February 5, 2025

Medexus Announces Strong Fiscal Q3 2025 Results, Well-Positioned to Launch GRAFAPEX (treosulfan) for Injection in the United States

Fiscal Q3 2025 revenue of $30.0 million, net income of $0.7 million, operating income of $3.8 million, and Adjusted EBITDA* of $5.8 million

Management to host conference call at 8:00 AM Eastern time on Thursday, February 6, 2024

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - February 5, 2025) - 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, 2024 (the company's fiscal Q3 2025). All dollar amounts in this press release are in United States dollars unless specified otherwise.

Financial highlights

- Revenue of $30.0 million and $83.6 million for the three- and nine-month periods ended December 31, 2024, an increase of $4.8 million and a decrease of $3.5 million, or 19.0% and (4.0)%, compared to $25.2 million and $87.1 million for the three- and nine-month periods ended December 31, 2023. The $4.8 million year-over-year revenue increase in fiscal Q3 2025 was attributable in part to continuing growth in net sales of Rupall and an approximately $2.0 million beneficial impact of customer buying patterns of IXINITY. The $3.5 million year-over-year revenue decrease in fiscal year 2025 to date was primarily attributable to reduced year-to-date net sales of Rasuvo and Metoject in fiscal year 2025 and declines in net sales of IXINITY since fiscal Q3 2024, partially offset by year-over-year increases in year-to-date net sales of Rupall (in Canada) and Gleolan (in both the United States and Canada).

- Adjusted EBITDA* of $5.8 million and $17.9 million for the three- and nine-month periods ended December 31, 2024, an increase of $2.6 million and $2.8 million, or 81.3% and 18.5%, compared to $3.2 million and $15.1 million for the three- and nine-month periods ended December 31, 2023. The $2.6 million and $2.8 million year-over-year Adjusted EBITDA* increases were primarily attributable to the effects of the Company's ongoing financial discipline efforts, together with the fiscal Q3 2025 effect of customer buying patterns mentioned above, and partially offset by the GRAFAPEX™ personnel and infrastructure investments discussed below.

- Available liquidity of $8.4 million (December 31, 2024), consisting of cash and cash equivalents, compared to $5.3 million (March 31, 2024), an increase of $3.1 million.

Subsequent to period end, in January 2025, Medexus completed a public offering of Common Shares for C$30 million aggregate gross proceeds (or C$28.3 million aggregate net proceeds before expenses).

- Operating income of $3.8 million and $9.4 million for the three- and nine-month periods ended December 31, 2024, an increase of $2.2 million and a decrease of $0.6 million, or 137.5% and (6.0)%, compared to $1.6 million and $10.0 million for the three- and nine-month periods ended December 31, 2023.

- Net income of $0.7 million and $2.8 million for the three- and nine-month periods ended December 31, 2024, an increase of $1.2 million and $3.8 million compared to net loss of $0.5 million and $1.0 million for the three- and nine-month periods ended December 31, 2023. The $1.2 million and $3.8 million year-over-year net income increases were primarily attributable to the effects of the Company's ongoing financial discipline efforts and a year-over-year reduction in financing costs, partially offset by the changes in revenue mentioned above and a $2.5 million impairment of intangible assets in fiscal Q2 2025.

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

"We are pleased to report a strong third quarter delivering solid revenue and producing positive net income for our third quarter in a row," commented Ken d'Entremont, Chief Executive Officer of Medexus. "Our core portfolio continues to provide Medexus with a solid foundation as we prepare for the next phase of our growth focused on GRAFAPEX™. To this end, over fiscal year 2025 to date, we have been increasing our investments in personnel and infrastructure to support a successful commercial launch of GRAFAPEX™, which we are planning for in the first half of calendar year 2025, with product expected to be commercially available by April."

Mr d'Entremont continued: "Given our experience in Canada with Trecondyv® (treosulfan for injection), we are very optimistic about the potential of GRAFAPEX™ in the US market. As we have previously mentioned, not only will GRAFAPEX™ make a substantial contribution to alloHSCT in the United States, but it also solidifies Medexus's leadership position in this therapeutic field. We anticipate that GRAFAPEX™ will have a meaningful impact on Medexus's total revenue and believe that annual product-level revenue in the United States has the potential to exceed US$100 million within five years after commercial launch, providing a significant uptick to our growth profile."

Brendon Buschman, Chief Financial Officer of Medexus, added: "Our strong overall performance in the third fiscal quarter, and fiscal year 2025 to date, has provided the necessary operating cash flow to continue to repay principal and interest under our BMO term loan, substantially reducing total debt under our BMO credit facilities – which now sits at a combined $40.9 million as of December 31, 2024. We have managed to do so while generating positive net income in all three fiscal quarters to date, for a total of $2.8 million, and a healthy $17.9 million of Adjusted EBITDA* from $83.6 million of revenue year-to-date, for an Adjusted EBITDA Margin* of over 21%. Our operating cash flow, including this quarter's $6.7 million of cash flow from operations, has also provided working capital to invest in our preparations for GRAFAPEX™ in the US."

"As part of our capital strategy, we completed a public offering of common shares for C$30 million in gross proceeds," continued Mr Buschman. "In addition to financing the regulatory milestones that have become payable under our GRAFAPEX™ agreement, particularly given the favorable payment terms we negotiated in the fourth amendment we announced in December 2024, we are now in a better position to pursue our growth strategy."

Operational highlights

Leading products

Hematology-oncology

- **GRAFAPEX (US):** In January 2025, Medexus was informed that the FDA approved GRAFAPEX™ (treosulfan) for Injection, an alkylating agent, with fludarabine as a preparative regimen for allo-HSCT in adult and pediatric patients one year of age and older with AML or MDS. GRAFAPEX holds Orphan Drug Designation under the Orphan Drug Act, meaning that the product will benefit from a seven-year period of regulatory exclusivity in the FDA-approved indication, which may potentially be extended to seven-and-a-half years in accordance with and subject to the requirements of the Orphan Drug Act. Medexus holds exclusive commercial rights to GRAFAPEX in the United States under a February 2021 exclusive license agreement with medac (GRAFAPEX Agreement). Medexus is targeting a commercial launch of GRAFAPEX in the first half of calendar year 2025, with product expected to be commercially available by April 2025, and does not expect to begin recognizing significant revenue from GRAFAPEX until early fiscal year 2026 (or second calendar quarter 2025) at the earliest. Based on internal estimates and research, Medexus believes that annual product-level revenue from GRAFAPEX has the potential to exceed US$100 million within five years after commercial launch, with the specific nature and level of success of Medexus's commercialization initiatives in support of GRAFAPEX, among other factors, determining the extent to which the Company realizes this potential. In November 2024, Medexus and medac entered into a fourth amendment to the GRAFAPEX Agreement. Among other things, the fourth amendment adjusted the unpaid regulatory milestone payments under the GRAFAPEX Agreement as provided in the fourth amendment. The regulatory milestone amount payable to medac under the fourth amendment upon an FDA approval of GRAFAPEX is based on the language of the product label approved by the FDA. Based on the terms of the approval, including the FDA-approved product label, Medexus has determined that medac will earn a regulatory milestone amount of US$15 million. The final regulatory milestone amount is subject to review and confirmation by the parties in light of the terms of the GRAFAPEX Agreement. The regulatory milestone amount is payable in three installments, subject to Medexus's right to temporarily defer installment amounts, on terms described in the fourth amendment. For a regulatory milestone amount of US$15 million, one-sixth of the total amount (US$2.5 million) is payable by June 30, 2025, one-third of the total amount (US$5 million) is payable by October 1, 2025, and the remaining 50% of the total (US$7.5 million) is payable by January 1, 2026, subject to Medexus's temporary deferral option in respect of the second and/or third such payments. Given the FDA approval of GRAFAPEX, Medexus has also now repaid a US$2.5 million credit received from medac in September 2021.

- **Trecondyv (Canada):** Unit demand for Trecondyv remained strong during the 12-

month period ended December 31, 2024, which is reflected in the unit demand growth of 55% over the trailing 12-month period ended December 31, 2024. This strong performance reflects successful execution of the Company's initiatives since its September 2021 commercial launch, but does not yet include the effect of the successful November 2024 completion of the negotiation process with the pan-Canadian Pharmaceutical Alliance and any subsequent decisions by participating government organizations on public reimbursement of Trecondyv for their regions and jurisdictions. For example, Medexus has now completed listing agreements for public reimbursement of Trecondyv with British Columbia's Provincial Health Services Authority and with Ontario's Ministry of Health and Ontario Health, which Medexus expects to benefit product-level revenue in future quarters. 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.

- **IXINITY (US):** Unit demand in the United States decreased by 1% over the trailing 12-month period ended December 31, 2024. (Source: customer-reported dispensing data.) Medexus expects that unit demand will remain stable when measured for the trailing 12-month period ending March 31, 2025. This performance reflects the success of the Company's efforts to maintain existing demand, despite a reduced allocation of sales force resources to IXINITY since January 2024. Medexus's investments in its IXINITY manufacturing process improvement initiative have generally had a positive impact on batch yield and manufacturing costs over fiscal year 2024 and now extending into fiscal year 2025.

- **Gleolan (US and Canada):** Unit demand in the United States grew more than 8% over the trailing 12 months ended December 31, 2024, reflecting the sustained positive response to the Company's commercialization efforts and successful execution of the Company's commercial plan to date. Medexus has used an efficient allocation of sales force resources to foster broader adoption of the product at additional institutions while maintaining focus on key customer institutions. There nevertheless continue to be disagreements with the licensor of Medexus's rights to the product in the United States regarding the terms of the parties' existing agreement (US Gleolan Agreement), which Medexus continues to seek to resolve through mutual negotiation and pursuant to the terms of the US Gleolan Agreement, including its dispute resolution process. Medexus is confident that it has performed its obligations under the US Gleolan Agreement and, pending resolution of the US Gleolan Agreement, whether by mutually acceptable agreement or otherwise in accordance with its existing terms, currently intends to continue commercializing Gleolan in the United States through to at least March 31, 2025 in accordance with and subject to the terms of the US Gleolan Agreement. Medexus also remains focused on delivering strong performance commercializing Gleolan in Canada. Unit demand in Canada grew 50% over the trailing 12 months ended December 31, 2024, reflecting continued successful execution of the Company's commercial plan in that market.

Allergy, dermatology, and rheumatology

- **Rupall (Canada):** Unit demand in Canada remained strong during the 12-month period ended December 31, 2024, which is reflected in the unit demand growth of 18% over the trailing 12-month period ended December 31, 2024. (Source: IQVIA CDH units –

Drugstores and hospitals purchases, MAT December 2024.) This strong performance reflects successful execution of the Company's initiatives to sustain the product's strong performance, 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, expired in January 2025. Medexus expects that Rupall will now begin to face generic competition in Canada and has initiated unit-level pricing strategies that will likely result in effective unit-level price reductions in fiscal Q4 2025, which are expected to persist thereafter.

- **Rasuvo (US):** Unit demand for Rasuvo remained strong during the three-month period ended December 31, 2024. (Source: IQVIA MAT December 2024.) However, sustained competition in the US branded methotrexate autoinjector market and statutory discounts and rebates in respect of Rasuvo under government-sponsored programs have and will continue to adversely affect total product-level revenue. Medexus has now largely eliminated investments in non-statutory discounts offered to large customers.

- **Metoject (Canada):** Unit demand for Metoject increased by more than 7% over the trailing 12-month period ended December 31, 2024 in spite of the direct and indirect effects of sustained generic competition. (Source: IQVIA – TSA database.) Medexus has implemented unit-level pricing strategies to defend the product's strong market position, which has adversely impacted product-level revenue, particularly following the launch of a second generic product in March 2024.

Other highlights

- **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. In January 2025, Health Canada delivered to Medexus a notice of deficiency regarding the terbinafine NDS. The notice identified concerns and uncertainties associated with the design of the phase 3 trial submitted to support the requested indication and the interpretation of the efficacy results. Medexus remains focused on building its North American allergy and dermatology franchise and, pending a final determination as to regulatory strategy and response to this notice, if any, has redeployed existing resources to support other portfolio products in this therapeutic area, including Rupall and NYDA, pending any launch of additional commercialization opportunities.

- **Public offering:** Subsequent to period end, in January 2025, Medexus completed a public offering of 7,500,000 Common Shares at a price of C$4.00 per Common Share for aggregate gross proceeds to Medexus of C$30 million (or C$28.3 million net proceeds before expenses). The underwriters have indicated to the Company that they do not intend to exercise the customary 30-day overallotment option to purchase up to 1,125,000 Common Shares for additional gross proceeds of C$4.5 million that was provided for in the underwriting agreement. The net proceeds from the offering, after deducting underwriting commissions and offering expenses, will be used to pay a portion of the regulatory milestone amounts payable to medac under the GRAFAPEX Agreement and for working capital and general corporate purposes, which may include funding the Company's ongoing business development activities and initiatives. The

Company used a portion of the net proceeds from the offering to repay a $2.5 million credit received from medac in September 2021.

Additional information

Medexus's financial statements and management's discussion and analysis for fiscal Q3 2025 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 Thursday, February 6, 2025 to discuss Medexus's results for fiscal Q3 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: 571655

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/2010/51991

A replay of the call will be available approximately one hour following the end of the call through Thursday, February 13, 2025. 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: 51991

A replay of the webcast will be available on theInvestors section of Medexus's corporate website until Friday, February 6, 2026.

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 hematology-oncology and allergy, dermatology, and rheumatology. 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 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", "budget", "potential", "targets", "could", "estimates", "expects", "forecasts", "goals", "intends", "may", "might", "objective", "outlook", "plans", "projects", "schedule", "should", "will", "would", "prospects", and "vision", or 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, including in respect of the stabilization of gross margin, selling and administrative expenses (including those specific to GRAFAPEX™ (treosulfan) for Injection), and net income (among other measures), in particular in light of investments in the commercial launch of GRAFAPEX; future growth, revenues, and expenses, including in respect of the commercialization of GRAFAPEX and the product-level revenue to be generated from its commercialization, and also in respect of IXINITY, the IXINITY manufacturing process improvement initiative (including the occurrence or timing of any further investments in that initiative), and Medexus's other leading products; Medexus's expectation that unit demand for IXINITY will remain stable when measured for the trailing 12-month period ending March 31, 2025; the expected benefit to product-level revenue for Trecondyv of the listing agreements for public reimbursement with provincial health services in British Columbia and Ontario; Medexus's ability to pay dividends, distributions, and other cash amounts in respect of Medexus's outstanding securities and other instruments, including the BMO Credit Agreement (defined below), and the Company's related capital allocation and capital management strategies; Medexus's overall capital allocation strategy, including expectations regarding availability of funds from operations, cash flow generation, and capital allocation, and also including expectations regarding cash needs, capital requirements, and needs for and ability to secure additional financing (whether in addition to the January 2025 public offering of Common Shares (defined below) discussed below in this news release or otherwise, and in particular in respect of any expectations regarding payment of the regulatory milestone amount that became payable under the GRAFAPEX Agreement upon the occurrence of, and which depends on the terms of, the FDA's approval); anticipated trends and challenges in Medexus's business and the markets in which it operates, including in respect of the Company's competitive position in and demographics of those markets, the Company's product pricing strategies, and product opportunities available to the Company, and, in particular, Medexus's ability to secure and fund commercialization rights to promising products and the performance of those products against expectations; the ability of Medexus and its business partners to secure regulatory approvals from the US Food and Drug Administration, or FDA, Health Canada, and other agencies when required, and the legislative, regulatory, and policy environment in the United States (including in light of the outcome of the November 2024 federal elections) and

Canada (including in respect of potential expanded prescribing authority for pharmacists); and the impact of Medexus's balance-sheet and cost management strategies and any benefits from those strategies. In addition, forward-looking statements in this news release also include statements regarding the potential benefits of GRAFAPEX; expectations regarding milestone and royalty payments that may become payable under the GRAFAPEX Agreement, including the expected outcome of Medexus's and medac's ongoing evaluation of the milestone amount payable under the GRAFAPEX Agreement; and the expected timing of any commercial launch of GRAFAPEX and related expectations regarding the product's prospects and performance, including in respect of its potential adoption and use in the United States and any related product-level revenue, 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 and disagreements with the licensor of Medexus's commercialization rights to Gleolan with respect to the US Gleolan Agreement (defined below), including any informal and/or formal dispute resolution processes that the parties are currently pursuing and could continue to pursue in future, and otherwise regarding the business relationship of the parties in the United States and Canada. The forward-looking statements and information included in this news release 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 GRAFAPEX is based on a number of such factors and assumptions as most recently described in Medexus's most recent management's discussion and analysis, and including the Company's planned commercial, market access, and medical strategies, the success of which will depend in part on the US regulatory landscape and related dynamics, including potential future changes to each, and can introduce and affect exposure to commercial, legal, and regulatory risk. 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 (and Adjusted EBITDA Margin) as a measure of Medexus's performance. EBITDA (earnings before interest, taxes, depreciation, and amortization) and Adjusted EBITDA (and Adjusted EBITDA Margin) 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, and are hereby incorporated by reference. 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 December 31,		**Nine-month periods ended December 31,**	
(Amounts in $ '000s)	**2024**	**2023**	**2024**	**2023**
Net income (loss)	733	(534)	2,800	(976)
Add back:				
Depreciation and amortization (property, equipment, intangible assets)	1,756	1,448	4,742	4,357
Interest expense	1,996	2,656	6,190	11,140
Income tax expense (recovery)	147	(261)	(601)	92
EBITDA	4,632	3,309	13,131	14,613
Add back:				
Share-based compensation	282	211	937	814
Termination benefits	-	-	356	-
Foreign exchange loss (gain)	905	(293)	1,003	(212)
Unrealized gain on fair value of derivatives	-	-	-	(82)

Impairment loss	-	-	2,463	-
Adjusted EBITDA	**5,819**	**3,227**	**17,890**	**15,133**

To view the source version of this press release, please visit https://www.newsfilecorp.com/release/239817

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