November 7, 2024

Medexus Announces Strong Fiscal Q2 2025 Results

Fiscal Q2 2025 revenue of $26.3 million, net income of $0.1 million, operating income of $1.6 million, and Adjusted EBITDA* of $6.0 million

Management to host conference call at 8:00 AM Eastern time on Friday, November 8, 2024

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - November 7, 2024) - Medexus Pharmaceuticals (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, 2024 (the company's fiscal Q2 2025). All dollar amounts in this press release are in United States dollars unless specified otherwise.

Financial highlights

- Revenue of $26.3 million and $53.6 million for the three- and six-month periods ended September 30, 2024, a decrease of $4.0 million and $8.3 million, or 13.2% and 13.4%, compared to $30.3 million and $61.9 million for the three- and six-month periods ended September 30, 2023. The $4.0 million and $8.3 million year-over-year revenue decreases were primarily attributable to reduced year-to-date net sales of Rasuvo in fiscal year 2025 and continuing declines in net sales of IXINITY since fiscal Q3 2024.

- Adjusted EBITDA* of $6.0 million and $12.1 million for the three- and six-month periods ended September 30, 2024, an increase of $0.7 million and $0.2 million, or 13.2% and 1.7%, compared to $5.3 million and $11.9 million for the three- and six-month periods ended September 30, 2023. The $0.7 million and $0.2 million year-over-year Adjusted EBITDA increases were primarily attributable to the effects of the Company's ongoing financial discipline efforts and improvements in IXINITY cost of sales of products attributable to Medexus's investments in its IXINITY manufacturing process improvement initiative.

- Available liquidity of $7.0 million (September 30, 2024), consisting of cash and cash equivalents, compared to $5.3 million (March 31, 2024), an increase of $1.7 million.

- Operating income of $1.6 million and $5.6 million for the three- and six-month periods ended September 30, 2024, a decrease of $2.0 million and $2.8 million, or 55.6% and 33.3%, compared to $3.6 million and $8.4 million for the three- and six-month periods ended September 30, 2023.

- Net income of $0.1 million and $2.1 million for the three- and six-month periods ended September 30, 2024, an increase of $1.2 million and $2.5 million compared to net loss of $1.1 million and $0.4 million for the three- and six-month periods ended September

30, 2023. The $1.2 million and $2.5 million year-over-year net income increases were primarily attributable to the effects of the Company's ongoing financial discipline efforts, partially offset by the changes in revenue mentioned above and a $2.5 million impairment of intangible assets.

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

Ken d'Entremont, Chief Executive Officer of Medexus, commented: "We are pleased with our fiscal Q2 2025 results. Our core portfolio continues to provide Medexus with a solid foundation as we begin to prepare for the next phase of our growth. In particular, we are proud of the improvements we have realized in IXINITY cost of sales of products, which represent the payoff from our sustained investment in our manufacturing process improvement initiative."

"We have begun to make initial investments in personnel and infrastructure for treosulfan in the US in order to be prepared in the event of a positive FDA decision by January 2025," Mr d'Entremont continued. "Although these investments are currently relatively minor, if and when treosulfan is approved, we will increase these investments to support a successful commercial launch, which we are planning for in the first half of calendar year 2025. We remain optimistic about the prospect of FDA approval and estimate that, if approved, annual product-level revenue in the United States has the potential to exceed $100 million within five years after commercial launch, providing a significant uptick to our growth profile."

Mr d'Entremont then concluded, "In the meantime, we continue to negotiate a further amendment to our agreement with medac. We remain highly focused on quickly achieving clarity on the remaining contractual milestones under our agreement. Our team remains committed to delivering value to our shareholders, partners, and, most importantly, the patients who rely on our products."

Brendon Buschman, Chief Financial Officer of Medexus, further commented, "We are pleased to report a sound second fiscal quarter with revenues meeting our expectations and looking steady for the remainder of fiscal year 2025. Our strong overall performance in fiscal year 2025 to date has provided the necessary operating cash flow to repay a combined $7.5 million in principal under our BMO term loan, substantially reducing total debt under our BMO credit facilities - which now sits at a combined $44.2 million as of September 30, 2024. We have managed to do so while generating positive net income in both fiscal quarters, for a total of $2.1 million, and a healthy $12.1 million of Adjusted EBITDA* from $53.6 million of revenue year-to-date. Our operating cash flow, including this quarter's $6.9 million of cash flow from operations, has also provided the necessary working capital to invest in our preparations for treosulfan in the US."

"As part of our capital strategy, we intend to file an unallocated base shelf prospectus in the coming days for up to $100 million in gross proceeds in order to enhance liquidity and provide additional access to capital," concluded Mr Buschman. "With our strong operating performance and growth prospects, having a shelf prospectus in place will provide additional flexibility to add growth capital as needed and when we judge the time to be right. In addition to financing any milestones that become payable under our US treosulfan agreement, we will be in an even better position to act on new business development opportunities, acquisitions, and other opportunities."

Operational highlights

Leading products

- **IXINITY (US)**: Unit demand in the United States decreased by 4% over the trailing 12-month period ended September 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 will continue seeking to maintain existing demand, and to improve management of product supply to the market primarily by means of an August 2024 agreement with a national operator of specialty pharmacies. Medexus's investments in its IXINITY manufacturing process improvement initiative have had a positive impact on batch yield and manufacturing costs over fiscal year 2024 and now extending into fiscal year 2025.

- **Rupall (Canada)**: Unit demand in Canada remained strong during the 12-month period ended September 30, 2024, which is reflected in the unit demand growth of 17% over the trailing 12-month period ended September 30, 2024. (Source: IQVIA CDH units - Drugstores and hospitals purchases, MAT September 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 September 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. Medexus implemented an effective unit-level price reduction in fiscal Q2 2025 and continued to reduce investments in non-statutory discounts offered to large customers, which together contributed to a meaningful adverse impact on Rasuvo net sales in each of the first two quarters of fiscal year 2025, and which the Company believes may have a continuing near-term adverse impact on product-level revenue.

- **Gleolan (US)**: Unit demand in the United States grew 7% over the trailing 12 months ended September 30, 2024, as Medexus's commercialization efforts continued to result in new customers adopting the product. While the product has continued to respond 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. Medexus continues to discuss the future of the Company's involvement in commercializing Gleolan with the licensor of Medexus's rights to the product in the United States under the parties' existing agreement. In the meantime, Medexus continues to commercialize Gleolan in the United States and, in addition, continues to work with the licensor on the parties' successful business relationship commercializing the product in Canada.

- **Metoject (Canada)**: Unit demand in Canada increased by 10% in the trailing 12-month period ended September 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.

- **Trecondyv (treosulfan) (Canada)**: Unit demand in Canada remained strong during the 12-month period ended September 30, 2024, which is reflected in the unit demand growth of 49% over the trailing 12-month period ended September 30, 2024. This strong performance reflects successful execution of the Company's initiatives to sustain the product's strong performance since its September 2021 commercial launch. In addition, in November 2024, following a March 2024 reimbursement recommendation from Canada's Drug Agency (formerly CADTH), Medexus successfully completed a negotiation process with the pan-Canadian Pharmaceutical Alliance, an independent organization whose membership includes the provincial, territorial, and federal governments, seeking to make Trecondyv accessible to publicly funded drug programs and patients in Canada. Now that these negotiations are successfully completed, the next step will be for participating government organizations to make their respective final decisions on public reimbursement for their regions. Medexus sees these developments in the Canadian market as important indicators of the product's prospects and potential in both the Canadian and US markets.

Pipeline opportunities

- **Treosulfan (US)**: In September 2024, Medexus was informed by medac, licensor of Medexus's commercialization rights to treosulfan, that the FDA had extended the review period for the now-accepted New Drug Application, or NDA, for treosulfan by three months. The FDA has set a new target action date of January 30, 2025, which is the date by which Medexus now expects that the FDA will complete its review of the treosulfan NDA and issue a decision. 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 with AML and MDS. 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 investments in personnel and infrastructure to prepare for a potential positive FDA decision by January 2025. These investments totaled $0.4 million and $0.5 million for the three- and six-month periods ended September 30, 2024, and are expected to increase meaningfully in fiscal Q3 2025 and thereafter. 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, among other key financial performance indicators. 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 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. While Medexus expects that the parties will arrive at a commercially reasonable outcome and that certain milestone and royalty payments will need to be made to medac from time to time under the US treosulfan agreement, Medexus will have no obligation to make any milestone payments before the effective date of any such further amendment to the US treosulfan agreement.

- **Topical terbinafine (Canada):** In December 2023, Health Canada accepted for review Medexus's New Drug Submission, or NDS, for terbinafine hydrochloride nail lacquer to treat fungal nail infections. The topical terbinafine NDS seeks Health Canada approval for a distinctive once-a week treatment regimen. Topical terbinafine is currently the subject of an ongoing regulatory review process with Health Canada. Medexus currently expects that Health Canada will complete its review of the topical terbinafine NDS and issue a decision in fiscal Q4 2025, which is consistent with Medexus's plan to target a commercial launch in the first half of calendar year 2025, subject to Health Canada approval. Topical terbinafine has been widely used in other markets to treat fungal nail infections. If and when approved, the product will enter the Canadian topical fungicides market that is estimated to be C$88 million on an annual basis. (Source: IQVIA Canadian drugstore and hospital purchases, September 2023 MAT.) Medexus is monitoring potential regulatory changes in Ontario regarding expanded prescribing authority for pharmacists for common ailments, including fungal nail infections. If adopted, Medexus believes that these regulatory changes could enhance availability and accessibility of topical terbinafine, if and when approved, which could increase unit demand.

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 Gleolan and over-the-counter products such as NYDA and Relaxa - each of which Medexus commercializes in Canada. Each of these three products demonstrated improvements in year-to-date net sales performance in fiscal year 2025 relative to fiscal year 2024, largely reflecting successful execution of the Company's sales and marketing initiatives, together with NYDA's typical seasonality. 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

- as did similar changes in Quebec that came into effect in June 2015 - which could increase unit demand and prompt Medexus to make additional investments in the product's growth in the Ontario market.

Additional information

Medexus's financial statements and management's discussion and analysis for fiscal Q2 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 Friday, November 8, 2024 to discuss Medexus's results for fiscal Q2 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: 511254

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/2010/51522

A replay of the call will be available approximately one hour following the end of the call through Friday, November 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: 51522

A replay of the webcast will be available on theInvestors section of Medexus's corporate website until Saturday, November 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.ca.

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Forward-looking statements

Certain statements 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", "prospects", 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, information contained in statements regarding any of the following: 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 (in particular any milestone payments that may become due under the Company's US treosulfan agreement, and including any statements regarding Medexus's intent to file one or more prospectuses, including the potential filing of an unallocated base shelf prospectus, with relevant securities authorities and any related financing initiatives); the legislative, regulatory, and policy environment in the United States (including in light of the November 2024 federal elections) and Canada (including in respect of potential expanded prescribing authority for pharmacists in Ontario); and the impact of Medexus's balance-sheet and cost management strategies (including the cost reduction initiative implemented in January 2024) and any benefits from those strategies. In addition, forward-looking statements in this news release also include statements regarding the potential benefits of treosulfan and terbinafine hydrochloride; the occurrence, timing, and expected outcome of the FDA review process for treosulfan and the Health Canada review process for terbinafine hydrochloride; the occurrence, timing, and expected outcome of the Company's ongoing negotiations with medac to further amend the US treosulfan agreement, including expectations regarding milestone and royalty payments that may become payable under that agreement; and, if approved by the FDA (in the case of treosulfan) and Health Canada (in the case of terbinafine hydrochloride), and if the Company's ongoing negotiations with medac are successful (in the case of treosulfan), 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 and information are based on Medexus's current expectations and assumptions, including factors or assumptions that were applied in drawing a conclusion or making a forecast or projection, and 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 condensed interim consolidated financial statements for the three- and six-month periods ended September 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.

	Three-month periods ended September 30,		**Six-month periods ended September 30,**	
(Amounts in $ '000s)	**2024**	**2023**	**2024**	**2023**
Net income (loss)	110	(1,093)	2,067	(442)
Add back:				
Depreciation and amortization (property, equipment, intangible assets)	1,576	1,463	2,986	2,909
Interest expense	2,163	4,229	4,194	8,484
Income tax expense	(691)	120	(748)	353
EBITDA	3,158	4,719	8,499	11,304
Add back:				
Share-based compensation	293	308	655	603
Transaction-related fees and expenses	-	-	-	-
Termination benefits	-	-	356	-
Foreign exchange loss	55	373	98	81
Unrealized gain on fair value of derivatives	-	(75)	-	(82)
Impairment loss	2,463	-	2,463	-
Adjusted EBITDA	**5,969**	**5,325**	**12,071**	**11,906**

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