November 10, 2021

Medexus Pharmaceuticals Reports Financial and Operational Results for the Three- and Six-Month Periods Ending September 30, 2021

Achieved $17.9 million revenue driven by continued strength of Rupall™

Positioned for revenue growth along with expected recovery of IXINITY® sales

Commercially launched Trecondyv® (treosulfan) in Canada

Available liquidity of $9.6 million

Management to host conference call at 8:00 AM Eastern Time on November 11th, 2021

TORONTO and CHICAGO, Nov. 10, 2021 (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 September 30, 2021. All dollar amounts below are in United States dollars unless specified otherwise.

Second Quarter Fiscal 2022 Financial Highlights:

- Revenue of $17.9 million compared to $17.8 million for the same period last year. Sales during the quarter were positively impacted by Rupall™ sales, which saw unit demand growth of 33% in the trailing twelve-months ended September 30, 2021[1]. This growth was partially offset by a decline in ex-factory sales of IXINITY®, when compared to the same quarter last year, while Rasuvo and Metoject continue to make strong contributions to revenue.
- Adjusted EBITDA* decreased to ($2.0) million compared to $2.3 million for the same period last year, due to an increase in research & development costs over the comparative period, and the significant investments the Company made to prepare for the expected launch of treosulfan in the US.
- Net cash flow outflow of ($2.1) million in the period, compared to ($1.1) million for the same period last year.
- Net income was $10.1 million, primarily due to gains on the fair value of derivatives, compared to ($1.6) million for the same period last year.
- Adjusted Net Income* (which adjusts for such unrealized losses or gains on the fair value of derivatives) was ($6.1) million compared to ($1.3) million for the same period last year.
- Cash and cash equivalents of $8.1 million with $9.6 million of available liquidity at

September 30, 2021.

Ken d'Entremont, Chief Executive Officer of Medexus, commented, "IXINITY ex-factory sales increased 14% in the three months ending September 30, 2021 vs. the three months ending June 30, 2021. While still not back to historical levels, we believe this signals the beginning of IXINITY® ex-factory revenue growth as the channel normalizes and patient demand continues to be strong. We are executing supply chain improvements and believe that this will help normalize IXINITY® sales in the coming quarters and put the Company back on a positive growth trajectory."

"In August, we received notice of a Complete Response Letter ("**CRL**") from the FDA in regard to treosulfan. In the CRL, the FDA explained their reasons for non-approval and provided recommendations for how to address the outstanding issues, primarily relating to the provision of additional clinical and statistical data and analyses pertaining to the primary endpoint of the completed pivotal Phase III study. We are pleased that our licensing partner, medac GmbH, has since been granted a Type A Meeting with the FDA on November 23 rd to discuss the pathway to approval in the United States. We are looking forward to working with medac and the FDA in order to meet the requirements for approval and plan to update shareholders as we progress through each stage with the FDA. In Canada, we successfully launched treosulfan commercially this past September, under the brand name Trecondyv®. Our overall product portfolio has remained strong over the last few quarters and we expect that strength to continue into the second half of the year. We continue to see a number of opportunities for growth within our current portfolio as well as through business development initiatives."

Operational Highlights:

Operational highlights for the three-month period ended September 30, 2021, or subsequent to the period end, include:

- **Rupall™ growth:** Rupall™ saw strong and continued unit demand growth of 33% for the trailing twelve-months ended September 30, 2021[1]. This was due to a strong allergy season across Canada, and further market share gained by the brand. Rupall™ is one of the fastest growing anti-histamines in the Canadian prescription market[1].
- **Treosulfan:** On August 2, 2021 the Company received notice from medac, Medexus' licensor for treosulfan, that is had received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration ("FDA") with respect to the New Drug Application ("NDA") for use of treosulfan in in United States. Via the CRL, the FDA has communicated that it cannot approve the NDA in its present form. The FDA has, however, provided recommendations for how to address what they see as the outstanding issues. These are primarily around the provision of additional clinical and statistical data and analyses pertaining to the primary endpoint of the completed pivotal Phase III study. These recommendations are already covered by medac's existing development plan for treosulfan, which medac is contractually responsible to execute and fund. The Company, together with medac, will move forward with the FDA, to meet the agency's requests. It is the Company's belief that the CRL provides a pathway to review and approval that does not require additional clinical studies, provided we can satisfy the FDA's data requirements and post marketing commitments. The Company expects that this can be done with already available data

from the existing completed Phase III study and the current development plan. On September 30, 2021 the Company and medac signed an amendment to the licencing agreement, in which medac paid back to the Company a regulatory milestone totaling $2.5 million, to be repaid upon FDA approval of the NDA. The $2.5 million was offset against existing invoices and payments the Company owed medac, and as such, was treated as a non-cash transaction by the Company. On November 1, 2021 the Company announced that the FDA has granted a Type A meeting to medac, which has been scheduled to occur on November 23, 2021.

- **Trecondyv® (treosulfan in Canada)**: Medexus formalized its licensing agreement with medac for treosulfan in Canada on July 12, 2021. It subsequently announced on September 21, 2021 that it initiated its first commercial shipment of the product under the brand name Trecondyv®. The product is currently being used at Princess Margaret, the largest cancer centre in Canada and one of the largest in the world.
- **IXINITY®:** Medexus announced the completed enrollment of the Phase 4 Clinical Trial of IXINITY® on August 12, 2021. The Trial is investigating IXINITY® as a prophylactic treatment for pediatric patients under 12 years of age with hemophilia B, a hereditary bleeding disorder characterized by a deficiency of clotting factor IX. On completion, the Company believes this study may support an expansion of the indicated patient population for IXINITY®. Management expects to submit the full data set to the FDA by the end of 2022.
- **Rasuvo®:** Ex-factory unit sales of Rasuvo® have increased over the trailing 12 months ending September 30, 2021[2], while the Company has adjusted price to maintain its dominant market share.
- **Metoject®:** Product sales continue to remain relatively stable even with a generic entry into the Canadian methotrexate market in 2020. Metoject® unit demand experienced growth of 3% in the trailing twelve-months ended September 30, 2021[3].
- **Appointment of New Chief Financial Officer ("CFO") and Internal Counsel:**On July 19, 2021, the Company introduced Marcel Konrad as the new CFO, replacing Roland Boivin. On November 8th, the Company announced the appointment of Ian C Wildgoose Brown as general counsel and corporate secretary.

Operating and Financial Results Summary for the Three Months Ended September 30, 2021:

Total revenue was $17.9 million for the three-month period ended September 30, 2021, compared to revenue of $17.8 million for the three-month period ended September 30, 2020. As previously disclosed by the Company, the comparative period revenue figures do not account for 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. After adjusting for that event (i.e. assuming that such revenue had been recognized in September), the three-month period ended September 30, 2021 saw a year-over-year decrease in revenue due mainly to a temporary drop in IXINITY® net sales. This decrease was partially offset by strong Rupall™ sales, which saw unit demand growth of 33% in the trailing twelve-months ended September 30, 2021[1]. This was partially offset by a decline in net sales of IXINITY®, as pharmacy and wholesale customers continued to work through inventory on hand. Rasuvo and Metoject® continue to perform reliably in increasingly

competitive markets.

Gross profit was $9.4 million for the three-month period ended September 30, 2021, compared to gross profit of $9.7 million for the three-month period ended September 30, 2020.

The gross margin was 52.4% for the three-month period ended September 30, 2021, compared to 54.4% for the three-month period ended September 30, 2020.

Operating loss for the three-month period ended September 30, 2021, was $5.0 million compared to an operating income of $0.5 million for the three-month period ended September 30, 2020.

Adjusted EBITDA loss was $(2.0) million for the three-month period ended September 30, 2021, compared to positive Adjusted EBITDA of $2.3 million for the three-months period ended September 30, 2020. The three-month period ended September 30, 2021 saw a year-over-year decrease due to an increase in research & development costs over the comparative period, and the significant investments the Company made to improve its capacity for future growth and prepare for the anticipated commercialization of treosulfan in the United States. The Company reacted quickly to defer or cancel any further significant expenditures related to the treosulfan launch after receiving notice of the CRL on August 2, 2021. However, the Company believes that the CRL provides a path to review and approval and continues to incur some expenses in anticipation of treosulfan's eventual commercial launch.

Net income was $10.1 million compared to a loss of $1.6 million for the same period last year. This included a non-cash unrealized gain of $16.3 million in the current period 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 applicable period.

Operating and Financial Results Summary for the Six Months Ended September 30, 2021:

Total revenue was $35.2 million for the six-month period ended September 30, 2021, compared to revenue of $37.8 million for the six-month period ended September 30, 2020. Revenue for the comparative period was lower than expected due to the delayed receipt of finished product in the fall of 2020 noted above. The period saw a year-over-year decrease in revenue due mainly to a temporary drop in IXINITY® net sales. This decrease was partially offset by strong Rupall™ sales. Despite being on the market for more than four years, the trailing twelve-months ended September 30, 2021, saw unit demand growth of 33%[1]. This was due to a strong allergy season across Canada, and further market share gained by the brand.

Gross profit was $16.3 million for the six-month period ended September 30, 2021, compared to gross profit of $20.5 million for the three-month period ended September 30, 2020. The decline for the six-month periods ended September 30, 2021 was due, in part, to a previously disclosed increase in cost of goods sold, caused by additional expenses related to IXINITY®, due to failures during the manufacturing process in the quarter ended June 30, 2021.

Gross margin was 46.4% for the six-month period ended September 30, 2021, compared to 54.4% for the three-month period ended September 30, 2020.

Operating loss for the six-month period ended September 30, 2021, was $12.2 million compared to an operating income of $1.6 million for the three-month period ended September 30, 2020.

Adjusted EBITDA loss was $6.9 million for the six-month period ended September 30, 2021, compared to a positive Adjusted EBITDA of $5.9 million for the same period last year.

Net income was $3.6 million compared to a loss of $5.0 million for the same period last year. This included a non-cash unrealized gain of $19.5 million in the current period 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 applicable periods.

The Company's financial statements and management discussion and analysis ("MD&A") for the period ended September 30, 2021 are available on our corporate website at www.medexus.com and in our corporate filings on SEDAR at 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, November 11, 2021 to discuss the Company's financial results for the fiscal 2022 second quarter ended September 30, 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: 329156. A webcast of the call may be accessed at https://www.webcaster4.com/Webcast/Page/2010/43455 or on the Company's Investor Events section of the website: https://www.medexus.com/en_US/investors/news-events.

A webcast replay will be available on the Company's Investor Events section of the website (https://www.medexus.com/en_US/investors/news-events) through Friday, November 11, 2022. A telephone replay of the call will be available approximately one hour following the call, through Thursday, November 18, 2021 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: 43455.

[1] *Source: IQVIA CDH units – Drugstores and hospitals purchases*
[2] *Source: Symphony Sub National 9/30/2021 Data & Chargebacks, PAP*
[3] *Source: IQVIA – TSA database*

About Medexus

Medexus is a leader in innovative rare disease treatment solutions with a strong North American commercial platform. From a foundation of proven best in class products we are building a highly differentiated company with a portfolio of innovative and high value orphan and rare disease products that will underpin our growth for the next decade. The Company's

vision is to provide the best healthcare products to healthcare professionals and patients, through our core values of Quality, Innovation, Customer Service and Teamwork. Medexus Pharmaceuticals is focused on the therapeutic areas of hematology, auto-immune disease, and allergy. The Company's 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. The Company has also licensed treosulfan, a preparative regimen for allogeneic hematopoietic stem cell transplantation to be used in combination with fludarabine, from medac GmbH for Canada and the United States.

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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" and similar expressions are often intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Specific forward-looking statements contained in this news release include, but are not limited to, statements with respect to the implementation of supply chain improvements and their expected impact on IXINITY® sales the Company's growth trajectory; opportunities for growth within the Company's current portfolio and through business development initiatives; the ability to obtain FDA approval for treosulfan and the possibility of a path to such approval that does not require additional clinical studies; expected timing for completion of the Company's Phase 4 clinical trial for IXINITY® and the

possibility of a related expansion of the indicated patient population. 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. The Company 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 the Company's materials filed with the Canadian securities regulatory authorities from time to time, including the Company'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; the Company's ability to implement its business plan; the Company's ability to leverage its United States and Canadian infrastructure to promote additional growth; regulatory approval by the health authorities; product reimbursement by third party payers; patent litigation or patent expiry; 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 apply only as of the date hereof. Other than as specifically required by law, the Company undertakes no obligation to update any forward-looking statements to reflect new information, subsequent or otherwise.

Non-IFRS Financial Measures

This press release uses the terms "Adjusted Net Income (Loss)" and "Adjusted EBITDA" which are non-IFRS financial measures, which do not have any standardized meaning prescribed by IFRS and are therefore unlikely to be comparable to similar measures presented by other companies. Rather, these measures are provided as additional information to complement those IFRS measures by providing further understanding of the Company's results of operations from management's perspective. Accordingly, they should not be considered in isolation nor as a substitute for analysis of the Company's financial information reported under IFRS. In particular, management uses Adjusted Net Income (Loss) and Adjusted EBITDA as measures of the Company's performance. The Company defines Adjusted Net Income (Loss) as net income (loss) before unrealized loss (gain) on fair value of derivatives. The Company defines Adjusted EBITDA as earnings before financing and special transaction costs (including, for greater certainty, fees related to the acquisitions and related financings), interest expenses, income taxes, interest income, depreciation of property and equipment, amortization of intangible assets, non cash share-based compensation, income from sale of assets, gain or loss on the convertible debenture embedded derivative, foreign exchange gains or losses, termination benefits, and impairment of intangible assets. The Company considers Adjusted Net Income (Loss) and Adjusted EBITDA as key metrics in assessing business performance and considers Adjusted EBITDA to be an important measure of operating performance and cash flow, providing useful information to investors and analysts. These non-IFRS measures are not intended to represent cash provided by operating activities, net earnings or other measures of financial performance calculated in accordance with IFRS. Additional information relating to the use of these non-IFRS measures, including the reconciliation of each of Adjusted Net Income (Loss) and Adjusted EBITDA to Net Income (Loss), can be found in our MD&A, which is available through the SEDAR website (www.sedar.com).



Source: Medexus Pharmaceuticals Inc