

February 9, 2022



# Medexus Pharmaceuticals Generated \$21.3M in Fiscal 2022 Third Quarter Revenues and Achieved \$1.9M Positive EBITDA for the Three Months Ended December 31, 2021

Achieved \$21.3 million revenue driven by a recovery in IXINITY sales

Treosulfan NDA resubmission expected in second calendar quarter 2022 with final FDA decision anticipated 2-6 months after resubmission

Available liquidity of \$10.1 million at end of period

Management to host conference call at 8:00 AM Eastern Time on February 10, 2022

TORONTO and CHICAGO, Feb. 09, 2022 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals Inc. ("Medexus" or the "Company") (TSX: MDP) (OTCQX: MEDXF) today announced its financial results and provided a business update for the three-month period ended December 31, 2021. All dollar amounts below are in United States dollars unless specified otherwise.

## Third Quarter Fiscal 2022 Financial Highlights:

- Revenue of \$21.3 million, an increase of 19% compared to \$17.9 million in Q2 of fiscal 2022 and a 12% decrease compared to \$24.3 million in Q3 of fiscal 2021. Sequential quarterly revenue growth was primarily attributable to an increase in IXINITY sales in Q3.
- Adjusted EBITDA\* of \$1.9 million, an increase from (\$2.0) million in Q2 of fiscal 2022 and a decrease from \$3.9 million in Q3 of fiscal 2021. Sequential quarterly improvement was primarily attributable to improved IXINITY net sales in Q3 and the reduction of expenses. The Company's recent inventory management and manufacturing process modernization initiatives have also started to produce positive results.
- Net loss of \$1.2 million, compared to \$12.8 million in Q3 of fiscal 2021.
- Adjusted net loss\*, which adjusts for unrealized losses (or gains) on the fair value of derivatives, of \$3.4 million, compared to \$0.4 million in Q3 of fiscal 2021.
- Net cash flow of \$1.4 million, compared to \$2.8 million in Q3 of fiscal 2021.
- Cash and cash equivalents of \$9.6 million (with \$10.1 million of total available liquidity) at end of Q3 of fiscal 2022.

Ken d'Entremont, Chief Executive Officer of Medexus, commented, "We are encouraged to see sequential quarter-over-quarter growth in revenue and adjusted EBITDA this past quarter. In particular, IXINITY saw improved sales in Q3 versus Q2 of fiscal 2022 aided by supply chain improvements. We plan to build on this momentum by continuing to pursue opportunities to complement our existing product portfolio, while also preparing for the commercial launch of Treosulfan in the United States later this year, assuming approval by the FDA."

### **Third Quarter Fiscal 2022 Operational Highlights:**

- **IXINITY:** The Company continued to see positive trends with respect to IXINITY sales, with unit market demand in the United States experiencing continuous growth in the trailing 12 twelve-months ended December 31, 2021 (Source: customer reported dispensing data), which the Company views as indicating a moderate level of patient conversions on top of a stable, existing base of patients. IXINITY net sales and gross margins in the period were both affected by the Company's recent initiatives to reset the supply chain and selling process and preliminary results of the Company's ongoing manufacturing process modernization initiative. The Company expects gross margins for the product will ultimately improve further as a result of these operational efficiencies.
- **Rupall:** The product continued to generate strong unit demand growth of 30% for the trailing twelve-months ended December 31, 2021. This positions Rupall as one of the fastest growing anti-histamines in the Canadian prescription market (Source: IQVIA CDH units – Drugstores and hospitals purchases, MAT December 2021). This strong growth reflects a severe allergy season across Canada and physicians increasingly switching patients to Rupall from either the generic prescription anti-histamines or over-the-counter products.
- **Treosulfan:** On November 23, 2021, the Company participated in medac's Type A meeting with the FDA to review medac's resubmission plan for its new drug application ("NDA") for Treosulfan. Following that meeting, and based on further discussions with medac, the Company's conclusion is that there is a path towards approval that does not involve completing an additional phase 3 study, provided medac delivers to the FDA materials that address the FDA's outstanding issues. The NDA resubmission is currently expected to occur in the second calendar quarter of 2022, with a final FDA decision expected 2 to 6 months thereafter.

### **Operating and Financial Results Summary for the Three Months Ended December 31, 2021:**

Total revenue reached \$21.3 million for the three-month period ended December 31, 2021, compared to revenue of \$24.3 million for the three-month period ended December 31, 2020. Revenue for the quarter benefited from a large late-December order totaling approximately \$2.0 million, which was originally anticipated to be received in Q4 of fiscal 2022. In addition, as previously disclosed, revenue for the comparison period includes over \$2.5 million in revenue from IXINITY sales, which was originally expected to be realized in September 2020, but was instead realized in early October 2020 due a delay in receipt of finished product from the Company's contract manufacturing partner. The Company expects that timing of such large orders will continue to affect quarter-to-quarter comparisons of the

Company's revenues.

Gross profit reached \$11.5 million for the three-month period ended December 31, 2021, compared to gross profit of \$12.7 million for the three-month period ended December 31, 2020.

Gross margin was 54.1% for the three-month period ended December 31, 2021, compared to 52.2% for the three-month period ended December 31, 2020. This higher gross margin is due to an increase in sales of higher margin products in Canada, as well as improvements made to the IXINITY manufacturing process, which has begun to generate improved yields, reducing the Company's cost per unit of IXINITY.

Operating loss was \$0.3 million for the three-month period ended December 31, 2021, compared to operating income of \$1.5 million for the three-month period ended December 31, 2020.

Adjusted EBTIDA\* was \$1.9 million for the three-month period ended December 31, 2021, compared to \$3.9 million for the three-month period ended December 31, 2020. This lower adjusted EBITDA is due to the impact of the significant investments the Company made to improve its capacity for future business development and prepare for the anticipated commercialization of Treosulfan in the United States.

Net loss was \$1.2 million for the three-month period ended December 31, 2021, compared to \$12.8 million for the three-month period ended December 31, 2020. Net loss for the quarter included a \$2.2 million non-cash unrealized gain on the fair value of the embedded derivatives in the Company's convertible debentures, which was driven by a change in the Company's share price at the end of the relevant periods.

### **Operating and Financial Results Summary for the Nine Months Ended December 31, 2021:**

Total revenue reached \$56.4 million for the nine-month period ended December 31, 2021, compared to revenue of \$62.0 million for the nine-month period ended December 31, 2020. Revenue for the period was lower than the comparison period due to comparatively weaker IXINITY sales, particularly earlier in the period. Rupall sales also contributed significantly to revenue for the period, notwithstanding typical seasonality that resulted in more moderate sales later in the period. Despite being on the market for more than four years, Rupall saw unit demand growth of 30% over the trailing twelve-months ended December 31, 2021 (Source: IQVIA CDH units – Drugstores and hospitals purchases). This is due to a severe allergy season across Canada, and further market share gained by the brand.

Gross profit reached \$27.8 million for the nine-month period ended December 31, 2021, compared to gross profit of \$33.2 million for the nine-month period ended December 31, 2020. The decline for the nine-month period ended December 31, 2021 was due, in part, to an increase in cost of goods sold, caused by additional expenses related to failures during the IXINITY manufacturing process in the quarter ended June 30, 2021, as previously disclosed. The Company is currently focusing on modernizing the manufacturing process to mitigate the risk of future manufacturing failures and to improve yields. Preliminary results of this initiative positively affected IXINITY performance later in the period.

Gross margin was 49.3% for the nine-month period ended December 31, 2021, compared to 53.5% for the nine-month period ended December 31, 2020. This lower gross margin is due to the additional expenses related to failures during the IXINITY manufacturing process earlier in the period, discussed above.

Operating loss for the nine-month period ended December 31, 2021 was \$12.5 million, compared to operating income of \$3.2 million for the nine-month period ended December 31, 2020.

Adjusted EBTIDA\* was \$(5.0) million for the nine-month period ended December 31, 2021, compared to \$9.8 million for the nine-month period ended December 31, 2020. This lower adjusted EBITDA is due to the impact of the IXINITY manufacturing failures during the three-months ended June 30, 2021, the large increase in research & development costs over the comparative period, and the significant investments the Company made to improve its capacity for future business development and prepare for the anticipated commercialization of Treosulfan in the United States.

Net income was \$2.4 million for the nine-month period ended December 31, 2021, compared to net loss of \$17.8 million for the nine-month period ended December 31, 2020. Net loss for this period included a \$21.8 million non-cash unrealized gain on the fair value of the embedded derivatives in the Company's convertible debentures, which was driven by changes to the Company's share price at the end of the relevant periods.

The Company's financial statements and management discussion and analysis, or MD&A, for the period ended December 31, 2021 are available on the Company's corporate website at [www.medexus.com](http://www.medexus.com) and in the Company's corporate filings on SEDAR at [www.sedar.com](http://www.sedar.com).

\* Refer to "Non-IFRS Financial Measures" at the end of this press release.

#### Conference Call Details

Medexus will host a conference call at 8:00 AM Eastern Time on Thursday, February 10, 2022, to discuss the Company's financial results for the fiscal 2022 third quarter ended December 31, 2021, as well as the Company's corporate progress and other developments.

The conference call will be available via telephone by dialing toll free 888-506-0062 for Canadian and U.S. callers or +1 973-528-0011 for international callers and by entering access code: 826598. A webcast of the call may be accessed at <https://www.webcaster4.com/Webcast/Page/2010/44502> or on the Investors—News and Events section of the Company's corporate website at [https://www.medexus.com/en\\_US/investors/news-events](https://www.medexus.com/en_US/investors/news-events).

A webcast replay will be available on the Investors—News and Events section of the Company's corporate website at [https://www.medexus.com/en\\_US/investors/news-events](https://www.medexus.com/en_US/investors/news-events) through Friday, February 10, 2023. A telephone replay of the call will be available approximately one hour following the call through Thursday, February 17, 2022 and can be accessed by dialing 877-481-4010 for Canadian and U.S. callers or +1 919-882-2331 for international callers and entering conference ID: 44502.

About Medexus

Medexus is a leader in innovative rare disease treatment solutions with a strong North American commercial platform and a portfolio of proven best-in-class products. Our current focus is on the therapeutic areas of rheumatology, transplant, auto-immune disease, hematology, and allergy. We continue to build a highly differentiated company with a growing portfolio of innovative and high-value orphan and rare disease products that will underpin our growth for the next decade.

Our current leading products are Rasuvo™ and Metoject®, a unique formulation of methotrexate (auto-pen and pre-filled syringe) designed to treat rheumatoid arthritis and other auto-immune diseases; IXINITY®, an intravenous recombinant factor IX therapeutic for use in patients 12 years of age or older with Hemophilia B (a hereditary bleeding disorder characterized by a deficiency of clotting factor IX in the blood, which is necessary to control bleeding); and Rupall®, an innovative prescription allergy medication with a unique mode of action.

We have also licensed Treosulfan, a preparative regimen for allogeneic hematopoietic stem cell transplantation to be used in combination with fludarabine, for commercialization in the United States and Canada. Treosulfan was approved by Health Canada in June 2021 and is marketed in Canada as Trecondyv®. Treosulfan is currently under review by the U.S. Food and Drug Administration.

Our mission is to provide the best healthcare products to healthcare professionals and patients. We strive to deliver on this mission by acting on our core values: Quality, Innovation, Customer Service, and Collaboration.

## Contacts

For more information, please contact any of the following:

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## Forward-Looking Statements

Certain statements made in this press release contain forward-looking information within the meaning of applicable securities laws (forward-looking statements). The words “anticipates”,

“believes”, “expects”, “will”, “plans”, “potential”, and similar words or expressions are often intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. More specifically, forward-looking information in this press release may include, but is not limited to, information contained in statements with respect to: business strategy or outlook and future growth plans; expectations regarding future financial or operating performance; ability to obtain FDA and other regulatory approvals when required; and competitive position and anticipated trends and challenges in Medexus’s business and the markets in which it operates; among others. These statements are based on factors or assumptions that were applied in drawing a conclusion or making a forecast or projection, including assumptions based on historical trends, current conditions and expected future developments. Since forward-looking statements relate to future events and conditions, by their very nature they require making assumptions and involve inherent risks and uncertainties. Medexus cautions that although it is believed that the assumptions are reasonable in the circumstances, these risks and uncertainties give rise to the possibility that actual results may differ materially from the expectations set out in the forward-looking statements. Material risk factors include those set out in Medexus’s materials filed with the Canadian securities regulatory authorities from time to time, including Medexus’s most recent annual information form and management’s discussion and analysis; future capital requirements and dilution; intellectual property protection and infringement risks; competition (including potential for generic competition); reliance on key management personnel; Medexus’s ability to implement its business plan; Medexus’s ability to leverage its U.S. and Canadian infrastructure to promote additional growth; regulatory approval by relevant health authorities, including the FDA; product reimbursement by third party payers; litigation or expiry with respect to patents or other intellectual property rights; litigation risk; stock price volatility; government regulation; and potential third party claims. Given these risks, undue reliance should not be placed on these forward-looking statements, which are made only as of the date hereof. Other than as specifically required by law, Medexus undertakes no obligation to update any forward-looking statements to reflect new information, subsequent or otherwise.

#### Other notes

This press release may contain references to trademarks and service marks. Solely for convenience, trademarks and trade names referred to in this press release may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that the holder or holders of the relevant intellectual property rights will not assert, to the fullest extent under applicable law, their rights to these trademarks and trade names.



Source: Medexus Pharmaceuticals Inc