August 8, 2022

Medexus Announces Record Fiscal Q1 2023 Revenue of US$23.0 Million, a 33% Increase versus Fiscal Q1 2022

Results include first U.S. revenue from Gleolan, full commercial launch expected in fiscal Q2

Treosulfan NDA resubmitted to the FDA, regulatory milestone payments deferred to October 2023

Management to host conference call at 8:00 AM Eastern Time on Tuesday, August 9, 2022

TORONTO and CHICAGO, Aug. 08, 2022 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals (**Medexus**) (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, 2022. All dollar amounts in this press release are in United States dollars unless specified otherwise.

Financial Highlights

- Delivered record total revenue of $23.0 million in fiscal Q1 2023, an increase of 33% compared to $17.3 million in fiscal Q1 2022 and an increase of 13% compared to $20.3 million in fiscal Q4 2022. This represents the strongest fiscal Q1 in Medexus's history. Primary drivers for the $5.7 million increase over fiscal Q1 2022 were an increase in net sales of IXINITY and recognition of a portion of revenue from Gleolan sales in the United States.
- Achieved Adjusted EBITDA* of $1.9 million in fiscal Q1 2023 compared to $(4.9) million in fiscal Q1 2022 and $1.1 million in fiscal Q4 2022. Organic increases in product revenue, a reduction in research & development costs, and recognition of a portion of revenue from Gleolan sales in the United States were the primary drivers of the $6.8 million increase over fiscal Q1 2022. Medexus achieved this Adjusted EBITDA increase while continuing to maintain appropriate investments in preparations for a commercial launch of treosulfan in the United States.
- Yielded operating profit of $0.0 million in fiscal Q1 2023, a $7.2 million improvement compared to operating loss of $7.2 million in fiscal Q1 2022.
- Produced net loss of $1.4 million in fiscal Q1 2023, a $5.2 million improvement compared to $6.6 million in fiscal Q1 2022.
- Generated Adjusted Net Loss* of $3.6 million in fiscal Q1 2023, a $6.2 million improvement compared to $9.8 million in fiscal Q1 2022.

- Held cash and cash equivalents of $7.3 million (with $8.7 million of total available liquidity) at end of fiscal Q1 2023.

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

Ken d'Entremont, Chief Executive Officer of Medexus, commented, "We are proud to announce the strongest fiscal Q1 in our company's history driven by a strong base business and complemented by initial revenues generated through our license agreement for Gleolan in the U.S. We anticipate completing our transition to full commercial responsibility for Gleolan within the current quarter and will begin to report Gleolan net sales in our revenues starting at that time. So far Gleolan sales have performed to our expectations, and we are excited about Gleolan's contribution to growing our revenues over the coming quarters."

Mr d'Entremont continued, "We are also moving forward with treosulfan. In July 2022, our partner medac resubmitted the treosulfan NDA to the FDA. If the response is considered complete by the FDA, a subsequent FDA approval will allow for the commercial launch of treosulfan in the U.S. in the first half of calendar year 2023. If approved, Treosulfan is expected to significantly contribute to our sustained overall growth in the years ahead."

Operational Highlights

Operational highlights for the three-month period ended June 30, 2022 and subsequent period include:

- **IXINITY**: Pharmacy and wholesale customers have now returned to normal buying patterns that are better aligned with patient unit demand. This contributed to an increase in IXINITY product revenue over fiscal Q1 2022. Medexus also continues to invest in an ongoing initiative to improve the IXINITY manufacturing process. Medexus expects the resulting operational efficiencies to improve IXINITY gross margins over the coming quarters.
- **Rupall**: Increasingly severe allergy seasons across Canada and successful sustained execution of sales and marketing initiatives yielded continued strong growth in Rupall sales in fiscal Q1 2023, with unit demand growth of 22% for the 12 months ended June 30, 2022. (Source: IQVIA CDH units – Drugstores and hospitals purchases, MAT March 2022.) This performance continues to position Rupall as one of the fastest-growing antihistamines in the Canadian prescription market.
- **Rasuvo**: Unit demand increased in the 12 months ended June 30, 2022. (Source: Symphony Sub National 6/30/2022 Data & Chargebacks, PAP.) However, increasing competition in the U.S. branded methotrexate market continue to negatively affect Rasuvo product-level revenue. Medexus has implemented effective unit-level price reductions to defend its strong market position.
- **Gleolan**: In March 2022, Medexus acquired the exclusive right to commercialize Gleolan in the United States. Gleolan sales during the ongoing transition period, including fiscal Q1 2023, have been in line with expectations, and Medexus recognized a portion of net sales in its revenue accordingly. Transition of commercialization responsibility to Medexus under the license agreement continues to go well, and Medexus expects to complete this process in full in the current quarter. This will result

in Medexus having full responsibility for commercializing Gleolan in the United States, which will therefore allow Medexus to begin fully recognizing product revenue within fiscal Q2 2023.

- **Treosulfan**: In July 2022, medac, a strategic partner of Medexus, resubmitted its NDA for treosulfan with the FDA. The resubmission included updates to data files and supporting information in response to the FDA's information request received in May 2022. The review clock for the FDA's review of the NDA resubmission will then start if and when the response is considered complete by the FDA. In addition, in August 2022, Medexus and medac signed an amendment to their February 2021 license agreement for treosulfan. The amendment extends the payment date for regulatory milestones triggered by an FDA approval to October 2023, which therefore allows Medexus to launch and begin commercialization well before these license payments must be paid.

Additional Information

Medexus's financial statements and management's discussion and analysis for the first fiscal quarter ended June 30, 2022 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 Tuesday, August 9, 2022, to discuss the company's operating and financial results and corporate updates for fiscal Q1 2023.

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: 379918

A live webcast of the call will be available on the Investors—News & Events—IR Calendar section of Medexus's corporate website or at the following link:

https://www.webcaster4.com/Webcast/Page/2010/46315

A replay of the call will be available approximately one hour following the end of the call through Tuesday, August 16, 2022. 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: 46315

A replay of the webcast will be available on the Investors—News & Events—IR Calendar section of Medexus's corporate website until Wednesday, August 9, 2023.

About Medexus

Medexus is a leader in innovative rare disease treatment solutions with a strong North American commercial platform and a portfolio of proven best-in-class products. Our current focus is on the therapeutic areas of hematology, auto-immune diseases, and allergy. We continue to build a highly differentiated company with a growing portfolio of innovative and high-value orphan and rare disease products that will underpin our growth for the next decade.

Our current leading products are Rasuvo™ and Metoject®, a unique formulation of methotrexate (auto-pen and pre-filled syringe) designed to treat rheumatoid arthritis and other auto-immune diseases; IXINITY®, an intravenous recombinant factor IX therapeutic for use in patients 12 years of age or older with Hemophilia B (a hereditary bleeding disorder characterized by a deficiency of clotting factor IX in the blood, which is necessary to control bleeding); and Rupall®, an innovative prescription allergy medication with a unique mode of action. We also hold exclusive US and Canadian rights to commercialize Gleolan™ (aminolevulinic acid hydrochloride or ALA HCl), an FDA-approved, orphan drug designated optical imaging agent currently indicated in patients with glioma (suspected World Health Organization Grades III or IV on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery.

We have also licensed treosulfan, part of a preparative regimen for allogeneic hematopoietic stem cell transplantation to be used in combination with fludarabine, for commercialization in the United States and Canada. Treosulfan was approved by Health Canada in June 2021 and is marketed in Canada as Trecondyv®. Treosulfan is currently the subject of a regulatory review process with the U.S. Food and Drug Administration.

Our mission is to provide the best healthcare products to healthcare professionals and patients. We strive to deliver on this mission by acting on our core values: Quality, Innovation, Customer Service, and Collaboration.

Contacts

For more information, please contact any of the following:

Medexus

Ken d'Entremont, Chief Executive Officer
Medexus Pharmaceuticals
Tel: 905-676-0003
Email: ken.dentremont@medexus.com

Marcel Konrad, Chief Financial Officer
Medexus Pharmaceuticals
Tel: 312-548-3139
Email: marcel.konrad@medexus.com

Investor Relations

Victoria Rutherford
Adelaide Capital
Tel: 1-480-625-5772

Email: victoria@adcap.ca

Forward-Looking Statements

Certain statements made in this press release contain forward-looking information within the meaning of applicable securities laws (**forward-looking statements**). The words “anticipates”, “believes”, “expects”, “will”, “plans”, “potential”, and similar words or expressions are often intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Specific forward-looking statements contained in this news release include, but are not limited to, statements regarding Medexus’s business strategy or outlook and future growth plans, expectations regarding future financial or operating performance (including with respect to the expected benefits of improvements made to the IXINITY manufacturing process and expected results from sales of Gleolan in the United States), ability to obtain FDA approval for treosulfan, the timing of treosulfan launch in the United States, and competitive position of and anticipated trends and challenges in the company’s business and the markets in which it operates. These statements are based on factors or assumptions that were applied in drawing a conclusion or making a forecast or projection, including assumptions based on historical trends, current conditions and expected future developments. Since forward-looking statements relate to future events and conditions, by their very nature they require making assumptions and involve inherent risks and uncertainties. Medexus cautions that although it is believed that the assumptions are reasonable in the circumstances, these risks and uncertainties give rise to the possibility that actual results may differ materially from the expectations set out in the forward-looking statements. Material risk factors include 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; future capital requirements and dilution; intellectual property protection and infringement risks; competition (including potential for generic competition); reliance on key management personnel; Medexus’s ability to implement its business plan; Medexus’s ability to leverage its U.S. and Canadian infrastructure to promote additional growth; regulatory approval by relevant health authorities, including the FDA; product reimbursement by third party payers; litigation or expiry with respect to patents or other intellectual property rights; litigation risk; stock price volatility; government regulation; and potential third party claims. Given these risks, undue reliance should not be placed on these forward-looking statements, which are made only as of the date hereof. Other than as specifically required by law, Medexus undertakes no obligation to update any forward-looking statements to reflect new information, subsequent or otherwise.

Trademarks and trade names

This press release contains references to trademarks and service marks, including those belonging to other companies, persons, or entities. Solely for convenience, trademarks and trade names referred to in this document may appear without the “®” or “™” symbols. Each such reference should be read as though it appears with the relevant symbol. Any such references are not intended to indicate, in any way, that the holder or holders of the relevant intellectual property rights will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names.

Non-GAAP measures

Company management uses, and this press release refers to, financial measures that are not recognized under IFRS and do not have a standard meaning prescribed by generally accepted accounting principles (**GAAP**) in accordance with IFRS or other financial or accounting authorities (**non-GAAP measures**). These non-GAAP measures may include "non-GAAP financial measures" and "non-GAAP ratios" (each defined in National Instrument 52-112, *Non-GAAP and Other Financial Measures Disclosure*). Medexus's method for calculating these measures may differ from methods used by other companies and therefore these measures are unlikely to be comparable to similarly-designated measures used or presented by other companies.

In particular, management uses Adjusted Net Income (Loss) and Adjusted EBITDA as measures of Medexus's performance. Adjusted Net Income (Loss), EBITDA (earnings before interest, taxes, depreciation, and amortization) and Adjusted EBITDA are non-GAAP financial measures. In addition, Adjusted Net Income (Loss) may be presented on a per share basis.

An explanation and discussion of each of these non-GAAP measures, including their limitations, is set out under the heading "Preliminary Notes—Non-GAAP measures" in Medexus's most recent management's discussion and analysis. A reconciliation of each of these non-GAAP measures to the most directly comparable IFRS measure can be found under the heading "Reconciliation of Adjusted Net Income (Loss) and Adjusted EBITDA to Net Income (Loss)" below.

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

The following tables are derived from and should be read together with Medexus's consolidated statement of operations for the three-month period ended June 30, 2022. This supplementary disclosure is intended to more fully explain disclosures related to Adjusted Net Income (Loss) and Adjusted EBITDA and provides additional information related to Medexus's operating performance. However, Medexus's non-GAAP measures have limitations as analytical tools and should not be considered in isolation or as a substitute for analysis of Medexus's financial information as reported under IFRS.

(Amounts in $ '000s)		
For the three-month period ended June 30	**2022**	**2021**
Net loss	(1,398)	(6,587)
Add back:		
Unrealized gain on fair value of derivatives	(2,239)	(3,246)
Adjusted net income (loss)	**(3,637)**	**(9,833)**

(Amounts in $ '000s)		
For the three-month period ended June 30	**2022**	**2021**
Net loss	(1,398)	(6,587)
Add back:		

Depreciation and amortization (property, equipment, intangible assets)	1,542	1,579
Interest expense	3,149	2,884
Income tax recovery	(154)	-
EBITDA	3,139	(2,124)
Add back:		
Share-based compensation	303	671
Transaction fees	28	-
Foreign exchange loss (gain)	675	(213)
Unrealized loss (gain) on fair value of derivatives	(2,239)	(3,246)
Adjusted EBITDA	**1,906**	**(4,912)**

Source: Medexus Pharmaceuticals Inc