November 8, 2022

Medexus Announces Strongest Quarter in Company History with Fiscal Q2 2023 Revenue of US$27.7 Million, a 55% Increase Over Fiscal Q2 2022

Results reflect strong growth across all leading prescription products, including IXINITY, Rupall, and Gleolan

Management to host conference call at 8:00 AM Eastern Time on Wednesday, November 9, 2022

TORONTO and CHICAGO, Nov. 08, 2022 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals (**Medexus**) (TSX: MDP) (OTCQX: MEDXF) today announced its operating and financial results and provided a business update for the company's second fiscal quarter ended September 30, 2022. All dollar amounts in this press release are in United States dollars unless specified otherwise.

Financial Highlights for Fiscal Q2 2023

- Record total revenue of $27.7 million, a year-over-year increase of 55%, and a quarter-over-quarter increase of 20%. This represents the strongest fiscal quarter in Medexus's history. Increased net sales of IXINITY and Rupall and recognition of 100% of revenue from Gleolan sales in the United States starting September 2022 were strong contributors to this substantial year-over-year improvement.
- Adjusted EBITDA* of $4.2 million, a year-over-year improvement of $6.3 million and a quarter-over-quarter increase of $2.3 million. The primary drivers for this substantial year-over-year improvement were increases in revenues, a reduction in research & development costs, and an increase in gross margin.
- Operating profit of $1.9 million, a year-over-year improvement of $6.9 million.
- Net loss of $(2.7) million, a year-over-year change of $(12.8) million, primarily due to unrealized gains on the change in fair value of the embedded derivatives in Medexus's convertible debentures in the prior year's net profit.
- Adjusted Net Loss*, which adjusts for the unrealized gains and losses included in net profit (loss), of $2.8 million, a year-over-year improvement of $3.3 million.
- Cash and cash equivalents of $9.6 million (with $10.1 million of total available liquidity) at end of fiscal Q2 2023.

** Refer to "Non-GAAP Measures" at the end of this press release for information about Adjusted EBITDA and Adjusted Net Income (Loss).*

Ken d'Entremont, Chief Executive Officer of Medexus, commented, "This was an excellent quarter for Medexus, demonstrating both the robustness of our product portfolio and our initiatives to improve margins and drive sales. Preliminary results of our IXINITY manufacturing initiative have started to produce improved yields, which contributed to this quarter's improvements in our gross margins. During the quarter, we delivered organic growth across all our leading prescription products, and completed the transition to full commercial responsibility for Gleolan in the U.S. We are excited to see Gleolan's contribution over the coming quarters as we execute on our commercial plan, which includes improved sales and marketing initiatives."

Marcel Konrad, Chief Financial Officer of Medexus, further noted, "During the second quarter we delivered an increase in our cash position versus previous quarter and generated positive operating cash flow this quarter. We also invested in our net working capital, including inventory and accounts receivable, as we prepare for continued growth and new business, especially as it relates to Gleolan. We anticipate seeing the benefit of these investments in our cash flow in the coming quarters. We are also actively evaluating strategies to optimize our balance sheet and capital structure to support this growth and have engaged third-party advisors to help us in this initiative."

Operational Highlights

Operational highlights for the three-month period ended September 30, 2022 and subsequent period include:

Leading products

- **IXINITY**: Unit demand in the United States remained strong during the quarter and increased year-over-year, growth that was also reflected in the 12 months ended September 30, 2022 – reflecting an acceleration of patient conversions on top of a stable, existing base of patients, following resumption of in-person selling earlier in the year. Medexus also continues to invest in an ongoing initiative to improve the IXINITY manufacturing process. Preliminary results have indicated meaningfully improved yields and Medexus has started to see moderate improvements in gross margins for the product.
- **Rasuvo**: The company maintained its market leading position during the quarter, with an estimated 80% unit share during the 12 months ended September 30, 2022, and achieved a near-record sales month in August, as unit demand for Rasuvo remained strong in the moderately-growing U.S. branded methotrexate market with a limited sales force allocation. (Source: Symphony Sub National 9/30/2022 Data & Chargebacks, PAP.) However, increasing competition in the U.S. branded methotrexate market continue to negatively affect Rasuvo product-level revenue.
- **Rupall**: Unit demand for the quarter increased year-over-year given peak allergy season across Canada during the quarter and successful sustained execution of sales and marketing initiatives, which was reflected in the unit demand growth of 25% for the 12 months ended September 30, 2022. (Source: IQVIA CDH units – Drugstores and hospitals purchases, MAT September 2022.) This performance continues to position Rupall as one of the fastest-growing antihistamines in the Canadian prescription market.

- **Gleolan**: Medexus acquired the exclusive right to commercialize Gleolan in the United States in March 2022. During the quarter Medexus successfully completed the full transition of U.S. commercial responsibility to Medexus, which puts the company in position to successfully execute its commercial plan, including improved sales and marketing initiatives. The company began shipping Medexus-labeled product as of August, meaning that September was the first full month, and that the three-month period ended December 31, 2022 will be the first full fiscal quarter, in which Medexus recognizes 100% of Gleolan net sales.
- **Metoject**: Unit demand in Canada for the quarter increased year-over-year, growth that was also reflected in the 12 months ended September 30, 2022. Product-level performance continues to experience disruption from the launch of a generic product in the Canadian methotrexate market in calendar year 2020. Medexus and medac, licensor of Medexus's commercialization rights to market and sell Metoject in Canada, continue their joint preparations for trial in the related patent litigation, a date for which has been set for early calendar year 2023.

Product pipeline highlights

- **Treosulfan (United States)**: In September 2022, Medexus was informed by medac, licensor of Medexus's commercialization rights to treosulfan, that the FDA had delivered to medac a second notice of incomplete response regarding medac's July 2022 new drug application resubmission for treosulfan (**NDA**). This notice requested further supporting information from medac to complete medac's NDA resubmission but did not require submission of new clinical data. Medexus will provide an update to its shareholders and other stakeholders once management knows whether the resubmission has been accepted and is better able to assess the impact of this delay. The company has applied much of the infrastructure added in anticipation of a treosulfan launch to support Gleolan, gaining experience in many of the same institutions that are expected to use treosulfan if and when it is approved. Medexus also implemented a restructuring plan in October 2022 to focus resources on existing products.
- **IXINITY (pediatric study)**: Medexus continues to explore opportunities to expand the patient population eligible to use IXINITY. In the first half of calendar year 2023, Medexus expects to submit to the FDA the results of Medexus's phase 4 clinical trial evaluating the safety and efficacy of IXINITY in previously treated patients under 12 years of age with hemophilia B.
- **Gleolan (meningioma indication)**: The licensor of Medexus's commercialization rights to Gleolan continues to pursue research and development activities regarding a meningioma indication for Gleolan (aminolevulinic acid hydrochloride or ALA HCl). Medexus's exclusive commercialization rights include this additional meningioma indication.

Additional Information

Medexus's financial statements and management's discussion and analysis for the fiscal quarter ended September 30, 2022 are available on Medexus's corporate website at www.medexus.com and in the company's corporate filings on SEDAR at www.sedar.com.

Conference Call Details

Medexus will host a conference call at 8:00 AM Eastern Time on Wednesday, November 9, 2022, to discuss the company's operating and financial results and corporate updates for fiscal Q2 2023.

To participate in the call, please dial the following numbers:

888-506-0062 (toll-free) for Canadian and U.S. callers
+1 973-528-0011 for international callers

Access code: 424091

A live webcast of the call will be available on the Investors—News & Events—IR Calendar section of Medexus's corporate website or at the following link:

https://www.webcaster4.com/Webcast/Page/2010/47041

A replay of the call will be available approximately one hour following the end of the call through Wednesday, November 16, 2022. To access the replay, please dial the following numbers:

877-481-4010 for Canadian and U.S. callers
+1 919-882-2331 for international callers

Conference ID: 47041

A replay of the webcast will be available on the Investors—News & Events—IR Calendar section of Medexus's corporate website until Thursday, November 9, 2023.

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 hematology, auto-immune diseases, 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 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); Rasuvo™ and Metoject®, a unique formulation of methotrexate (auto-pen and pre-filled syringe) designed to treat rheumatoid arthritis and other auto-immune diseases; Rupall®, an innovative prescription allergy medication with a unique mode of action; and Gleolan™ (aminolevulinic acid hydrochloride or ALA HCl), an FDA-approved, orphan drug designated optical imaging agent currently indicated in patients with glioma (suspected World Health Organization Grades III or IV on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery.

We have also licensed treosulfan, part of 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 the subject of a regulatory review process with 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

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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. Specific forward-looking statements contained in this news release include, but are not limited to, statements regarding Medexus's business strategy or outlook and future growth plans, expectations regarding future financial or operating performance (including with respect to the expected benefits of improvements made to the IXINITY manufacturing process and expected results from sales of Gleolan in the United States), ability to obtain FDA approval for treosulfan, the possibility of expanding the patient population eligible for IXINITY and the timing of a related submission to the FDA, the possibility of expanding the approved indications for Gleolan, and competitive position of and anticipated trends and challenges in the company's business and the markets in which it operates. 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.

Trademarks and trade names

This press release contains references to trademarks and service marks, including those belonging to other companies, persons, or entities. Solely for convenience, trademarks and trade names referred to in this document may appear without the "®" or "™" symbols. Each such reference should be read as though it appears with the relevant symbol. Any 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, its rights to these trademarks and trade names.

Non-GAAP measures

Company management uses, and this press release refers to, financial measures that are not recognized under IFRS and do not have a standard meaning prescribed by generally accepted accounting principles (**GAAP**) in accordance with IFRS or other financial or accounting authorities (**non-GAAP measures**). These non-GAAP measures may include "non-GAAP financial measures" and "non-GAAP ratios" (each defined in National Instrument 52-112, *Non-GAAP and Other Financial Measures Disclosure*). Medexus's method for calculating these measures may differ from methods used by other companies and therefore these measures are unlikely to be comparable to similarly-designated measures used or presented by other companies.

In particular, management uses Adjusted Net Income (Loss) and Adjusted EBITDA as measures of Medexus's performance. Adjusted Net Income (Loss), EBITDA (earnings before interest, taxes, depreciation, and amortization) and Adjusted EBITDA are non-GAAP financial measures. In addition, Adjusted Net Income (Loss) may be presented on a per share basis.

An explanation and discussion of each of these non-GAAP measures, including their limitations, is set out under the heading "Preliminary Notes—Non-GAAP measures" in

Medexus's most recent management's discussion and analysis. A reconciliation of each of these non-GAAP measures to the most directly comparable IFRS measure can be found under the heading "Reconciliation of Adjusted Net Income (Loss) and Adjusted EBITDA to Net Income (Loss)" below.

Reconciliation of Adjusted Net Income (Loss) and Adjusted EBITDA to Net Income (Loss)

The following tables are derived from and should be read together with Medexus's consolidated statement of operations for the three- and six-month periods ended September 30, 2022. This supplementary disclosure is intended to more fully explain disclosures related to Adjusted Net Loss and Adjusted EBITDA and provides additional information related to Medexus's operating performance. However, Medexus's non-GAAP measures have limitations as analytical tools and should not be considered in isolation or as a substitute for analysis of Medexus's financial information as reported under IFRS.

(Amounts in $ '000s)	**Three-month periods ended September 30**		**Six-month periods ended September 30**	
	2022	**2021**	**2022**	**2021**
Net income (loss)	(2,730)	10,145	(4,128)	3,558
Add back:				
Unrealized gain on fair value of derivatives	(113)	(16,280)	(2,352)	(19,526)
Adjusted net loss	**(2,843)**	**(6,135)**	**(6,480)**	**(15,968)**

	Three-month periods ended September 30		**Six-month periods ended September 30**	
(Amounts in $ '000s)	**2022**	**2021**	**2022**	**2021**
Net loss	(2,730)	10,145	(4,128)	3,558
Add back:				
Depreciation and amortization (property, equipment, intangible assets)	1,537	1,549	3,079	3,128
Interest expense	3,293	3,072	6,442	5,956
Income tax recovery	189	(2,525)	35	(2,525)
EBITDA	2,289	12,241	5,428	10,117
Add back:				
Share-based compensation	331	642	634	1,313
Transaction-related fees	144	-	172	784
Termination benefits	238	784	238	-
Foreign exchange loss	1,308	597	1,983	384
Unrealized gain on fair value of derivatives	(113)	(16,280)	(2,352)	(19,526)
Adjusted EBITDA	**4,197**	**(2,016)**	**6,103**	**(6,928)**



Source: Medexus Pharmaceuticals Inc