August 7, 2024

# Medexus Announces Strong Fiscal Q1 2025 Results

**Fiscal Q1 2025 revenue of $27.3 million, net income of $2.0 million, operating income of $4.0 million, and Adjusted EBITDA* of $6.1 million**

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

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - August 7, 2024) - Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) today announced its operating and financial results and provided a business update for the company's first fiscal quarter ended June 30, 2024 (the company's fiscal Q1 2025). All dollar amounts in this press release are in United States dollars unless specified otherwise.

**Financial highlights**

- Revenue of $27.3 million, a decrease of $4.3 million, or 13.6%, compared to $31.6 million for fiscal Q1 2024, which prior quarter remains the strongest quarterly revenue result in Medexus's history. The decrease was primarily attributable to reduced net sales of Rasuvo in fiscal Q1 2025 and declines in net sales of IXINITY since fiscal Q3 2024. The decrease was partially offset by continuing growth in Rupall net sales, which were also meaningfully affected by the product's typical seasonality in both periods, and a slight year-over-year increase in Gleolan net sales.

- Adjusted EBITDA* of $6.1 million, a decrease of $0.5 million, or 7.6%, compared to $6.6 million for fiscal Q1 2024, which prior quarter remains the strongest quarterly Adjusted EBITDA* result in Medexus's history. The decrease was primarily attributable to the changes in revenue mentioned above. The decrease was partially offset by reductions in operating expenses over fiscal year 2024 and extending into fiscal Q1 2025 and improvements in IXINITY cost of sales of products attributable to Medexus's investments in its IXINITY manufacturing process improvement initiative over the same period.

- Available liquidity of $8.5 million (June 30, 2024), consisting of cash and cash equivalents, compared to $5.3 million (March 31, 2024), an increase of $3.2 million.

- Operating income of $4.0 million, a decrease of $0.8 million, or 16.7%, compared to $4.8 million for fiscal Q1 2024, which prior quarter remains the strongest quarterly operating income result in Medexus's history.

- Net income of $2.0 million, an increase of $1.3 million compared to net income of $0.7 million for fiscal Q1 2024. Net income for fiscal Q1 2025 was positively impacted by the effects of the Company's initiatives in calendar year 2024 to date, including the

January 2024 cost reduction initiative (discussed below), which have had a positive effect on Medexus's operating costs and cost structure.

** Refer to "Non-GAAP measures" at the end of this press release for information about Adjusted EBITDA.*

"We are pleased with our fiscal Q1 2025 results - particularly our positive net income and strong Adjusted EBITDA* which allowed us to comfortably pay down principal under our credit facility," commented Ken d'Entremont, Chief Executive Officer of Medexus. "Rupall's outperformance during the allergy season was a notable contributor to revenue, combined with resilience from the rest of our product portfolio."

"The FDA's commitment to review the treosulfan NDA brings us a step closer to making this product a viable treatment option in the United States and is consistent with our plan to target a commercial launch in the first half of calendar year 2025," Mr d'Entremont continued. "We remain optimistic about the prospect of a treosulfan approval in the United States, and about treosulfan's potential in the US market, because we continue to believe that treosulfan would make a substantial contribution to this therapeutic space, as it has in Europe and Canada. If approved, the commercialization of treosulfan in the United States has the potential to significantly grow our revenues over the coming years."

Mr d'Entremont concluded, "In the meantime, we continue to negotiate a further amendment to our agreement with medac. We are highly focused on quickly achieving clarity on the remaining contractual milestones under our agreement."

Brendon Buschman, Chief Financial Officer of Medexus, further noted, "We are particularly pleased with our $2.0 million positive net income for fiscal Q1 2025, which is a result of strong overall quarterly performance, together with a streamlined capital structure, and our $6.1 million Adjusted EBITDA* from $27.3 million of revenue. We continue to generate cash from our operating activities, with record quarterly operating cash flow of $8.2 million driving our positive cash flow in fiscal Q1 2025. As of June 30, 2024, we had a combined $48.3 million outstanding under our two BMO credit facilities, consisting of $3.5 million drawn under our revolving credit facility and the remainder outstanding under our term loan facility. Both facilities mature in March 2026, and we will continue to pay down principal over the remaining term."

**Operational highlights**

- **IXINITY (US):** Unit demand in the United States decreased by 6% over the trailing 12-month period ended June 30, 2024. (Source: customer-reported dispensing data.) Demand continues to reflect the effects of lower observed average quantities of IXINITY consumed by newer patients and a greater than expected impact of other developments in the broader hemophilia B treatment solutions market specifically relating to greater availability and use of extended half-life products that compete with IXINITY. Medexus believes that these trends are likely to persist. Medexus expects that this challenging 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 continue seeking to maintain existing demand, including by taking advantage of the product messaging opportunity presented by the now-approved

pediatric indication. Medexus has reduced investments in IXINITY's growth, in particular by seeking to reduce investments in non-statutory discounts typically offered to large customers. Medexus's investments in its IXINITY manufacturing process improvement initiative has had a positive impact on batch yield and manufacturing costs over fiscal year 2024 and now extending into fiscal Q1 2025.

- **Rupall (Canada):** Unit demand in Canada remained strong during the 12-month period ended June 30, 2024, which is reflected in the unit demand growth of 17% over the trailing 12-month period ended June 30, 2024. (Source: IQVIA CDH units - Drugstores and hospitals purchases, MAT June 2024.) This strong performance reflects successful execution of the Company's sales and marketing initiatives to sustain the product's strong performance since its January 2017 commercial launch, together with the product's typical seasonality, particularly in the three-month period ended June 30, 2024. Rupall's market exclusivity, granted by Health Canada, will expire at the end of January 2025. Medexus expects that Rupall will thereafter face generic competition in Canada, which will likely result in effective unit-level price reductions at that time.

- **Rasuvo (US):** Unit demand in the United States remained strong during the three-month period ended June 30, 2024. However, competition has adversely affected Rasuvo product-level revenue. In addition, the share of product-level revenue attributable to government-sponsored programs, which benefit from statutory discounts and rebates, has and will continue to adversely affect total product-level revenue, despite contributing to the product's strong market position in the US branded methotrexate autoinjector market. Medexus continues to evaluate its unit-level pricing strategies, intended to defend the product's strong market position, in light of these evolving market dynamics. As part of this ongoing evaluation, Medexus reduced investments in non-statutory discounts offered to large customers, which contributed to a meaningful adverse impact on Rasuvo net sales in the three-month period ended June 30, 2024, and which the Company believes may have a continuing near-term adverse impact on product-level revenue.

- **Gleolan (US):** Although Gleolan performance has remained lower than originally expected, unit demand grew slightly over the trailing 12 months ended June 30, 2024, as Medexus's commercialization efforts continued to result in new customers adopting the product. While the product has to some extent responded to Medexus's commercial plan, Medexus has continued to evaluate its focus on Gleolan in the context of the Company's evolving US product portfolio, in particular relative to products and product candidates that present growth opportunities for the Company. In July 2024, Medexus received notice from the licensor of Medexus's commercialization rights to Gleolan seeking to conclude the business relationship of the parties in the United States. Medexus is confident that it has successfully performed all obligations under the agreement of the parties for commercialization of Gleolan in the United States. However, in connection with the Company's ongoing evaluation of Gleolan, Medexus responded by proposing to the licensor that the parties begin discussing a mutually acceptable and orderly resolution regarding responsibility for Gleolan in the United States, and these discussions are now underway. Medexus will continue to work with the licensor on the parties' successful business relationship commercializing Gleolan in Canada.

- **Metoject (Canada):** Unit demand increased by 11% in the trailing 12-month period ended June 30, 2024 in spite of direct generic competition. (Source: IQVIA - TSA database.) Product-level performance continues to experience moderate disruption from the launch of generic products in the Canadian methotrexate market. Medexus has implemented unit-level pricing strategies to defend the product's strong market position.

**Product pipeline highlights**

- **Treosulfan (US):** In June 2024, Medexus was informed by medac, licensor of Medexus's commercialization rights to treosulfan, that the FDA had accepted for review medac's April 2024 resubmission of the New Drug Application, or NDA, for treosulfan. Medexus expects that the FDA will complete its review of the treosulfan NDA and issue a decision by October 30, 2024. The treosulfan NDA seeks approval of treosulfan in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation in adult and pediatric patients. medac's resubmission provided additional information that had previously been requested by the FDA relating to the pivotal phase 3 clinical trial of treosulfan conducted by medac. medac is the party responsible for regulatory matters under Medexus's February 2021 exclusive license agreement relating to commercialization of treosulfan in the United States. Medexus continues to believe that treosulfan would make a substantial contribution to this therapeutic space, as it has in Europe and Canada. The FDA's commitment to review the treosulfan NDA brings Medexus a step closer to making the product a viable treatment option in the United States and is consistent with Medexus's plan to target a commercial launch in the first half of calendar year 2025. Given this positive development, and the revenue opportunity this product represents, Medexus has therefore begun making judicious investments in personnel to prepare for a potential positive FDA decision in October 2024. However, Medexus would not expect to begin recognizing significant US revenue from treosulfan until early fiscal year 2026 (or second calendar quarter 2025) at the earliest. Medexus currently expects that commercialization of treosulfan, if approved by the FDA, would have a materially positive impact on total revenue. Based on internal estimates and research, Medexus currently believes that annual product-level revenue in the United States has the potential to exceed $100 million within five years after commercial launch, and the specific nature and level of success of Medexus's commercialization initiatives in support of treosulfan, among others, will determine the extent to which the Company realizes this potential. Under the terms of a September 2023 amendment to the Company's US treosulfan agreement, Medexus and medac now have a specified negotiation period, which is currently underway, to agree to a further amendment with respect to any adjustments to the value of unpaid regulatory and sales-based milestone payments that the parties may agree are appropriate in the prevailing circumstances. Medexus will have no obligation to make any milestone payments before the effective date of any such further amendment to the US treosulfan agreement.

**Other highlights**

- **Selected additional products:** Medexus remains focused on delivering strong overall performance across the rest of the Company's portfolio of products, which is currently

centered within the Company's Canadian operations. Medexus saw continued overall strength and stability in this group of products, which includes specialty products such as Trecondyv (treosulfan) and Gleolan and over-the-counter products such as NYDA and Relaxa - each of which Medexus commercializes in Canada. Each of these four products demonstrated improvements in performance in fiscal Q1 2025 relative to fiscal Q1 2024, largely reflecting successful execution of the Company's sales and marketing initiatives, together with NYDA's typical seasonality, particularly in the three-month period ended June 30, 2024. Medexus is monitoring potential regulatory changes in Ontario regarding expanded prescribing authority for pharmacists for common ailments, including head lice. If adopted, Medexus believes that these regulatory changes could enhance availability and accessibility of NYDA, a treatment for head lice, which could increase unit demand and prompt Medexus to make additional judicious investments in the product's growth in that market.

- **Cost reduction initiative:** In January 2024, Medexus formulated and implemented a cost reduction initiative, primarily intended to reduce selling and administrative expenses beginning fiscal Q4 2024. The effects of this cost reduction initiative are now fully reflected in Medexus's operating costs and cost structure, including the Company's financial results for fiscal Q1 2025, and are consistent with Medexus's previous expectations. Medexus believes that this stabilized cost structure establishes a solid foundation to manage the future needs of the Company's business, including any commercial launch of treosulfan in the United States.

- **Amendment to BMO Credit Agreement:** In June 2024, Medexus entered into an amendment to its senior secured credit agreement with BMO as agent and lender. The amendment provided for a temporary adjustment to the fixed charge coverage ratio under the BMO credit agreement, among other amendments.

**Additional information**

Medexus's financial statements and management's discussion and analysis for fiscal Q1 2025 are available on Medexus's corporate website at www.medexus.com and in the company's corporate filings on SEDAR at www.sedarplus.ca.

**Conference call details**

Medexus will host a conference call at 8:00 am Eastern Time on Thursday, August 8, 2024 to discuss Medexus's results for fiscal Q1 2025.

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: 570092

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

https://www.webcaster4.com/Webcast/Page/2010/50994

A replay of the call will be available approximately one hour following the end of the call through Thursday, August 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: 50994

A replay of the webcast will be available on theInvestors section of Medexus's corporate website until Friday, August 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+ at www.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, also known and/or referred to as "forward-looking information" or "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, outlook, and other expectations regarding financial or operational performance; anticipated trends and challenges in Medexus's business and the markets in which it operates; Medexus's expectations and plans regarding future growth, revenues, and expenses (including in respect of IXINITY, the IXINITY manufacturing process improvement initiative, the commercialization of treosulfan and the product-level revenue to be generated from its commercialization in the United States, and Medexus's other leading products); Medexus's expectations regarding the business strategies of its competitors, pricing of products, and product opportunities; Medexus's overall capital allocation strategy, including expectations regarding availability of funds from operations, cash flow generation, and capital allocation and anticipated cash needs, capital requirements, and needs for and ability

to secure additional financing; and the impact of Medexus's balance-sheet and cost management strategies (including the January 2024 cost reduction initiative) and any benefits from those strategies. In addition, forward-looking statements in this news release also include statements regarding the potential benefits of treosulfan; the occurrence, timing, and expected outcome of the FDA review process for treosulfan; the occurrence, timing, and expected outcome of the Company's ongoing negotiations with medac to further amend the US treosulfan agreement; and, if approved by the FDA, and if the Company's ongoing negotiations with medac are successful, 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. Finally, forward-looking statements in this news release include statements regarding the occurrence, timing, and expected outcome, and any related consequences for the product and the Company, of the Company's ongoing negotiations with the licensor of Medexus's commercialization rights to Gleolan with respect to the US Gleolan agreement, and otherwise regarding the business relationship of the parties in the United States and Canada. 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 regulatory guidelines, historical trends, current conditions, and expected future developments. In particular, and without limiting the generality of the foregoing, Medexus's estimate of product-level revenue from commercialization of treosulfan in the United States, if approved by the FDA, is based on a number of such factors and assumptions. 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 the assumptions are believed to be reasonable in the circumstances, these risks and uncertainties mean that actual results could differ, and could differ materially, from the expectations contemplated by 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. Accordingly, 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.

**Protected names and marks**

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 news release may appear without the "®", "™", or other similar 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 will not assert those rights to the fullest extent under applicable law.

**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 EBITDA as a measure of Medexus's performance. EBITDA (earnings before interest, taxes, depreciation, and amortization) and Adjusted EBITDA are non-GAAP financial measures.

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 Adjusted EBITDA to the most directly comparable IFRS measure can be found under the heading "Reconciliation of Adjusted EBITDA to Net Income (Loss)" below.

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

The following table is derived from and should be read together with Medexus's interim condensed consolidated statement of operations for the three-month period ended June 30, 2024. This supplementary disclosure is intended to more fully explain disclosures related to 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)

| **For the three-month period ended June 30,** | **2024** | **2023** |
|---|---|---|
| Net income | 1,957 | 651 |
| Add back: | | |
| Depreciation and amortization (property, equipment, intangible assets) | 1,410 | 1,446 |
| Interest expense | 2,031 | 4,255 |
| Income tax expense (recovery) | (57 ) | 233 |
| EBITDA | 5,341 | 6,585 |
| Add back: | | |
| Share-based compensation | 362 | 295 |
| Termination benefits | 356 | - |
| Foreign exchange loss (gain) | 43 | (292 ) |
| Unrealized gain on fair value of derivatives | - | (7 ) |
| Adjusted EBITDA | **6,102** | **6,581** |




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