



## **Nuvo Pharmaceuticals™ Announces 2017 Fourth Quarter and Year-End Results**

**- Nuvo to Host Conference Call/Audio Webcast March 23 at 8:30 a.m. ET -**

Mississauga, Ontario, Canada – March 23, 2018 – Nuvo Pharmaceuticals Inc. (Nuvo or the Company) (TSX:NRI ; OTCQX:NRIF), a commercial healthcare company with a portfolio of commercial products and pharmaceutical manufacturing capabilities, today announced its financial and operational results for the fourth quarter and year ended December 31, 2017. For further details on the results, please refer to Nuvo's Management, Discussion and Analysis (MD&A) and Consolidated Financial Statements which are available on the Company's website ([www.nuvopharmaceuticals.com](http://www.nuvopharmaceuticals.com)). All figures are in Canadian dollars, unless otherwise noted.

### **Fourth Quarter 2017 and Business Update**

#### Pennsaid® 2%

- U.S. prescriptions of Pennsaid 2% were 110,000 in the fourth quarter of 2017 compared to 108,000 prescriptions in the third quarter of 2017. According to IMS Health/IQVIA, for the year ended December 31, 2017, U.S. prescriptions of Pennsaid 2% were 434,000 compared to 457,000 for the year ended December 31, 2016.
- In December 2017, the Company entered into a license and distribution agreement with Gebro Pharma AG (Gebro Pharma) for the exclusive right to register, distribute, market and sell Pennsaid 2% in Switzerland and Liechtenstein.

#### Resultz®

- In January 2018, the Company's wholly owned subsidiary, Nuvo Pharmaceuticals (Ireland) Limited (Nuvo Ireland) acquired the U.S. product and intellectual property rights to Resultz from Piedmont Pharmaceuticals LLC (Piedmont). The acquisition included all U.S. product and intellectual property rights. Resultz was cleared as a Class 1 medical device by the U.S. Food and Drug Administration (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 has already initiated discussions with potential licensees.
- In December 2017, the Company acquired the global, ex-U.S. product and intellectual property rights to Resultz from Piedmont. The transaction included existing royalty streams in France, Spain, Portugal, Belgium, Ireland and the United Kingdom, Canada, Russia, Australia, and Israel which are generated from a network of existing global licensees and license agreements that were assumed by Nuvo.

#### Corporate Developments

- In November 2017, the Toronto Stock Exchange (TSX) approved the Company's notice of intention to make a normal course issuer bid for a portion of its outstanding common shares as appropriate opportunities arise from time-to-time. Pursuant to the notice, Nuvo is authorized to acquire up to a maximum of 919,819 of its common shares, or approximately 10% of the public float of 9,198,191 as of November 30, 2017, for cancellation over the next 12 months. Nuvo believes that the repurchase of a portion of outstanding common shares is an appropriate use of available cash and is in the best interest of Nuvo and its shareholders.
- On November 28, 2017, the Company's common shares commenced trading on the OTCQX® market in the United States under the symbol "NRIF". Nuvo's common shares will continue to trade on the TSX under the symbol "NRI".

- In November 2017, the Board of Directors of the Company appointed Jesse Ledger to the position of President & Chief Executive Officer. Mr. Ledger had previously held the position of President. Mr. Ledger assumed the CEO role from John London who was appointed the Company's Executive Chairman and continues to serve on its Board of Directors.

#### **Fourth Quarter and Full Year Financial Summary<sup>(1)</sup>**

- As previously disclosed, the Company's supply of commercial bottles of Pennsaid 2% to its U.S. partner Horizon Pharma plc (Horizon) throughout 2017 was affected by the installation of new packaging equipment to facilitate compliance with the U.S. Federal Drug Supply Chain Security Act and Horizon's plan to draw down existing inventory during the installation process. Supply of Pennsaid 2% physician samples was negatively affected by the changes Horizon made to its commercial operation in 2017.
- Total revenue for the year ended December 31, 2017 was \$17.5 million compared to \$27.0 million for the year ended December 31, 2016. Total revenue was \$4.5 million for the three months ended December 31, 2017 compared to \$5.6 million for the three months ended December 31, 2016.
- Adjusted EBITDA<sup>(2)</sup> decreased to \$2.2 million for the year ended December 31, 2017 compared to \$8.9 million in the comparative year. Adjusted EBITDA decreased to \$36,000 for the three months ended December 31, 2017 compared to \$1.3 million for the three months ended December 31, 2016.
- Net income from continuing operations was \$1.6 million for the year ended December 31, 2017 compared to \$7.4 million in the comparative year. Net loss from continuing operations was \$0.2 million for the three months ended December 31, 2017 compared to net income from continuing operations of \$1.7 million for the three months ended December 31, 2016.
- Cash and short-term investments were \$10.4 million as at December 31, 2017 compared to \$17.7 million as at September 30, 2017. The decrease was primarily related to the US\$7.0 million (\$8.8 million) that was paid to Piedmont to acquire the ex-U.S. product and intellectual property rights to Resultz.

<sup>(1)</sup> The financial information presented herein reflects results from continuing operations with Nuvo's previously disclosed segment, Crescita, presented as a discontinued operation.

<sup>(2)</sup> Adjusted EBITDA is a non- International Financial Reporting Standards (IFRS) financial measure defined by the Company below.

"Pennsaid 2% prescriptions remained steady in the fourth quarter with a small increase over the third quarter 2017, but down slightly in 2017 compared to 2016. Considering the changes our U.S. partner Horizon made to their commercial business in 2017, we are pleased that prescriptions of Pennsaid were not significantly affected," said Jesse Ledger, Nuvo's President & CEO. "During the quarter, we shipped the first batches of serialized Pennsaid 2% commercial bottles to Horizon, within the timelines we had expected and well in advance of the FDAs revised deadline for implementation of the U.S. Federal Drug Supply Chain Security Act in November 2018."

Mr. Ledger added, "We also made considerable progress in our goal to further diversify our product portfolio and revenue streams with the global ex-U.S. acquisition of Resultz and its related royalty stream in December, followed by the acquisition of the U.S. Resultz rights in January. We now have an additional best in class product in our portfolio that offers significant international growth potential for our business."

#### **Growth Strategy**

The Company's focus, in the short-term, is to continue to maximize the value of Pennsaid 2% and Resultz through out-licensing to commercial partners in international markets, identifying new opportunities to acquire additional, accretive, late or commercial-stage products or businesses to further diversify the Company's existing product portfolio and revenue streams and to better utilize the Company's manufacturing facility in Varennes, Québec.

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

In January 2018, the Company's wholly owned subsidiary, Nuvo Ireland acquired the U.S. rights to Resultz (50% isopropyl myristate, 50% cyclomethicone D5 topical solution lice and egg removal kit) from Piedmont. The acquisition included all U.S. product and intellectual property rights. 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 has already initiated discussions with potential licensees. Under the terms of the agreement, US\$1.5 million (\$1.9 million) was paid to Piedmont. The transaction includes a single-digit royalty payable by Nuvo Ireland on net sales through 2034. Nuvo, through its Nuvo Ireland subsidiary, has also obtained a right of first refusal to license or acquire certain related assets from Piedmont targeting other human indications.

#### Acquisition of Global, ex-U.S. Rights to Resultz

In December 2017, the Company acquired the global, ex-U.S. product and intellectual property rights to Resultz from Piedmont. The transaction included existing royalty streams in France, Spain, Portugal, Belgium, Ireland and the United Kingdom, Canada, Russia, Australia and Israel (collectively the Royalty Markets), generated from a network of existing global licensees and license agreements that were assumed by Nuvo. Current global licensees include Reckitt Benckiser Group PLC, Aralez Pharmaceuticals Inc., Lapidot Medical and Takeda Belgium. Resultz is also pending registration in Japan, where the local license is held by Sato Pharmaceutical Co. Ltd. Resultz is protected by a portfolio of 40 issued patents globally. Resultz is currently approved for sale under its European Conformity (CE) mark as a class 1 medical device, but not yet partnered or generating revenue in all remaining E.U. territories. Under the terms of the agreement, Nuvo paid US\$7.0 million (\$8.8 million) on close to Piedmont. The transaction also included a single-digit royalty payable by Nuvo on net sales generated from non-Royalty Markets through 2023 and potential added future consideration in the form of payments for achieving certain aggregate annual net sales-based milestones.

#### Pennsaid 2% Out-licensing

In December 2017, the Company entered into a license and distribution agreement with Gebro Pharma for the exclusive right to register, distribute, market and sell Pennsaid 2% in Switzerland and Liechtenstein. Nuvo will provide Gebro Pharma with its existing Pennsaid 2% regulatory dossier and the FDA approval of Pennsaid 2%, which Gebro Pharma will use to support its application for regulatory approvals in Switzerland and Liechtenstein. Gebro anticipates meeting with Swissmedic, the Swiss regulatory approval organization, towards the end of Q2 or early Q3 2018 for scientific advice regarding an application for Swiss regulatory approval. 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 Gebro Pharma pursuant to an exclusive supply agreement from its manufacturing facility in Varennes, Québec.

In December 2017, the Company's Indian partner, Sayre Therapeutics PVT LTD submitted its marketing authorization application for Pennsaid 2% to the Drug Controller General of India. If regulatory approval is obtained as anticipated, the Company expects commercial launches of Pennsaid 2% will commence in late 2018 or early 2019. The Company received an upfront payment and is eligible to receive milestone payments and a double-digit royalty on net sales. Nuvo will supply Pennsaid 2% to Sayre Therapeutics on an exclusive basis from its manufacturing facility in Varennes, Québec.

Nuvo anticipates that incremental revenue from licensing agreements signed in 2017 will commence in late 2018 or early 2019, subject to obtaining regulatory approvals for Pennsaid 2% in the related territories.

#### **Pennsaid 2% U.S. Update**

##### Federal Drug Supply Chain Security Act Compliance

The Federal Drug Supply Chain Security Act (DSCSA) rules require all manufacturers of drug products sold in the U.S. to serialize each individual drug package to enhance drug traceability in the event of an adverse event and to prevent drug counterfeiting. In order to be in compliance with the DSCSA rules, the Company has purchased new packaging equipment and technology systems in coordination with Horizon. The Company commenced the process of installing and qualifying the new packaging equipment at its manufacturing plant in Varennes, Québec for commercial production; however, on June 30, after the Company had stopped commercial production of non-serialized commercial bottles for Horizon, the FDA announced that it was extending the date for serialization compliance by one year to November 27, 2018. As a result of this change, Horizon requested that the Company deliver non-serialized commercial bottles during the third quarter before the qualification process was completed. The Company completed its qualification and was fully compliant with the DSCSA rules during the fourth quarter.

##### Horizon Adjustment of Sales and Marketing Resources

When Horizon released its Q1 2017 results, it indicated that due to reimbursement pricing pressures, the profitability of its primary care group that sells Pennsaid 2% and other drug products had decreased. As a result, Horizon indicated that it was reallocating resources to better align its costs and profits. The reallocation included a reduction in the size of

Horizon's primary care sales force that markets Pennsaid 2% to physicians. Nuvo gets paid a fixed price per commercial bottle supplied to Horizon and is not directly impacted by any reduction in Horizon's profitability. With prescription volumes relatively consistent quarter-to-quarter in fiscal 2017, the Company has not yet seen a significant negative effect from Horizon's sales force reduction that might impact Horizon's typical commercial bottle ordering patterns moving forward. Horizon's cost reallocation initiatives have resulted in a decrease in the number of product samples Horizon distributes to physicians. A reduction in sample product orders from Horizon had a negative impact on the Company's 2017 financial results.

#### **Fourth Quarter and Full Year Financial Review**

##### **Table of Selected Financial Results**

For further details on the results, please refer to Nuvo's MD&A and the Consolidated Financial Statements which are available on the Company's website ([www.nuvopharmaceuticals.com](http://www.nuvopharmaceuticals.com)).

	Three months ended			Year ended		
	December 31, 2017	December 31, 2016	Change	December 31, 2017	December 31, 2016	Change
<i>(from continuing operations, in thousands, except gross margin)</i>	\$	\$	\$	\$	\$	\$
Product Sales	<b>4,199</b>	5,194	(995)	<b>16,338</b>	24,824	(8,486)
Gross Margin % on Product Sales	<b>46%</b>	51%	(5%)	<b>50%</b>	54%	(4%)
Other Revenue	<b>286</b>	379	(93)	<b>1,185</b>	2,215	(1,030)
Total Operating Expenses	<b>4,634</b>	3,959	675	<b>15,649</b>	19,307	(3,658)
Net Income (Loss)	<b>(186)</b>	1,739	(1,925)	<b>1,581</b>	7,409	(5,828)
Adjusted EBITDA	<b>36</b>	1,309	(1,273)	<b>2,169</b>	8,873	(6,704)

Total revenue, consisting of product sales, royalties and contract revenue for the three months ended December 31, 2017 was \$4.5 million compared to \$5.6 million for the three months ended December 31, 2016. The decrease in total revenue was primarily related to a decrease in Pennsaid 2% product sales. Total revenue for the year ended December 31, 2017 was \$17.5 million compared to \$27.0 million for the comparative year.

Total operating expenses for the three months ended December 31, 2017 increased to \$4.6 million compared to \$4.0 million for the three months ended December 31, 2016. The increase in operating expenses was primarily attributable to an increase in general and administrative (G&A) expenses, partially offset by a decrease in cost of goods sold (COGS) and research and development (R&D) expenses. Total operating expenses for the year ended December 31, 2017 decreased to \$15.6 million from \$19.3 million in the comparative year.

COGS for the three months ended December 31, 2017 was \$2.3 million compared to \$2.5 million for the three months ended December 31, 2016. The decrease in COGS was primarily related to a decrease in Pennsaid 2% product sales. The decrease in product sales reduced the gross margin on product sales to \$1.9 million or 46% for the three months ended December 31, 2017 compared to \$2.7 million or 51% for the three months ended December 31, 2016. For the year ended December 31, 2017, COGS was \$8.1 million compared to \$11.4 million in the comparative year. Gross margin on product sales was \$8.2 million or 50% for the year ended December 31, 2017 compared to a gross margin of \$13.5 million or 54% for the year ended December 31, 2016.

R&D expenses decreased to \$36,000 for the three months ended December 31, 2017 compared to \$0.6 million for the three months ended December 31, 2016. The decrease in the quarter related to costs associated with the 2016 Pennsaid 2% Trial for the treatment of acute ankle sprains which were recognized in the comparative period. The 2016 Pennsaid 2% Trial was completed in May of 2017 and the majority of the costs were previously recognized. R&D expenses were \$0.6 million for the year ended December 31, 2017 compared to \$1.4 million for the comparative year.

G&A expenses increased to \$2.4 million for the three months ended December 31, 2017 compared to \$0.9 million for the three months ended December 31, 2016. The increase in the current quarter of \$1.5 million was primarily related to a \$0.6 million increase in stock-based compensation (SBC) expense and increased employee head count which resulted from the strengthening of the executive and senior management team aimed to facilitate the Company's growth strategy. G&A expenses were \$7.1 million for the year ended December 31, 2017 compared to \$6.7 million for the year ended December 31, 2016.

Net interest income was \$39,000 for the three months ended December 31, 2017 compared to \$37,000 for the three months ended December 31, 2016. For the year ended December 31, 2017 net interest income was \$0.2 million and \$0.1 million in the comparative year. The Company earns interest income on its short-term investments and its high interest savings account.

Other expenses (income) primarily consists of net foreign currency gains or losses. Foreign currency gains or losses are recognized based on movements in the Canadian dollar against U.S. dollar and euro denominated cash, receivables, payables and other obligations

Net loss from continuing operations was \$0.2 million for the three months ended December 31, 2017 compared to net income from continuing operations of \$1.7 million for the three months ended December 31, 2016. The decrease in net income from continuing operations was primarily related to a decrease in gross margin and an increase in G&A expenses. Net income from continuing operations was \$1.6 million for the year ended December 31, 2017 compared to \$7.4 million for the year ended December 31, 2016.

Adjusted EBITDA decreased to \$36,000 for the three months ended December 31, 2017 compared to \$1.3 million for the three months ended December 31, 2016. In the current quarter, a decrease in Adjusted EBITDA primarily related to a decrease in gross margin. Adjusted EBITDA decreased to \$2.2 million for the year ended December 31, 2017 compared to \$8.9 million for the comparative year.

Cash and short-term investments were \$10.4 million as at December 31, 2017 compared to \$17.7 million as at September 30, 2017 and \$17.6 million as at December 31, 2016. The decrease was primarily related to the US\$7.0 million (\$8.8 million) that was paid to Piedmont to acquire the ex-U.S. product and intellectual property rights to Resultz.

The number of common shares outstanding as at December 31, 2017 was 11,550,897.

## **Non-IFRS Financial Measures**

### Adjusted EBITDA

EBITDA is a non-IFRS financial measure. The term EBITDA does not have any standardized meaning under IFRS and therefore may not be comparable to similar measures presented by other companies. The Company defines Adjusted EBITDA as net income from continuing operations before net interest income, plus income tax expense, depreciation, amortization and SBC. Management believes Adjusted EBITDA is a useful supplemental measure from which to determine the Company's ability to generate cash available for working capital, capital expenditures and income taxes.

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

	Three months ended		Year ended	
	December 31, 2017	December 31, 2016	December 31, 2017	December 31, 2016
in thousands	\$	\$	\$	\$
<b>Net income (loss) from continuing operations</b>	<b>(186)</b>	1,739	<b>1,581</b>	7,409
Add back:				
Net interest income	(39)	(37)	(157)	(144)
Income tax expense	-	-	1	-
Depreciation and amortization	84	55	258	225
<b>EBITDA</b>	<b>(141)</b>	1,757	<b>1,683</b>	7,490
Add back:				
Stock-based compensation	177	(448)	486	1,383
<b>Adjusted EBITDA</b>	<b>36</b>	1,309	<b>2,169</b>	8,873

### Management to Host Conference Call/Webcast

Management will host a conference call to discuss the results today (Friday, March 23, 2018) at 8:30 a.m. ET. To participate in the conference call, please dial 1 (888) 231-8191 or (647) 427-7450, reference number 1462349. Please call in 15 minutes prior to the call to secure a line. You will be put on hold until the conference call begins.

A taped replay of the conference call will be available two hours after the live conference call and will be accessible until March 30, 2018 by calling 1 (855) 859-2056 or (416) 849-0833, reference number 1462349.

A live audio webcast of the conference call will be available through [www.nuvopharmaceuticals.com](http://www.nuvopharmaceuticals.com). Please connect at least 15 minutes prior to the conference call to ensure adequate time for any software download that may be required to hear the webcast.

### About Nuvo Pharmaceuticals Inc.

Nuvo (TSX: NRI; OTCQX: NRIFF) is a global commercial healthcare company with a portfolio of commercial products and pharmaceutical manufacturing capabilities. Nuvo has four commercial products that are available in a number of countries: Pennsaid® 2%, Pennsaid, Resultz® and the heated lidocaine/tetracaine patch. Nuvo manufactures Pennsaid 2% for the U.S market, Pennsaid for the global market and the bulk drug product for the HLT Patch at its FDA, Health Canada and E.U. approved manufacturing facility in Varennes, Québec. The Company's focus is to maximize the value of Pennsaid 2% and Resultz through out-licensing to commercial partners in international markets and identifying new opportunities to acquire additional, accretive, late-stage products or businesses to further diversify the Company's existing product portfolio. For additional information, please visit [www.nuvopharmaceuticals.com](http://www.nuvopharmaceuticals.com).

### FOR MORE INFORMATION, PLEASE CONTACT:

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### Forward-Looking Statements

*This Press Release contains "forward-looking statements" within the meaning of applicable securities laws. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods.*

*Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on the Company's current beliefs, expectations and assumptions regarding the future of its business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of the Company's control. Nuvo's actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, readers should not rely on any of these forward-looking statements. Important factors that*

*could cause Nuvo's actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the risk factors included in Nuvo's most recent Annual Information Form dated March 22, 2018 under the heading "Risks Factors", and as described from time to time in the reports and disclosure documents filed by Nuvo with Canadian securities regulatory agencies and commissions. These and other factors should be considered carefully and readers should not place undue reliance on Nuvo's forward-looking statements. As a result of the foregoing and other factors, no assurance can be given as to any such future results, levels of activity or achievements and none of Nuvo or any other person assumes responsibility for the accuracy and completeness of these forward-looking statements.*

*Any forward-looking statement made by the Company in this Press Release is based only on information currently available to it and speaks only as of the date on which it is made. Except as required by applicable securities laws, Nuvo undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.*