2019, payments for lease obligations totalled \$0.3 million [December 31, 2018 - \$0.2 million].

Under the terms of the Pennsaid 2% U.S. Asset Sale with Horizon, Nuvo is contractually obligated to manufacture Pennsaid 2% for the U.S. market to December 2029 and, unless terminated, the supply agreement will renew for successive two-year terms, thereafter. The agreement provides for tiered pricing based on volumes of product shipped. The Company is also required to maintain certain raw material inventory levels. The Company has additional long-term supply contracts where the Company is contractually obligated to manufacture Pennsaid 2% and Pennsaid for its customers.

The Company has a long-term supply agreement with a third-party manufacturer for the supply of dimethyl sulfoxide, one of the key raw materials in Pennsaid 2% and Pennsaid, which expires in December 2022. The agreement automatically renews for successive three-year terms, unless terminated in writing by either party at least 12 months prior to the expiration of the current term. The agreement requires the Company to purchase 100% of its dimethyl sulfoxide requirements from the third-party manufacturer at specified pricing, but does not contain any minimum purchase commitments.

The Company has a long-term supply agreement with a third-party manufacturer for Blexten. The agreement automatically renews for successive five-year terms, unless terminated in writing by either party at least 12 months prior to the expiration of the current term in 2024. The agreement requires the Company to purchase 100% of its Blexten requirements from the third-party manufacturer at specified pricing.

Under certain licensing agreements for the Heated Lidocaine/Tetracaine (HLT) Patch, Resultz, Blexten, Cambia and Durela®, the Company is required to make royalty payments ranging from 1% to 30% for annual net sales and certain milestones payments.

Under certain exclusive distribution agreements, the Company is required to make minimum royalty payments to a company of \$0.3 million to \$0.5 million per year and 30% incremental royalty payments on net receipts above the minimum payments for Soriatane™.

During year ended December 31, 2019, the Company leased property for offices in Canada and Ireland. The Company expenses the lease payments for short-term leases and low-value leases as incurred. There are no financial covenants imposed by any of the leases.

	Year ended December 31, 2019
	\$
Interest expense on lease liabilities	128
Expenses related to variable lease payments not classified as lease obligations	238
Total cash outflow for leases classified as lease obligations	389

The Company did not have any sale and leaseback transactions during the year ended December 31, 2019.

The Company's future cash outflows may change due to variable lease payments, renewal options, termination options, residual value guarantees and leases not yet commenced to which the Company is committed that are not reflected in the lease obligations.

The following is a maturity analysis for undiscounted lease payments that are reflected in the lease obligations as at December 31, 2019:

	\$
Less than 1 year	250
1 to 2 years	191
2 to 3 years	116
3 to 4 years	116
Beyond 4 years	-
	<b>673</b>

On October 30, 2019, the Company received an application for an industry-wide class action in the Superior Court of Québec. In the application, the Company was named as a defendant, along with 33 other defendants, which includes a group of companies that manufacture, market, and/or distribute opioids in Québec. The claim is for \$30 plus interest for compensatory damages for each class member, \$25.0 million from each defendant for punitive damages and pecuniary damages for each class member. The financial impact cannot be estimated at this time, as the class has not yet been defined by the court. The Company is in the process of assessing this application with counsel and intends to defend itself vigorously.

## 25. FINANCIAL INSTRUMENTS AND RISK MANAGEMENT

### Financial Instruments at Amortized Cost

For year ended December 31, 2019, the Company recognized \$0.2 million in interest from financial assets held at amortized cost [December 31, 2018 - \$39].

For year ended December 31, 2019, the Company recognized \$12.8 million in interest from financial liabilities held at amortized cost [December 31, 2018 - \$nil].

### Credit Risk

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 and contract assets are subject to normal industry risks in each geographic region in which the Company operates. 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.

Pursuant to the Aralez Transaction, the Company has expanded its customer base primarily in Canada with well-established wholesale and retail pharmacy chains. Management does not expect the expanded customer base will have a significant impact on the Company's credit risk assessment.



As at December 31, 2019, the Company's largest customer represented 49% [December 31, 2018 - 47%] of accounts receivable. Pursuant to their collective terms, accounts receivable, net of allowance, were aged as follows:

	December 31, 2019	December 31, 2018
	\$	\$
Current	9,064	4,052
0 - 30 days past due	777	571
31 - 60 days past due	60	84
Over 60 days past due <sup>(i)</sup>	4,486	250
	<b>14,387</b>	<b>4,957</b>

<sup>(i)</sup> The Company collected \$3.7 million of receivables over 60 days past due subsequent to December 31, 2019. The remainder is withholding tax receivable.

The loss allowance provision for the Production and Service Business segment as at December 31, 2019 was determined using reference to expected loss rates and management judgment as follows:

		Less than 181	181 to 270	271 to 365	More than 365	
	Current	days past due	days past due	days past due	days past due	Total
Expected loss rate	%	0%	0%	25%	50%	100%
Gross carrying amount	\$	2,099	281	-	-	2,380

The loss allowance provision for the Licensing and Royalty Business and Commercial Business segment as at December 31, 2019 was determined using reference to expected loss rates and management judgment as follows:

		Less than 61	61 to 120	121 to 180	More than 181	
	Current	days past due	days past due	days past due	days past due	Total
Expected loss rate	%	0%	0%	25%	50%	100%
Gross carrying amount	\$	7,040	5,166	47	-	12,330
Loss allowance provision	\$	(74)	(144)	(46)	-	(323)

During the year ended December 31, 2019, the Company recorded bad debt reversal of \$0.1 million in total comprehensive income (loss) [December 31, 2018 - \$nil]. For the year ended December 31, 2019, the impairment of accounts receivable was assessed based on the incurred loss model. Individual receivables that were known to be uncollectible were written off by reducing the carrying amount directly.

For contract assets within the scope of IFRS 15, the Company recognizes an asset to the extent contractual minimums established in certain customer licensing agreements are deemed fixed consideration. After analysis of historical default rates and forward-looking estimates, the Company's contract assets were considered to have low credit risk, and as a result, the Company has not recognized a loss allowance as at December 31, 2019 [December 31, 2018 - \$nil].

The Company's cash and cash equivalents subject the Company to a concentration of credit risk. As at December 31, 2019, the Company had \$23.0 million deposited with three financial institutions in various bank accounts. These financial institutions are major banks located in Canada, the U.S. and Ireland, which the Company believes lessens the degree of credit risk. All of these financial institutions are considered to have low credit risk and, therefore, the provision recognized during the current period was limited to 12 months of expected losses. The Company has not recognized a loss allowance as at December 31, 2019 [December 31, 2018 - \$nil].

## Financial Instruments

IFRS 7 - *Financial Instruments: Disclosures* requires disclosure of a three-level hierarchy that reflects the significance of the inputs used in making fair value measurements. All assets and liabilities for which fair value is measured or disclosed in these Consolidated Financial Statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 - Unadjusted quoted prices at the measurement date for identical assets or liabilities in active markets
- Level 2 - Observable inputs other than quoted prices in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data
- Level 3 - Significant unobservable inputs that are supported by little or no market activity

The Company reviews the fair value hierarchy classification on a quarterly basis. Changes to the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy. The Company did not have any transfer of assets and liabilities between Level 1, Level 2 and Level 3 of the fair value hierarchy during the year ended December 31, 2019.

As at December 31, 2019, the Company's financial instruments consisted of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities, contingent and variable consideration, long-term debt and derivative liabilities. The Company has determined the estimated fair values of its financial instruments based on appropriate valuation methodologies. However, considerable judgment is required to develop these estimates. Accordingly, these estimated values are not necessarily indicative of the amounts the Company could realize in a current market exchange. The estimated fair value amounts can be materially affected by the use of different assumptions or methodologies.

The Company's cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities are measured at amortized cost and their fair values approximate carrying values. Cash and cash equivalents are Level 1, while the other short-term financial instruments are Level 3.

The fair values of the Company's Amortization Loan, Bridge Loan and host liability of the Convertible Loan are Level 3 measurements determined using a discounted cash flow model that considers the present value of the contractual cash flows using a risk-adjusted discount rate. The Company recognized \$123.4 million for the Amortization Loan, Bridge Loan and host liability of the Convertible Loan as at December 31, 2019 [December 31, 2018 - \$124.2 million].

The conversion feature that accompanies the Company's Convertible Loan is considered a Level 3 liability. The value is determined as the difference between the fair value of the hybrid Convertible Loan contract, determined using an income approach with a binomial lattice model and the fair value of the host liability contract, determined using a discounted cash flow model, as described in Note 13, *Derivative Liabilities*. The Company recognized \$0.8 million for the conversion feature as at December 31, 2019 [December 31, 2018 - \$14.5 million].

The fair values of the prepayment option that allows the Company to make prepayments against the Bridge Loan or Amortization Loan at any time is considered a Level 3 financial instrument. The fair value of the prepayment option bifurcated from the term loan was a derivative asset with a nominal value as at December 31, 2019 and is presented net of the non-current portion of the long-term debt (See Note 12, *Loans and Borrowings*). The fair value of this option was determined using a binomial-lattice model.

The fair value of the Company's Warrants is revalued at each reporting period using the Black-Scholes option pricing model. As at December 31, 2019, the Company recognized a \$1.4 million derivative liability related to outstanding Warrants [December 31, 2018 - \$19.1 million]. These Warrants are Level 3.

Level 3 liabilities include the fair value of contingent and variable consideration related to the acquisition of the ex-U.S. rights to Resultz and the Aralez Transaction.

## Risk Factors

The following is a discussion of liquidity risk and market risk and related mitigation strategies that have been identified. Credit risk has been discussed in the Company's assessment of impairment under IFRS 9. This is not an exhaustive list of all risks nor will the mitigation strategies eliminate all risks listed.

### Liquidity Risk

Liquidity risk is the risk that the Company will encounter difficulties in meeting its financial obligations as they become due.

As at December 31, 2019, the Company's financial liabilities had undiscounted contractual maturities (including interest payments where applicable) as summarized below:

	Total \$	Current	Non-current		
		Within 12 Months \$	1 to 2 Years \$	2 to 5 Years \$	> 5 years \$
Accounts payable and accrued liabilities	9,678	9,678	-	-	-
Other obligations	5,160	398	2,898	1,864	-
Senior secured Amortization Loan	93,925	14,548	23,899	55,478	-
Senior secured Bridge Loan <sup>(i)</sup>	4,504	4,504	-	-	-
Senior secured Convertible Loan	80,120	2,387	4,773	72,960	-
	<b>193,387</b>	<b>31,515</b>	<b>31,570</b>	<b>130,302</b>	-

<sup>(i)</sup> Subsequent to December 31, 2019, the Bridge Loan was repaid in its entirety.

The Company's ability to satisfy its debt obligations will depend principally upon its future operating performance. The Company's inability to generate sufficient cash flows to satisfy its debt service obligations or to refinance its obligations on commercially reasonable terms could have a materially adverse impact on the Company's business, financial condition or operating results.

The Deerfield Facility Agreement contains customary representations and warranties and affirmative and negative covenants, including, among other things, an annual financial covenant based on minimum levels of net sales per fiscal year and a mandatory quarterly repayment requirement under the Amortization Loan and the Bridge Loan equal to the greater of (i) 50% of excess cash flows (as defined in the Deerfield Facility Agreement) for such quarter, and (ii) US\$2.5 million, commencing with the quarter ended March 31, 2019, provided that, solely with respect to the first four fiscal quarters after the closing date, the US\$2.5 million quarterly minimum is not applicable as long as US\$10.0 million in principal repayments have been made over such four fiscal quarters. The Company agreed to an amendment to the financing agreement dated June 25, 2019, to provide, among other things, for a payment deferral mechanism in the event that Vimovo U.S. market exclusivity is lost. The amendment allows the Company to defer a portion of the mandatory minimum quarterly principal repayments by the difference between one quarter of the existing US\$7.5 million minimum annual royalty due from Vimovo sales in the U.S. and the actual amount of royalties received in the applicable quarter in the event Vimovo U.S. market exclusivity is lost earlier than had been expected (2022) prior to the Court of Appeals decision. The amount of any deferred principal repayment would, until repaid in accordance with the amendment, be subject to an interest rate of 12.5% per annum. As a result of this amendment, for the year ended December 31, 2019, the Amortization Loan and Bridge Loan were revalued and a loss of \$2.2 million was recorded due to both modification of debt and changes in the assumptions regarding the timing of the payments.

The Company anticipates that its current cash of \$23.0 million as at December 31, 2019, together with the cash flows generated from operations, will be sufficient to execute its current business plan for the next 12 months and will meet its current debt obligations.

### Interest Rate Risk

The Company's policy is to minimize interest rate cash flow risk exposures on its long-term financing. The Company's loans and borrowings and lease obligations are at fixed interest rates.

The fair value of the Company's prepayment option on the Amortization Loan and Bridge Loan and the Company's derivative liabilities are impacted by market rate changes.

## Currency Risk

The Company operates globally, which gives rise to a risk that income and cash flows may be adversely affected by fluctuations in foreign currency exchange rates. The Company is primarily exposed to the U.S. dollar, euro and British Pound (GBP), 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:

	U.S. Dollar		Euro		British Pound	
	December 31, 2019	December 31, 2018	December 31, 2019	December 31, 2018	December 31, 2019	December 31, 2018
	\$	\$	€	€	£	£
Cash	7,565	15,051	630	755	619	-
Accounts receivable	8,960	1,332	319	581	37	-
Contract assets	-	19,170	-	-	234	-
Loans and borrowings	(94,976)	(93,869)	-	-	-	-
Derivative liabilities	(644)	(10,654)	-	-	-	-
Accounts payable and accrued liabilities	(405)	(6,063)	(785)	(405)	(22)	-
Other obligations	(1,456)	(942)	(1,010)	(244)	-	-
	<b>(80,956)</b>	<b>(75,975)</b>	<b>(846)</b>	687	<b>868</b>	-

Based on the aforementioned net exposure as at December 31, 2019, 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 \$10.5 million on total comprehensive income (loss), a 10% appreciation or depreciation of the Canadian dollar against the euro would have an effect of \$123 on total comprehensive income (loss) and a 10% appreciation or depreciation of the Canadian dollar against the GBP would have an effect of \$149 on total comprehensive income (loss).

In terms of the U.S. dollar, the Company has five significant exposures: its U.S. dollar-denominated cash held in its Canadian operations, its U.S. dollar-denominated loans and borrowings and derivative liabilities held in its Canadian and European operations, its net investment and net cash flows in its European operations, the cost of purchasing raw materials either priced in U.S. dollars or sourced from U.S. suppliers and payments made to the Company under its U.S. dollar-denominated licensing arrangements.

The Company does not currently hedge its U.S. dollar cash flows. The Company funds its U.S. dollar-denominated interest expense and loan obligations using the Company's U.S. dollar-denominated cash and cash equivalents and payments received under the terms of the licensing and supply agreements. 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.

In terms of the euro, the Company has three significant exposures: its euro-denominated cash held in its Canadian operations, sales of Pennsaid by the Canadian operations to European distributors and the cost of purchasing raw materials priced in euros.

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 day-to-day expenses of the Nuvo Ireland 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.

In terms of the GBP, the Company has three significant exposures: its euro-denominated cash held in its Canadian operations and euro operations, the cost of purchasing raw materials or services priced in GBP and payments made to the Company under its GBP-denominated licensing arrangements, and minimum royalties received and accounted for as a contract asset in GBP.

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

### Market Risk

The Company's derivative liabilities - the Warrants and conversion feature that accompanies the Company's Convertible Loan, are impacted by a variety of valuation inputs (See Note 13, *Derivative Liabilities*), including changes in the Company's share price. As at December 31, 2019, a \$1.00 increase in the Company's share price would increase the value of the Warrants by \$9.0 million and an increase to the conversion feature of \$5.7 million, with a corresponding loss of \$14.7 million recognized in income for the change in fair value of derivative liabilities. As at December 31, 2019, a \$2.00 increase in the Company's share price would increase the value of the Warrants by \$14.8 million and increase the value of the conversion feature by \$9.3 million, with a corresponding loss of \$24.1 million recognized in income for change in fair value of derivative liabilities.

## 26. REVENUE

In the following table, revenue is disaggregated by primary geographic market, major categories of revenue and timing of revenue recognition as follows:

	Year ended December 31							
	2019	2018	2019	2018	2019	2018	2019	2018
	\$	\$	\$	\$	\$	\$	\$	\$
	United States		International		Canada		Total	
<b>Primary categories of revenue</b>								
Product sales	14,104	14,010	1,977	3,324	35,803	235	51,884	17,569
License revenue	5,351	408	9,989	1,646	418	208	15,758	2,262
Contract revenue	1,825	78	79	77	-	12	1,904	167
	<b>21,280</b>	14,496	<b>12,045</b>	5,047	<b>36,221</b>	455	<b>69,546</b>	19,998
<b>Timing of revenue recognition</b>								
Transferred over time	1,367	-	-	-	-	12	1,367	12
Transferred at a point in time	19,913	14,496	12,045	5,047	36,221	443	68,179	19,986
	<b>21,280</b>	14,496	<b>12,045</b>	5,047	<b>36,221</b>	455	<b>69,546</b>	19,998

### Accounts Receivable and Contract Assets

	December 31, 2019	December 31, 2018
	\$	\$
Accounts receivable	14,387	4,957
Contract assets	402	26,752

The timing of revenue recognition, billings and cash collections result in accounts receivable and unbilled receivables (contract assets). Generally, receipt of payment occurs subsequent to billing and revenue recognition, resulting in accounts receivable. The Company's contract assets relate to license revenue attributable to minimum guaranteed sales-based royalties, upfront fees and milestone payments, which have not been billed at the reporting date. Unbilled receivables (contract assets) will be billed (and subsequently transferred to accounts receivable) in accordance with the agreed-upon contractual terms.

Significant changes in the contract assets' current and long-term balance during the year were as follows:

	\$
Balance, December 31, 2018	26,752
Transfers to accounts receivable	(2,898)
Foreign exchange movements	(1,054)
Vimovo impairment	(22,398)
<b>Balance, December 31, 2019</b>	<b>402</b>

The Company's contract assets are subject to estimation regarding the likelihood of the minimum guaranteed sales-based royalties. In July 2019, the Company received notice that the Court of Appeals had denied the Company's and Horizon's request to reconsider the May 2019 decision with respect to the validity of the Vimovo '907 patent and the '285 patent in the U.S. On February 18, 2020, Dr. Reddy's second-filed ANDA for Vimovo in the U.S. received FDA approval and the Company anticipates a generic version of Vimovo could launch in the U.S. during 2020. It is the Company's understanding that Dr. Reddy does not have the benefit of 180-days of exclusivity, and, consequently, other generic companies may obtain final FDA approval for a generic version of Vimovo and be able to market the product in the U.S. If, and when, a competitor generic version of Vimovo enters the U.S. market, Nuvo will continue to receive a 10% royalty on net sales of Vimovo by its U.S. partner, subject to a step-down provision in the event that generic competition achieves a certain market share. Nuvo's US\$7.5 million minimum annual royalty due for Vimovo net sales in the U.S. will cease with the launch of a generic Vimovo in the U.S. The Company has written off its contract asset attributable to its Vimovo U.S. royalty and on June 30, 2019 recognized a \$23.6 million impairment charge of which \$22.4 million was attributable to the related contract asset balance with the remainder recorded as an increase in liabilities. This increase in liabilities was subsequently reversed, as a generic version of Vimovo did not launch in 2019 in the U.S. and the Company earned the minimum annual royalty of US\$7.5 million for the year ended December 31, 2019.

### Significant Customers

For the year ended December 31, 2019, the Company's four largest customers generating product sales represented 87% [December 31, 2018 - 97%] of total product sales and the Company's largest customer represented 30% [December 31, 2018 - 79%] of total product sales.

## 27. SEGMENT REPORTING

### Operating Segments

The Company has three operating segments: Commercial Business, Production and Service Business and Licensing and Royalty Business.

The Commercial Business segment is comprised of products commercialized by the Company in Canada. This includes products with dedicated promotional efforts - Blexten, Cambia and the Canadian business for Resultz, as well as 14 mature products sold by Aralez Canada.

The Production and Service Business segment includes revenue from the sale of products manufactured by Nuvo from its manufacturing facility in Varennes, Québec or contracted by Nuvo Ireland from its international headquarters in Dublin, Ireland, as well as service revenue for testing, development and related quality assurance and quality control services provided by the Company. Key revenue streams in this segment include Pennsaid 2%, Pennsaid, the bulk drug product for the HLT Patch, as well as transition services provided by Nuvo Ireland to two companies.

The Licensing and Royalty Business segment includes the revenue generated by the licensing of intellectual property and ongoing royalties from exclusive licensing agreements with global partners. Key revenue streams in this segment include royalties from the Company's Vimovo, Resultz and HLT Patch license agreements.

The Corporate and Other total includes overhead and financing costs incurred by the Company to support its public company infrastructure and the three operating segments.

	Commercial Business	Production and Service Business	Licensing and Royalty Business	Corporate and Other	Total
<b>Year ended December 31, 2019</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
Total revenue	35,578	18,210	15,758	-	69,546
Cost of goods sold	17,860	8,612	-	-	26,472
Gross profit	17,718	9,598	15,758	-	43,074
Sales and marketing expenses	9,796	-	-	-	9,796
General and administrative expenses	-	-	-	17,840	17,840
Interest expense (income)	-	-	(2,265)	12,570	10,305
Depreciation and amortization, excluded from cost of goods sold	-	-	-	8,356	8,356
Other income	-	-	-	(6,612)	(6,612)
Income tax expense	-	-	-	28	28
Segment net income (loss)	7,922	9,598	18,023	(32,182)	3,361
Total segment assets <sup>(i)</sup>	95,929	10,349	52,971	3,623	162,872

<sup>(i)</sup> As at December 31, 2019

	Commercial Business	Production and Service Business	Licensing and Royalty Business	Corporate and Other	Total
<b>Year ended December 31, 2018</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
Total revenue	-	17,736	2,262	-	19,998
Cost of goods sold	-	8,638	-	-	8,638
Gross profit	-	9,098	2,262	-	11,360
Sales and marketing expenses	-	-	-	-	-
General and administrative expenses	-	-	-	16,238	16,238
Interest income	-	-	-	(32)	(32)
Depreciation and amortization, excluded from cost of goods sold	-	-	-	1,989	1,989
Other expenses	-	-	-	(495)	(495)
Income tax recovery	-	-	-	(187)	(187)
Segment net income (loss)	-	9,098	2,262	(17,513)	(6,153)
Total segment assets <sup>(i)</sup>	101,548	9,973	70,532	22,359	204,412

<sup>(i)</sup> As at December 31, 2018

## 28. KEY MANAGEMENT COMPENSATION

Key management personnel are those persons having authority and responsibility for planning, directing and controlling the activities of the Company, including directors. In 2019, key management included the Company's President & Chief Executive Officer, Vice President & Chief Financial Officer, Vice President, Secretary & General Counsel, Vice President Operations & Chief Scientific Officer, Vice President, Sales & Marketing, the Executive Chairman and non-employee directors. In 2018, key management included the Company's President & Chief Executive Officer, Vice President & Chief Financial Officer, Vice President, Secretary & General Counsel, the Chief Scientific Officer, the Executive Chairman and non-employee directors. Compensation for the Company's key management personnel was as follows:

	Year ended December 31, 2019	Year ended December 31, 2018
	\$	\$
Short-term wages, bonuses and benefits	3,541	2,360
Share-based payments	399	670
<b>Total key management compensation</b>	<b>3,940</b>	<b>3,030</b>
<i>Included in:</i>		
Sales and marketing	488	-
General and administrative expenses	3,452	3,030
<b>Total key management compensation</b>	<b>3,940</b>	<b>3,030</b>

## 29. CAPITAL MANAGEMENT

The Company currently defines its capital to include its cash and cash equivalents, long-term debt (including current portion), derivative liabilities and shareholders' equity excluding AOCI.

The Company's objectives when managing capital are:

- (a) To allow the Company to respond to changes in economic and marketplace conditions;
- (b) To give shareholders sustained growth in shareholder value by increasing equity; and
- (c) To maintain a flexible capital structure that optimizes the cost of capital at acceptable levels of risk.

In the past, the Company has financed its business primarily through its operations, the net proceeds received from the sale of common shares and warrants, issuance of secured debt and convertible debentures, finance lease obligations and investment income earned on cash balances and short-term investments. The Company continues to manage its capital structure and will maintain or adjust its capital structure to facilitate the execution of the Company's objectives or in light of changes in the economic environment.

The Company's capital is comprised of debt and shareholders' equity as follows:

	December 31, 2019	December 31, 2018
	\$	\$
Cash and cash equivalents and restricted cash	23,019	28,074
Long-term debt, including current portion	123,377	124,207
Derivative liabilities	2,229	33,646
Shareholders' equity, excluding AOCI	24,155	20,337
	<b>172,780</b>	<b>206,264</b>



## Corporate Information

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Website: [www.nuvopharmaceuticals.com](http://www.nuvopharmaceuticals.com)

### INVESTOR RELATIONS

Email: [ir@nuvopharm.com](mailto:ir@nuvopharm.com)

### AUDITORS

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

### LEGAL COUNSEL

**Goodmans LLP**  
Toronto, Canada

### STOCK EXCHANGE LISTING

**The Toronto Stock Exchange**  
Symbol: NRI

### OTCQX

Symbol: NRIF

### TRANSFER AGENT/REGISTRAR

#### Common Shares

AST Trust Company (Canada)  
P.O. Box 700, Station B  
Montreal, QC  
H3B 3K3  
Canada  
Telephone: 1-800-387-0825  
or outside Canada and U.S. 416-682-3860  
Fax: 1-888-249-6189 or  
outside Canada and U.S. 514-985-8843  
Email: [inquiries@astfinancial.com](mailto:inquiries@astfinancial.com)  
Website: [www.astfinancial.com/ca](http://www.astfinancial.com/ca)

### CORPORATE GOVERNANCE

The Company's website [www.nuvopharmaceuticals.com](http://www.nuvopharmaceuticals.com) contains the Company's corporate governance documents including Articles and By-laws, Committee Charters and Key Position Descriptions and Corporate Policies and Practices.

## Board of Directors and Executive Officers

### Robert Harris

Executive Chairman

### David A. Copeland, BMath, CPA, CA

Lead Director  
Chair of the Audit Committee

### Daniel N. Chicoine, BComm, CPA, CA

Director

### Jesse F. Ledger, BBA

President & Chief Executive Officer

### Katina K. Loucaides, MSc, LLB

Vice President, Secretary & General Counsel

### John C. London, LLB, LLM

Vice Chairman

### Anthony E. Dobranowski, BSc, MBA, CPA, CA

Director  
Chair of the Compensation, Corporate  
Governance & Nominating Committee

### Mary-Jane E. Burkett, CPA, CA, HBA

Vice President & Chief Financial Officer