# Medexus Announces Fiscal Q1 2026 Results, Including Positive Results from

# US Launch of GRAFAPEX (treosulfan) for Injection

Fiscal Q1 2026 net revenue of \$24.6 million, net income of \$0.5 million, operating income of \$0.9 million, and Adjusted EBITDA\* of \$3.4 million

\$3.0 million of product-level net revenue from GRAFAPEX in fiscal Q1 2026, relative to \$3.0 million of personnel and infrastructure investments, further supporting Medexus's confidence in the product's potential

## Management to host conference call at 8:00 AM Eastern time on Wednesday, August 13, 2025

Toronto, Ontario and Chicago, Illinois (Newsfile Corp. - August 12, 2025) - 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, 2025 (the company's fiscal Q1 2026). All dollar amounts in this press release are in United States dollars unless specified otherwise.

# Key business update

Medexus is currently focused on delivering strong performance from GRAFAPEX. March 2025 was the first full month, and fiscal Q1 2026 was the first full fiscal quarter, in which Medexus recognized product-level net revenue from GRAFAPEX, which totaled \$3.0 million for fiscal Q1 2026, relative to \$3.0 million of GRAFAPEX personnel and infrastructure investments. Medexus also remains focused on delivering strong overall performance across the company's portfolio of products in both the United States and Canada.

Medexus has seen a positive market response to GRAFAPEX to date, with progress consistent with Company expectations:

- As of June 30, 2025, nine large commercial payers, together covering an estimated 48 million patient lives, and 14 individual healthcare institutions, representing 8% of the 180 transplant centers in the United States, have made positive formulary inclusion determinations, a promising indicator of the product's commercial potential. An additional 29 commercial payers have added GRAFAPEX on their "prior authorization" lists.
- Wholesaler data as of June 30, 2025 shows that 36 of the 180 transplant centers, representing an estimated 24% of total allo-HSCT procedures performed in the United States annually (Source: Allogeneic HSCT in HRSA 2016-2020; Health Resources and Services Administration), have already ordered GRAFAPEX for procedures in their institutions.
- Medexus expects that product-level net revenue from GRAFAPEX in fiscal Q2 2026 will be \$3.0 million to \$3.5 million, taking into account the wholesaler purchasing patterns observed to date and expected seasonality attributable to a lower frequency of procedures scheduled during summer months. Based on product-level performance to date, Medexus expects that

GRAFAPEX will be accretive to quarterly operating cash flows by fiscal Q3 2026 (calendar Q4 2025).

 Medexus also continues to expect that the annual product-level Adjusted Gross Margin\* of GRAFAPEX will ultimately be approximately 80%, although, as demonstrated by productlevel Adjusted Gross Margin\* for fiscal Q1 2026, product level Adjusted Gross Margin\* will be slightly higher in the initial months or quarters after commercial launch primarily due to the evolving reimbursement and tariff dynamics for the product (including as discussed below).

"The strong initial performance of GRAFAPEX™ is particularly important as other products in our portfolio shift to the later stages of their product life cycle," commented Ken d'Entremont, Chief Executive Officer of Medexus. "For instance, Rupall's revenues have experienced significant erosion after the loss of its exclusivity period in January 2025. Over time, we expect product-level performance of GRAFAPEX™ to significantly outweigh the relatively smaller impact of this decline in Rupall product-level performance in this transitional period. We design this portfolio approach to stay agile, resilient, and ultimately successful over the long term."

Medexus views product performance to date, and the response from the market and the attention to treosulfan from the medical and scientific community, as consistent with the Company's confidence that GRAFAPEX will make a substantial contribution to allo-HSCT in the United States, and also solidify Medexus's leadership position in this therapeutic field.

# Financial highlights

Key financial highlights for fiscal Q1 2026 include the following:

- Net revenue of \$24.6 million, a decrease of \$2.7 million, or 9.9%, compared to \$27.3 million for fiscal Q1 2025. The \$2.7 million year-over-year net revenue decrease was primarily due to reduced net sales of Rupall (due to significant generic competition, resulting in lower unit demand, and the effects of the resulting effective unit-level price reductions) and Gleolan in the United States (due to the March 2025 termination of the US Gleolan Agreement), partially offset by \$3.0 million of product-level net revenue from GRAFAPEX in fiscal Q1 2026.
- Adjusted EBITDA\* of \$3.4 million, a decrease of \$2.7 million, or 44.3%, compared to \$6.1 million for fiscal Q1 2025. The \$2.7 million year-over-year Adjusted EBITDA\* decrease was primarily due to the effect of significant generic competition on Rupall.
- Operating income of \$0.9 million, a decrease of \$3.1 million, or 77.5%, compared to \$4.0 million for fiscal Q1 2025.
- Net income of \$0.5 million, a decrease of \$1.5 million compared to net income of \$2.0 million for fiscal Q1 2025.
- Available liquidity of \$9.3 million (June 30, 2025), consisting of cash and cash equivalents, compared to \$24.0 million (March 31, 2025). The primary factor in this net decrease in cash was a payment of \$15.5 million that Medexus made in June 2025 under the terms of a June 2025 amendment to the Company's credit agreement.

- Cash provided by operating activities of \$3.9 million, a decrease of \$4.3 million compared to \$8.2 million for fiscal Q1 2025.
- \* Refer to "Non-GAAP measures" at the end of this press release for information about non-GAAP measures and related items, including Adjusted EBITDA and Adjusted Gross Margin.

"We are very pleased with the successful launch of GRAFAPEX™ in the United States," commented Ken d'Entremont, Chief Executive Officer of Medexus. "We believe this sequential quarter-over-quarter momentum we have seen will continue to build as GRAFAPEX™ is added to the formularies of additional key institutions and insurers, expanding patient access and driving further adoption. The positive initial response we have seen to date, including full results from the first full fiscal quarter of GRAFAPEX™ commercial availability, supports our expectation that GRAFAPEX™ will be accretive to quarterly operating cash flows by fiscal Q3 2026, or calendar Q4 2025."

Brendon Buschman, Chief Financial Officer of Medexus, added: "In addition to the successful progress on GRAFAPEX™ commercialization, we achieved \$0.5 million of positive net income for fiscal Q1 2026, and a healthy \$3.4 million of Adjusted EBITDA\* from \$24.6 million of net revenue. We realized gross margin of 56.0% and Adjusted Gross Margin\* of 65.5% for fiscal Q1 2026, compared to last year's 54.4% and 59.3%, respectively, demonstrating meaningful year-over-year improvement relative to steady gross profits of \$13.8 million and \$14.8 million and Adjusted Gross Profits\* of \$16.1 million and 16.2 million, respectively. These strong results provided \$3.9 million in cash flow from operating activities, which we have used in part to continue to repay principal and interest under our term loan, substantially reducing total debt under our credit facilities by \$15.5 million in fiscal Q1 2026 – meaning that total debt now sits at a combined \$22.0 million as of June 30, 2025, with remaining scheduled principal payments of \$1.1 million in September and December 2025."

Mr Buschman concluded: "We have entered fiscal year 2026 with strong momentum and expect continued quarter-over-quarter performance as our commercialization efforts for GRAFAPEX™ advance. Overall, we continue to execute with discipline and focus as we position Medexus for the opportunities ahead."

## Operational highlights

## Leading products

Hematology and hemato-oncology

GRAFAPEX (US): Medexus has seen a positive market response to GRAFAPEX since the
US commercial launch of the product in February 2025. Based on internal estimates and
research, and the preliminary market response to GRAFAPEX, Medexus continues to
expect that annual product-level net revenue from GRAFAPEX will 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 August 2025, the US Centers for Medicare & Medicaid Services (CMS) approved New Technology Add-On Payment (NTAP) reimbursement for eligible cases involving the use of

GRAFAPEX for CMS's fiscal year 2026, which runs from October 1, 2025 to September 30, 2026. The NTAP program is designed to provide temporary supplemental reimbursement to institutions that use designated new higher-cost medical technologies in the first few years after introduction to the market. To receive NTAP approval, designated technologies must demonstrate substantial clinical improvement in the diagnosis or treatment of Medicare beneficiaries compared to existing alternatives. Starting October 1, 2025, eligible procedures involving the use of GRAFAPEX™ will be eligible for additional reimbursement through the NTAP program. Cases involving the use of GRAFAPEX™ that are eligible for NTAP will be identified by ICD-10-PCS codes XW03388 or XW04388 and will benefit from a maximum NTAP of \$21,411 for CMS's fiscal year 2026. The GRAFAPEX™ approval was one of only five approvals for CMS's fiscal year 2026 under the new technology add-on payment traditional pathway, out of the 13 applications considered by CMS.

Medexus achieved \$3.0 million of product-level net revenue from GRAFAPEX in fiscal Q1 2026, including a \$1.0 million benefit from end-of-quarter wholesaler purchases in anticipation of future hospital demand, relative to the \$3.0 million of GRAFAPEX personnel and infrastructure investments discussed below. Medexus expects that product-level net revenue from GRAFAPEX in fiscal Q2 2026 will be \$3.0 million to \$3.5 million, taking into account the wholesaler purchasing patterns observed to date and expected seasonality attributable to a lower frequency of procedures scheduled during summer months. Based on product-level performance to date, Medexus expects that GRAFAPEX will be accretive to quarterly operating cash flows by fiscal Q3 2026 (calendar Q4 2025).

In July 2025, the current US administration announced a 15% tariff on imports of pharmaceutical products from the EU (July 2025 pharmaceutical tariffs). Based on the Company's preliminary assessment, which remains ongoing, the July 2025 pharmaceutical tariffs will apply to the Company's imports of GRAFAPEX at the announced rate of 15%. Medexus does not currently expect the impact of these tariffs on product-level performance to be material.

- Trecondyv (Canada): Unit demand for Trecondyv remained strong during the 12-month period ended June 30, 2025, which is reflected in the unit demand growth of 38% over the trailing 12-month period ended June 30, 2025. (Source: Hospitals Direct Sales Data, MAT June 2025.) This strong performance reflects successful execution of the Company's initiatives since its September 2021 commercial launch, but does not yet include the full effect of the successful November 2024 completion of the negotiation process with the pan-Canadian Pharmaceutical Alliance seeking to make Trecondyv accessible to publicly funded drug programs and patients in Canada and any subsequent decisions by participating government organizations on public reimbursement of Trecondyv for their regions and jurisdictions. For example, Medexus completed listing agreements for public reimbursement of Trecondyv with the provincial governments of Ontario and British Columbia in fiscal Q4 2025 and with the provincial governments of Quebec and Manitoba in fiscal Q1 2026. 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 June 30, 2025. (Source: customer-reported dispensing data.) Medexus expects that 12-month trailing unit demand will remain relatively stable, with only slight

continuing decreases, in the near term. See also "Selected Financial Information—Note regarding period-to-period variations" and "Discussion of Operations—Net revenue". 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 years 2024 and 2025 and now continuing into fiscal year 2026.

# Allergy, dermatology, and rheumatology

- Rupall (Canada): Rupall's market exclusivity, granted by Health Canada, expired in January 2025 and Rupall now faces generic competition in Canada. As a result, unit demand over the six-month period ended June 30, 2025 has decreased 29% when compared to the corresponding prior year period. (Source: IQVIA TSA units MAT June 2025.) Generic competition will continue to have an adverse impact on net sales of Rupall. Medexus initiated unit-level pricing strategies that resulted in effective unit-level price reductions in fiscal Q4 2025, which are expected to continue through fiscal year 2026 and thereafter.
- Rasuvo (US): Unit demand for Rasuvo decreased by 5% over the trailing 12-month period ended June 30, 2025. (Source: IQVIA MAT June 2025.) Sustained competition in the US branded methotrexate autoinjector market, among other factors, have and will continue to adversely affect total product-level net revenue. See also "Selected Financial Information—Note regarding period-to-period variations" and "Discussion of Operations—Net revenue". Based on the Company's preliminary assessment, which remains ongoing, the July 2025 pharmaceutical tariffs will apply to the Company's imports of Rasuvo at the announced rate of 15%. Medexus does not currently expect the impact of these tariffs on product-level performance to be material.
- Metoject (Canada): Unit demand for Metoject decreased by 5% over the trailing 12-month period ended June 30, 2025. (Source: IQVIA TSA database.) Medexus attributes this decrease in unit demand, which has corresponded with an adverse impact on product-level net revenue, to the continued effects of generic competition, in particular the launch of a second generic product in March 2024. Medexus implemented additional unit-level pricing strategies in April 2024 that resulted in effective unit-level price reductions to defend the product's strong market position, which has contributed to the adverse impact on product-level net revenue.

#### **Additional information**

Medexus's financial statements and management's discussion and analysis for fiscal Q1 2026 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 Wednesday, August 13, 2025 to discuss Medexus's results for fiscal Q1 2026.

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: 284388

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

https://www.webcaster4.com/Webcast/Page/2010/52801

A replay of the call will be available approximately one hour following the end of the call through Wednesday, August 20, 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: 52801

A replay of the webcast will be available on the <u>Investors section</u> of Medexus's corporate website until Thursday, August 13, 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.ca.

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### **Preliminary estimates**

The expected results discussed in this news release (which are distinct from the historical results included in Medexus's financial statements and discussed in this news release) are preliminary estimates only and have not been reviewed or audited by the Company's auditors. Expected results discussed in this news release include preliminary estimates of product-level net revenue generated from GRAFAPEX in fiscal Q2 2026. All such figures are based on information currently available to Medexus management and are subject to change and adjustment as Medexus's financial results for fiscal Q2 2026 are finalized. Accordingly, final

reported results may differ, and may differ materially, from these preliminary estimates, and investors therefore should not place undue reliance on any such preliminary estimates. All such preliminary estimates constitute forward-looking information within the meaning of applicable securities laws, are based on a number of assumptions, and are subject to a number of risks and uncertainties. For more information, see "Forward-looking statements".

# **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 and plans regarding financial or operational performance, including those specific to GRAFAPEX™ (treosulfan) for Injection, in particular in light of investments in the recent commercial launch of GRAFAPEX; future growth, revenues, and expenses, including in respect of the commercialization of GRAFAPEX and Medexus's other leading products, and including product-level performance in respect of same, and including, among others, the potential impact of the July 2025 tariff on imports of pharmaceutical products from the EU announced by the current US administration; the expected benefit to Trecondyv® (treosulfan for injection) of the listing agreements for public reimbursement with provincial health services, including in respect of product-level net revenue, and anticipated effects of Medexus's unit-level pricing strategies. 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 net 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", "non-GAAP ratios", and "supplementary financial measures" (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, Adjusted EBITDA Margin (Adjusted EBITDA divided by net revenue, expressed as a percentage), Adjusted Gross Profit (Loss) (gross profit (loss) before amortization of intangible assets), product-level Adjusted Gross Profit (Loss), Adjusted Gross Margin (Adjusted Gross Profit (Loss) divided by net revenue, expressed as a percentage), product-level Adjusted Gross Margin, and product-level net revenue as measures of Medexus's performance. EBITDA (earnings before interest, taxes, depreciation, and amortization), Adjusted EBITDA, Adjusted Gross Profit (Loss), and product-level Adjusted Gross Profit (Loss) are non-GAAP financial measures; Adjusted EBITDA Margin, Adjusted Gross Margin, and product-level Adjusted Gross Margin are non-GAAP ratios; and product-level net revenue and gross margin (gross profit (loss) divided by net revenue, expressed as a percentage) are supplementary 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 is 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. A reconciliation of Adjusted Gross Margin and product-level Adjusted Gross Margin to the most directly comparable IFRS measure can be found under the heading "Reconciliation of Adjusted Gross Profit (Loss) and Adjusted Gross Margin" below.

The following tables are derived from and should be read together with Medexus's consolidated financial statements for the three-month period ended June 30, 2025. The supplementary disclosure is intended to more fully explain disclosures related to Adjusted EBITDA, Adjusted Gross Margin, and product-level Adjusted Gross Margin, 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.

Reconciliation of Adjusted EBITDA to Net Income (Loss)

Three-month periods ended June 30,	2025	2024	
(Amounts in \$ '000s except percentages)			
Net income	\$516	\$1,957	
Add back:			
Depreciation and amortization (property, equipment, product licenses)	2,426	1,410	
Financing costs	1,406	2,031	
Income tax expense (recovery)	99	(57)	
EBITDA	4,447	5,341	-
Add back:			
Share-based compensation	167	362	
Termination benefits	_	356	
Business combinations payable – unrealized gain on change in fair value	(182)	-	
Foreign exchange (gain) loss	(581)	43	
Gain on disposal of assets	(408)	_	
Adjusted EBITDA	3,443	6,102	-
Adjusted EBITDA Margin	14.0%	22.4%	

# Reconciliation of Adjusted Gross Profit (Loss) and Adjusted Gross Margin Company

Three-month periods ended June 30,	2025	2024
(Amounts in \$ '000s except percentages)		
Net revenue	24,615	27,283
Cost of sales	10,841	12,448
Gross profit	13,774	14,835
Gross margin	56.0%	54.4%
Add back: Amortization of product licenses	2,356	1,351
Adjusted Gross Profit	16,130	16,186
Adjusted Gross Margin	65.5%	59.3%
GRAFAPEX		
Three-month periods ended June 30,	2025	2024
(Amounts in \$ '000s except percentages)		
Product-level net revenue	3,013	n/a
Product-level cost of sales	(1,518)	n/a
Product-level gross profit	1,495	n/a
Product-level gross margin	49.6%	n/a
Add back: Product-level amortization of product licenses	1,071	n/a
Product-level Adjusted Gross Profit	2,566	n/a
Product-level Adjusted Gross Margin	85.2%	n/a