February 7, 2024

Medexus Announces Fiscal Q3 2024 Results

Fiscal Q3 2024 revenue of $25.2 million, Operating income of $1.6 million, and Adjusted EBITDA* of $3.2 million

Management to host conference call at 8:00 AM Eastern time on Thursday, February 8, 2024

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - February 7, 2024) - Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) today announced its operating and financial results and provided a business update for the company's third fiscal quarter ended December 31, 2023 (the company's fiscal Q3 2024). All dollar amounts in this news release are in United States dollars unless specified otherwise.

Financial highlights

- Revenue of $25.2 million and $87.1 million for the three- and nine-month periods ended December 31, 2023, a decrease of $3.5 million and an increase of $7.6 million, or (12.2)% and 9.6%, compared to $28.7 million and $79.5 million for the three- and nine-month periods ended December 31, 2022. The $7.6 million year-over-year increase comparing the nine-month periods was primarily attributable to the recognition of 100% of Gleolan net sales in total revenue during the entire financial year 2024 period, continuing strong Rupall demand growth, and strong first fiscal quarter 2024 sales of IXINITY. The $3.5 million year-over-year decrease comparing the three-month periods was primarily attributable to decline in sales of IXINITY over the second and third fiscal quarters of 2024 and the accumulating effect of continued effective unit-level price reductions for Rasuvo.

- Adjusted EBITDA* of $3.2 million and $15.1 million for the three- and nine-month periods ended December 31, 2023, a decrease of $2.0 million and an increase of $3.8 million, or (38.5)% and 33.6%, compared to $5.2 million and $11.3 million for the three- and nine-month periods ended December 31, 2022. The changes in Adjusted EBITDA* were primarily attributable to the changes in revenue mentioned above, together with reductions in operating expenses in third fiscal quarter 2024.

- Available liquidity of $8.2 million (December 31, 2023), consisting of cash and cash equivalents, compared to $13.1 million (March 31, 2023). The primary factor in the net decrease in cash comparing March 31, 2023 to December 31, 2023 was Medexus's use of cash to make the final maturity date payment in respect of the company's convertible debentures in October 2023, offset by, among other things, cash provided by operating activities of $5.5 million and $17.1 million for the three- and nine-month periods ended December 31, 2023.

- Operating income of $1.6 million and $10.0 million for the three- and nine-month periods ended December 31, 2023, a decrease of $1.3 million and an increase of $5.1 million compared to $2.9 million and $4.9 million for the three- and nine-month periods ended December 31, 2022.

- Net loss of $0.5 million and $1.0 million for the three- and nine-month periods ended December 31, 2023, an improvement of $1.0 million and $4.6 million compared to net loss of $1.5 million and $5.6 million for the three- and nine-month periods ended December 31, 2022.

- Adjusted Net Loss* of $0.5 million and $1.1 million for the three- and nine-month periods ended December 31, 2023, an improvement of $0.4 million and $6.2 million compared to an Adjusted Net Loss* of $0.9 million and $7.3 million for the three- and nine-month periods ended December 31, 2022. Adjusted Net Income (Loss)* is adjusted for the non-cash unrealized gain of $0.0 million and $0.1 million for the three- and nine-month periods ended December 31, 2023 and the unrealized loss of $0.6 million and unrealized gain of $1.7 million for the three- and nine-month periods ended December 31, 2022.

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

"Our third quarter results reflect yet another quarter of positive operating income and positive Adjusted EBITDA*," commented Ken d'Entremont, Chief Executive Officer of Medexus. "However, we believe the results also reflect certain changing business conditions affecting our operations, in particular recent adverse trends in IXINITY demand and Rasuvo product-level performance. In response, we have moved quickly to reduce costs, including a reduction in allocation of sales force resources. For IXINITY, we will seek to maintain existing demand but reduce investments in IXINITY's growth, with the pediatric indication as a tailwind if and when approved. For Rasuvo, we will continue to defend Rasuvo's strong formulary status. We look forward to increasing our focus on Gleolan, as an institutional sales-based product that we believe will complement our commercialization activities for treosulfan if and when that product is approved."

"On treosulfan, we are pleased to report that the data collection phase of medac's effort to respond to the FDA's information requests on treosulfan is now complete," Mr d'Entremont continued. "It will take time for medac to process and submit the information as part of an NDA resubmission, but progress to date remains in line with our previous expectations for this to occur in the first half of calendar year 2024.

Marcel Konrad, Chief Financial Officer of Medexus, added, "We had an excellent third quarter from a cash perspective generating $5.5 million in cash provided from operating activities. This cash generation combined with our quick recognition of and reaction to the changing business environment provides a solid foundation to manage the future needs of our business."

Operational highlights

Leading products

- **IXINITY (US)**: Unit demand in the United States decreased by 5% over the trailing 12-month period ended December 31, 2023. (Source: customer-reported dispensing data.) Demand continues to reflect the effects of lower observed average quantities of IXINITY consumed by newer patients, together with lower apparent adherence by existing patients and other developments in the broader hemophilia B treatment solutions market. Medexus now believes that these emergent trends are likely to persist. Medexus expects that this demand environment, together with the anticipated impact of additional statutory discounts and rebates under the Inflation Reduction Act of 2022, will have a moderately adverse effect on product-level revenue going forward. Medexus will seek to maintain existing demand but reduce investments in IXINITY's growth, with the pediatric indication as a tailwind if and when approved.

- **Rasuvo (US)**: Medexus maintained its market leading position during the three-month period ended December 31, 2023, with an estimated >80% unit share during the trailing 12-month period ended December 31, 2023, as unit demand for Rasuvo remained strong in the moderately-growing US branded methotrexate market with a highly efficient allocation of sales force resources. (Source: Symphony Sub National 12/31/2023 Data & Chargebacks, PAP.) In the nine-month period ended December 31, 2023, unit demand for Rasuvo benefited from unanticipated shortages of competing product inventory. However, competition in the US branded methotrexate market continues to adversely affect Rasuvo product-level revenue. Medexus has also observed an increasing share of product-level revenue attributable to government-sponsored programs, which benefit from statutory discounts and rebates. This shift in the proportion of sales benefitting from such discounts and rebates, despite contributing to the product's strong market position, has adversely affected total product-level revenue. Medexus also expects that the anticipated impact of additional statutory discounts and rebates under the Inflation Reduction Act of 2022 will have an incrementally adverse effect on product-level revenue going forward.

- **Rupall (Canada)**: Unit demand in Canada remained strong during the three-month period ended December 31, 2023, which is reflected in the unit demand growth of 21% over the trailing 12-month period ended December 31, 2023. (Source: IQVIA CDH units - Drugstores and hospitals purchases, MAT December 2023.) This strong performance reflects successful execution of the company's sales and marketing initiatives to sustain the product's strong performance over the seven years since its January 2017 commercial launch.

- **Gleolan (US)**: Medexus continued to execute the company's post-transition commercial plan, including new sales and marketing initiatives. This has included improved distribution of relevant product information content in relevant forums and application of the company's broad range of commercial expertise to the relevant market. Medexus expects to continue developing insights regarding market dynamics and potential through these initiatives to inform the company's continued commercialization efforts as the company seeks to maximize product-level revenue, particularly in light of the minimum annual royalty amounts set out in the Gleolan license agreement for financial year 2024 and beyond, which Medexus expects to require additional royalty payments to the licensor for financial year 2024 and 2025. Medexus reduced its allocation of non-dedicated sales force resources to the product as part of the company's implementation of a cost reduction initiative in January 2024.

Although Gleolan performance has remained lower than expected and Medexus now does not expect to meet the minimum royalty threshold under the Gleolan license agreement for financial years 2024 or 2025, Medexus intends to further increase its focus on Gleolan, as an institutional sales-based product that the company believes will complement its commercialization activities for treosulfan if and when approved.

- **Metoject (Canada)**: Unit demand increased by 17% in the trailing 12-month period ended December 31, 2023 in spite of direct generic competition. (Source: IQVIA - TSA database.) Product-level performance continues to experience moderate disruption from the launch of a generic product in the Canadian methotrexate market in calendar year 2020. In the three-month period ended June 30, 2023, unit demand for Metoject benefited from unanticipated shortages of competing product inventory, which continues to benefit unit demand through the periods ended December 31, 2023. Medexus continues to implement unit-level pricing strategies to defend its strong market position. Medexus continues to await the decision of the Federal Court of Canada regarding the trial in Medexus's defense of the Canadian patent for Metoject (discussed in the AIF), which concluded in January 2023.

Product pipeline highlights

- **Treosulfan (US)**: medac, licensor of Medexus's commercialization rights to treosulfan and the party responsible for regulatory matters under Medexus's February 2021 exclusive license agreement relating to treosulfan, continues to work toward responding to the FDA in respect of medac's resubmission of its new drug application, or NDA, for treosulfan. The FDA continues to seek supporting information from medac relating to the pivotal phase 3 clinical trial of treosulfan conducted by medac, following the FDA's September 2022 and May 2022 notices of incomplete response and July 2021 complete response letter to medac. The data collection phase of medac's effort is now complete. It will take time for medac to process and submit the information requested by the FDA and obtain FDA acceptance of medac's treosulfan NDA resubmission, but progress to date remains in line with Medexus's previous expectations for this to occur in the first half of calendar year 2024. The parties will then have a specified negotiation period to agree to a further amendment with respect to any adjustments to the milestone payments. Medexus will have no obligation to make any milestone payments before the effective date of the further amendment (if any).

- **IXINITY (pediatric patient indication) (US)**: Medexus continues to engage in constructive dialogue with the FDA regarding the supplemental Biological License Application for IXINITY for treatment of pediatric patients under 12 years of age with hemophilia B, which the FDA accepted for review in June 2023. Medexus is optimistic about the prospects for a favorable FDA decision in the first half of calendar year 2024 and believes that, if approved, the new pediatric indication would, in addition to expanding the current market potential for the product, provide Medexus with an opportunity to reinforce brand awareness and messaging for IXINITY in relevant markets.

- **Topical Terbinafine (Canada)**: In March 2023, Medexus secured exclusive Canadian rights to commercialize terbinafine hydrochloride nail lacquer supplied by Polichem, an Almirall group company focused on medical dermatological treatments for skin health.

Medexus has continued to make progress on the new drug submission, or NDS, seeking Health Canada approval of topical terbinafine nail lacquer to treat fungal nail infections. Medexus successfully submitted the NDS in December 2023 and in January 2024 learned that Health Canada had accepted the NDS for review. Management views this product as a strategic fit with Rupall and expects that it will both contribute to the company's Canadian revenues and engage the commercial infrastructure previously put in place to support Rupall, one of Medexus's current leading products. Management views the timing of Health Canada's acceptance of the NDS for review as consistent with Medexus's plans to target a commercial launch in the first half of calendar year 2025, subject to Health Canada approval.

Other highlights

- **Cost reduction initiative**: In light of changing business conditions affecting its operations, in particular the recent trends in IXINITY demand and Rasuvo product-level performance, Medexus moved quickly to evaluate its management structure and operating expenses subsequent to period end, in January 2024. As a result of and based on this evaluation, Medexus formulated and implemented a cost reduction initiative. As part of this initiative, Medexus incurred termination benefits paid to departing personnel, which are considered to be outside the normal course of business and will be excluded from Adjusted EBITDA*. These personnel reductions included a reduction in allocation of sales force resources to IXINITY and to Rasuvo. Medexus also implemented an expense management initiative that is expected to further reduce operating expenses. Together Medexus expects that these actions will reduce operating expenses by an estimated $4 million to $6 million on an annualized basis, establishing a solid foundation to manage the future needs of the company's business and generate cash flows from operations.

- **Bought-deal public offering**: In October 2023, Medexus completed a bought-deal public offering (including full exercise of the customary overallotment option provided for under the underwriting agreement) and issued an aggregate of 3,898,384 units at a price of C$2.95 per unit for aggregate gross proceeds to Medexus of C$11.5 million (or C$10.8 million aggregate net proceeds before expenses). Each unit issued in the offering consisted of one common share and one-half of one warrant.

- **2023 NCIB**: In May 2023, the Toronto Stock Exchange accepted Medexus's notice of intention to make a normal course issuer bid for its convertible debentures. Medexus repurchased C$1.7 million principal amount of its Convertible Debentures under the 2023 NCIB. The 2023 NCIB expired in accordance with its terms upon the maturity of the convertible debentures on October 16, 2023.

- **Maturity of convertible debentures**: In connection with the maturity of the convertible debentures, in October 2023, Medexus made in cash the final maturity date payment of C$51.1 million (or approximately $37.5 million) to Computershare Trust Company of Canada as trustee for holders of the convertible debentures. Following their October 16, 2023 maturity date, the convertible debentures are no longer outstanding.

Additional information

Medexus's financial statements and management's discussion and analysis for the fiscal

quarter ended December 31, 2023 are available on Medexus's corporate website at www.medexus.com and in the company's corporate filings on SEDAR+ at www.sedarplus.com.

Conference call details

Medexus will host a conference call at 8:00 AM Eastern time on Thursday, February 8, 2024, to discuss the company's operating and financial results and corporate updates for fiscal Q3 2024.

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: 913043

A live webcast of the call will be available on the Investors section of Medexus's corporate website or at the following link:

https://www.webcaster4.com/Webcast/Page/2010/49777

A replay of the call will be available approximately one hour following the end of the call through Thursday, February 15, 2024. 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: 49777

A replay of the webcast will be available on the Investors section of Medexus's corporate website until Saturday, February 8, 2025.

About Medexus

Medexus is a leading specialty pharmaceutical company with a strong North American commercial platform and a growing portfolio of innovative and rare disease treatment solutions. Medexus's current focus is on the therapeutic areas of oncology, hematology, rheumatology, auto-immune diseases, allergy, and dermatology. For more information about Medexus and its product portfolio, please see the company's corporate website at www.medexus.com and its filings on SEDAR+ atwww.sedarplus.com.

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Forward-looking statements

Certain statements made in this news 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, phrases, or expressions are often intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words, phrases, or expressions. Specific forward-looking statements 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; expectations regarding availability of funds from operations, cash flow generation, and capital allocation (including anticipated cash needs, capital requirements, and needs for and ability to secure additional financing, and specifically including the effects and potential benefits and costs of the January 2024 cost reduction initiative discussed in this news release); the occurrence, timing, and expected outcome of the FDA review process for treosulfan (including any related collection and submission of information to the FDA and the FDA's acceptance and review of that information) and the Health Canada review process for terbinafine hydrochloride; and, if approved by the FDA (in the case of treosulfan) and Health Canada (in the case of terbinafine hydrochloride), the expected timing of any commercial launch of the product in the relevant market and related expectations regarding the product's prospects, and the potential competitive position of the product and anticipated trends and potential challenges in the market in which the product is expected to compete; 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, but are not limited to, 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. Given these risks, undue reliance should not be placed on these forward-looking statements, which are made only as of the date of this news release. 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 news release contains references to trademarks and other protected names and marks, including those belonging to other companies, persons, or entities. Solely for convenience, trademarks and other protected names and marks 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 other protected names and marks.

Non-GAAP measures

Company management uses, and this news 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 nine-month periods ended December 31, 2023. This supplementary disclosure is intended to more fully explain disclosures related to Adjusted Net Income (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 December 31**		**Nine-month periods ended December 31**	
	2023	**2022**	**2023**	**2022**
Net loss	(534)	(1,507)	(976)	(5,635)
Add back:				
Unrealized loss (gain) on fair value of derivatives	-	646	(82)	(1,706)
Adjusted Net Loss	**(534)**	**(861)**	**(1,058)**	**(7,341)**

(Amounts in $ '000s)	Three-month periods ended December 31		Nine-month periods ended December 31	
	2023	**2022**	**2023**	**2022**
Net loss	(534)	(1,507)	(976)	(5,635)
Add back:				
Depreciation and amortization (property, equipment, intangible assets)	1,448	1,515	4,357	4,594
Interest expense	2,656	3,552	11,140	9,994
Income tax expense (recovery)	(261)	547	92	582
EBITDA	3,309	4,107	14,613	9,535
Add back:				
Share-based compensation	211	436	814	1,070
Transaction-related fees	-	-	-	172
Termination benefits	-	372	-	610
Foreign exchange loss (gain)	(293)	(338)	(212)	1,645
Unrealized gain (loss) on fair value of derivatives	-	646	(82)	(1,706)
Adjusted EBITDA	**3,227**	**5,223**	**15,133**	**11,326**

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