

# Miravo Healthcare<sup>™</sup> Announces First Quarter 2022 Results

- Blexten Canadian Prescriptions Increased 21% Year-Over-Year -
- Suvexx Canadian Prescriptions Increased 120% Year-Over-Year -

## Miravo to Hold Virtual Annual Meeting May 16th at 9:00 a.m. ET

**Mississauga, Ontario, Canada** – May 16, 2022 – Nuvo Pharmaceuticals Inc. (TSX:MRV; OTCQX:MRVFF) d/b/a Miravo Healthcare (Miravo or the Company), a Canadian-focused healthcare company with global reach and a diversified portfolio of commercial products, today announced its financial and operational results for the three months ended March 31, 2022. For further details on the results, please refer to Miravo's Management, Discussion and Analysis (MD&A) and Condensed Consolidated Interim Financial Statements for the three months ended March 31, 2022, which are available on the Company's website (<a href="www.miravohealthcare.com">www.miravohealthcare.com</a>). All figures are in Canadian dollars, unless otherwise noted.

# **Key Developments**

Three months ended March 31, 2022 include the following:

- Total revenue was \$15.6 million, an increase of 8% compared to \$14.4 million for the three months ended March 31, 2021. Adjusted total revenue<sup>(1)</sup> was \$15.7 million, an increase of 8% compared to \$14.5 million for the three months ended March 31, 2021.
- Net income was \$2.0 million compared to net loss of \$18.0 million for the three months ended March 31, 2021.
  Adjusted EBITDA<sup>(1)</sup> was \$3.1 million, a decrease of 28% compared to \$4.4 million for the three months ended March 31, 2021.
- Revenue related to the Blexten® franchise, Cambia® and Suvexx® was \$8.1 million, an increase of 38% compared to revenue of \$5.9 million for the three months ended March 31, 2021. Total Canadian prescriptions of Blexten, Cambia and Suvexx increased by 21%, 1% and 120%, respectively compared to the three months ended March 31, 2021.
- The Company repaid \$3.5 million (US\$2.8 million) of the Amortization Loan to Deerfield Management Company, L.P. (Deerfield).
- As at March 31, 2022, cash and cash equivalents were \$26.5 million.

<sup>(1)</sup> Non-IFRS financial measure. These measures are not recognized under IFRS and do not have standardized meanings prescribed by IFRS. See the Non-IFRS Measures section for definitions, reconciliations and the basis of presentation of the Company's non-IFRS measures.

# **Business Update**

- In May 2022, Miravo become aware that the United States' Food & Drug Administration (FDA) approved Apotex Inc.'s abbreviated new drug application for a generic version of Pennsaid 2% on May 6, 2022. Miravo's partner in the United States owns the Pennsaid 2% intellectual property rights in the United States and has carriage and full decision-making authority with respect to any litigation related to this matter. Miravo is the exclusive manufacturer of Pennsaid 2% for its U.S. partner. The entry of a generic version of Pennsaid 2% may have a material and adverse impact on Miravo's Production and Service Business segment.
- In May 2022, Miravo filed U.S., Canadian, European and PCT patent applications for a reformulated and improved version of Resultz. This new formulation maintains the original 5-minute treatment claim, but is now enhanced with a 100% effectiveness claim for killing nits (the lice eggs) in addition to head lice. The Company believes this enhanced efficacy against nits adds value to existing Resultz partners, as well as other companies active in the head lice category globally who may be interested in licensing the technology. The Company will begin the partnering process for this new intellectual property during Q2 2022. Additional basic development work is anticipated to be conducted to support the new product.
- In February 2022, the United States District Court for the District of New Jersey granted a motion for summary judgment filed by Dr. Reddy's Laboratories Inc. (Dr. Reddy's). As a result, the asserted claims of Nuvo Pharmaceuticals (Ireland) DAC's (Miravo Ireland) U.S. Patent Nos. 8,858,996 (the '996 Patent) and 9,161,920 (the '920 Patent) related to Vimovo in the U.S. were found to be invalid. Both the '996 and the '920 patents were to expire May 31, 2022. Miravo Ireland and its partner have not appealed this decision.
- In February 2022, Blexten for pediatric use in patients 4 years of age and older\* was commercially launched in Canada. The pediatric use includes two new dosage formats; a 2.5mg/mL oral solution and a 10mg orodispersible tablet (quick melt) for the treatment of the symptoms of seasonal allergic rhinitis and chronic spontaneous urticaria (such as itchiness and hives). The pediatric formats are available to patients with a prescription from their healthcare provider.

"Our Commercial Business segment continues to perform well with Q1 year-over-year adjusted total revenue growth driven by increased Blexten, Suvexx and Cambia prescriptions. Our final \$375,000 sales-based milestone for the Blexten business was triggered during the quarter. This payment recognized the achievement of \$60 million in cumulative net sales of Blexten in Canada - a milestone we are very proud of. As we look to the remainder of 2022, we anticipate continued year-over-year quarterly growth in the Commercial Business segment consistent with the seasonality this business has experienced in the past," said Jesse Ledger, Miravo's President & CEO. "The financial impact of generic competition on our U.S. Vimovo royalty stream is now fully realized resulting in revenue stabilization in our Licensing and Royalty Business segment moving forward. Certain shipments to international customers were produced, but due to COVID-related delays, were not delivered in time to be recognized as revenue during Q1 in our Production and Service Business segment. While our business continues to be impacted by the COVID-19 pandemic, we are encouraged to see increasing numbers of patient/physician visits and look forward to a return to pre-COVID activity levels in the coming quarters."

# First Quarter 2022 Financial Results

Adjusted total revenue was \$15.7 million for the three months ended March 31, 2022 compared to \$14.5 million for the three months ended March 31, 2021. The \$1.2 million increase in adjusted total revenue in the current quarter was primarily attributable to an increase of \$2.4 million of revenue in the Commercial Business segment, offset by a decrease of \$0.9 million of revenue in the Production and Service Business segment combined with a decrease of \$0.3 million in the Licensing and Royalty Business segment.

Revenue attributable to the Commercial Business segment increased during the three months ended March 31, 2022 due to a \$2.2 million increase in sales of the Company's promoted products (Blexten, Cambia, Suvexx and NeoVisc®) and a \$0.2 million increase in sales of the Company's mature products.

<sup>\*</sup> Blexten (bilastine) is indicated for the symptomatic relief of nasal and non-nasal symptoms of seasonal allergic rhinitis and chronic spontaneous urticaria (e.g. pruritus and hives) in patients 4 years of age and older with a body weight of at least 16 kg.

The Production and Service Business segment revenue decreased during the three months ended March 31, 2022, primarily due to a decrease in Pennsaid 2% product sales, slightly offset by an increase in sales of Pennsaid and Resultz.

The decrease in revenue attributable to the License and Royalty business segment during the three months ended March 31, 2022 was primarily attributable to a \$0.5 million reduction in U.S. Vimovo royalty revenue due to a step-down in royalty to 5% of net sales compared to 10% of net sales in the comparative quarter, as well as a \$0.1 million reduction in the Company's Vimovo ex-U.S. royalties. In the current quarter, the decline in license revenue was offset by a \$0.2 million milestone payment related to a sublicensee agreement for Vimovo ex-U.S.

Adjusted EBITDA was \$3.1 million for the three months ended March 31, 2022 compared to \$4.4 million for the three months ended March 31, 2022, a \$0.9 million increase in gross profit from the Commercial Business segment was more than offset by a \$0.3 million decrease in the contribution from the License and Royalty Business segment, a \$0.7 million decrease in gross profit contribution from the Production and Service Business segment and a \$0.9 million increase in G&A expenses.

#### **Non-IFRS Measures**

The Company discloses non-IFRS financial measures (adjusted total revenue, adjusted EBITDA, and cash value of loans) and non-IFRS ratios (adjusted EBITDA per share and net debt leverage ratio) that are not recognized under and do not have standardized meanings prescribed by IFRS. Accordingly, such measures are not necessarily comparable and may not have been calculated in the same way as similarly named financial measures presented by other companies. These measures should be considered as supplemental in nature and not as a substitute for related financial information prepared in accordance with IFRS. The Company believes that shareholders, investment analysts and other readers find such measures and ratios helpful in understanding and assessing the Company's financial performance. We utilize these measures in managing our business, including as means of performance measurement, cash management, debt compliance and assessing leverage and borrowing capacity. Because non-IFRS financial measures and non-IFRS ratios do not have standardized meanings prescribed under IFRS, securities regulations require that such measures be clearly defined, identified, and for non-IFRS financial measures, reconciled to their nearest IFRS measure. The applicable definition, calculation and reconciliation of each such measure used in this press release is provided below.

#### **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, reconciled to the nearest IFRS measure:

	Three Months ended March 31, 2022	Three Months ended March 31, 2021
	\$	\$
Total revenue	15,641	14,422
Add:		
Amounts billed to customers for existing contract assets	107	127
Adjusted Total Revenue	15,748	14,549

## **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 EBITDA, plus amounts billed to customers for existing contract assets, inventory step-up expenses, stock-based compensation expense, loss on fair value of derivative liabilities, loss on fair value of contingent and variable consideration, impairment loss, foreign currency loss, other losses less revenue recognized upon recognition of a contract asset, stock-based compensation recovery, gain on fair value of derivative liabilities, gain on fair value of contingent and variable consideration, impairment recovery, foreign currency gain 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, reconciled to the nearest IFRS measure:

	Three Months ended March 31, 2022	Three Months ended March 31, 2021
	\$	\$
Net income (loss)	2,033	(17,989)
Add back:		· · ·
Income tax expense <sup>(1)</sup>	345	256
Net interest expense	2,417	2,586
Depreciation and amortization	1,896	2,076
EBITDA	6,691	(13,071)
Add back:		
Amounts billed to customers for existing contract assets	107	127
Stock-based compensation	101	105
Deduct:		
Change in fair value of derivative liabilities <sup>(2)</sup>	(3,310)	18,389
Change in fair value of contingent and variable consideration	154	(616)
Foreign currency gain	(664)	(714)
Inventory step-up	-	35
Other losses	54	96
Adjusted EBITDA	3,133	4,351

<sup>(1)</sup> Income tax expense for the three months ended March 31, 2022 includes \$0.3 million for deferred income tax due to the utilization of loss carryforwards that were previously recognized [\$0.3 million for the three months ended March 31, 2021].

## Management to Host Conference Call/Webcast

Miravo's 2022 Annual Meeting of Shareholders (Meeting) will be held as an online meeting only. The Meeting will take place on Monday, May 16, 2022 (today) at 9:00 a.m. Registered shareholders can attend the Meeting online, vote shares electronically if they have not voted by proxy in advance of the Meeting in accordance with the proxy instructions, and submit questions during the Meeting. You will need to have your 16-digit Control Number (the Control Number) to participate in the Meeting. If you are a shareholder and do not have a Control Number or if you are not a Miravo shareholder, you can attend the Meeting as a guest, but you will not be able to vote at the Meeting.

The link to participate in the Meeting is: <a href="www.virtualshareholdermeeting.com/mrv2022">www.virtualshareholdermeeting.com/mrv2022</a>. If you encounter any difficulties accessing the virtual meeting during the check-in or meeting time, please call the technical support number that will be posted on the Virtual Shareholder Meeting log in page.

#### **About Miravo Healthcare**

Miravo is a Canadian-focused, healthcare company with global reach and a diversified portfolio of commercial products. The Company's products target several therapeutic areas, including pain, allergy, neurology and dermatology. The Company's strategy is to in-license and acquire growth-oriented, complementary products for Canadian and international markets. Miravo's head office is located in Mississauga, Ontario, Canada, the international operations are located in Dublin, Ireland and the Company's 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. For additional information, please visit <a href="https://www.miravohealthcare.com">www.miravohealthcare.com</a>.

The Company's derivative liabilities are measured at fair value through profit or loss at each reporting date. As a result of the decrease in the share price in the current quarter and a decrease in the volatility of the Company's shares, amongst other inputs, the value of the Company's derivative liabilities decreased and the Company recognized a net non-cash gain of \$3.3 million on the change in fair value of derivative liabilities for the three months ended March 31, 2022.

### FOR MORE INFORMATION, PLEASE CONTACT:

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## **Forward-Looking Statements**

This press release contains "forward-looking information" as defined under Canadian securities laws (collectively, "forward-looking statements"). 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", "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. These forward-looking statements include statements regarding anticipated product launches, responses to COVID-19, milestone payments, royalties and license approvals.

Forward-looking statements are not historical facts but instead represent management's expectations, estimates and projections regarding future events or circumstances, including the anticipated receipt of certain milestone and royalty payments, the anticipated launch of certain products and approvals therefor, and the potential impact of COVID-19. 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 press release, are inherently subject to significant business, economic and competitive uncertainties and contingencies and may prove to be incorrect. Material factors and assumptions used to develop the forward-looking statements, and material risk factors that could cause actual results to differ materially from the forward-looking statements, include but are not limited to, the denial of regulatory approvals, the delay or failure to meet anticipated product launches, the failure to meet certain milestones or collect certain royalties, the potential impact of COVID-19 on the Company's operations, business and financial results and other factors, many of which are beyond the control of the Company. Additional factors that could cause the Company'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 the Company's most recent Annual Information Form dated March 25, 2022 under the heading "Risks Factors", and as described from time to time in the reports and disclosure documents filed by the Company with Canadian securities regulatory agencies and commissions. These and other factors should be considered carefully and readers should not place undue reliance on the Company's forward-looking statements. 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

All forward-looking statements are based only on information currently available to the Company and are made as of the date of this press release. 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 press release are qualified by these cautionary statements.