

## **Company update** May 15, 2024

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This presentation contains forward-looking statements, including statements regarding Company's expectations for (i) the timing, progress and outcome of its clinical trials; (ii) the clinical benefits and competitive positioning of its product candidates; (iii) the ability of its products to obtain regulatory approvals, commence commercial production and achieve market penetration and sales; (iv) its future portfolio; (v) its future partnering arrangements; (vi) its future capital needs, capital expenditure plans and ability to obtain funding; and (vii) prospective financial matters regarding our business. Although the Company believes that its expectations are based on reasonable assumptions, any statements other than statements of historical facts that may be contained in this presentation relating to future events are forward-looking statements and subject to change without notice, factors beyond the Company's control and the Company's financial capabilities.

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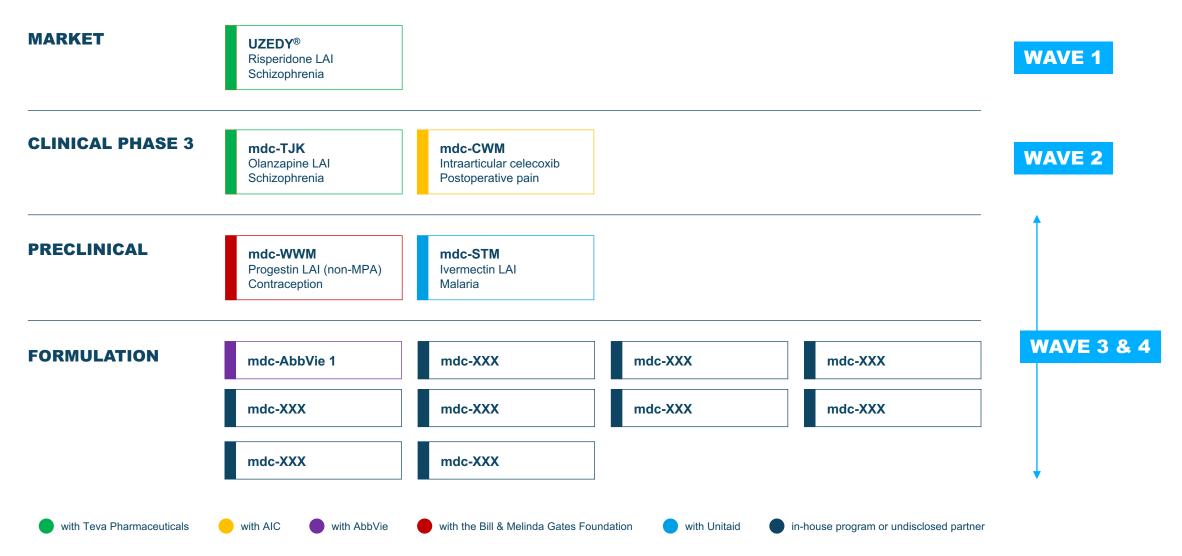
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UZEDY® is trademark of Teva Pharmaceuticals

## **2024, Potential Spectacular Year**

UZEDY®	Sales ramp up	$\checkmark$
<b>mdc-TJK</b> Olanzapine LAI	Positive Phase 3 efficacy results No PDSS (3600 injections)	✓ ✓
mdc-CWM	Encouraging Phase 3 results	$\checkmark$
Partnering	Strategic collaboration with AbbVie	$\checkmark$

## **Growing portfolio and R&D pipeline**

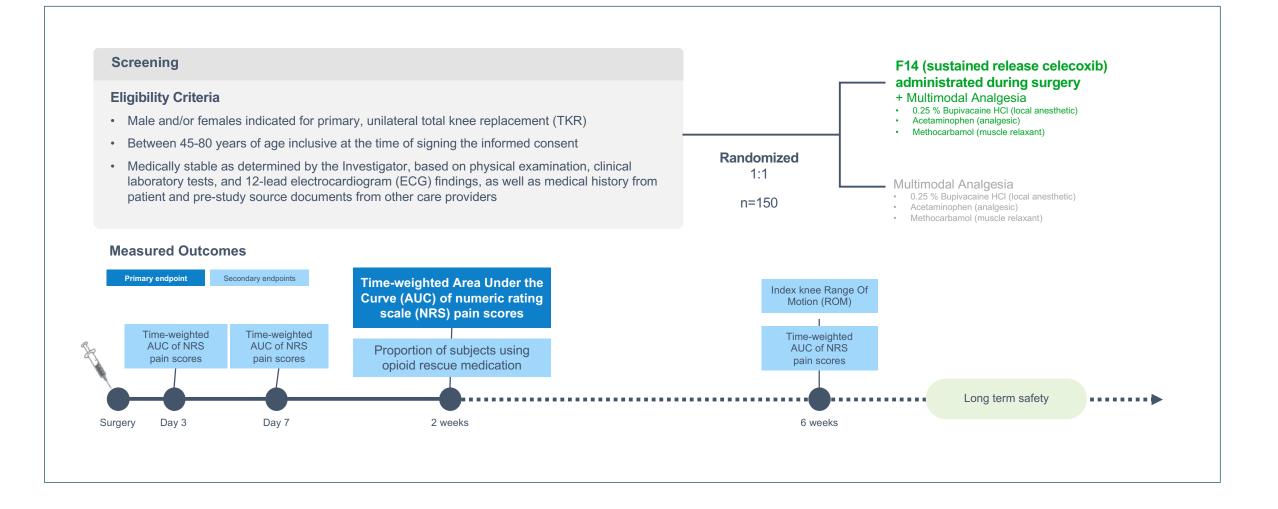


#### mdc-CWM

Intraarticular celecoxib for postoperative inflammation and pain management

## Encouraging Phase 3 results in Total Knee Replacement (TKR)

## mdc-CWM, phase 3 study design



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## mdc-CWM, phase 3 results

#### Primary endpoint of time-weighted AUC of pain intensity over 14 days not met

#### Numerical improvement favoring the treated group observed for

- The primary endpoint
- Secondary endpoints of time-weighted AUC of pain over 3 and 7 days

#### Other positive outcomes related to inflammation

- Improvement for knee range of motion (ROM) at 6 weeks (p<0.005), as well as at 3 months (p<0.0005)
- Improvement for swelling at 6 weeks (p<0.005) and 3 months (p<0.05)
- Improvement of the Timed-Up-and-Go (TUG) test at 6 weeks

#### Far greater improvement in a sub-group of 108 patients

- Patients had not previously undergone TKR in their contralateral knee
- Improvement in endpoints of time-weighted AUC of pain, opioid consumption, ROM, effusion, and TUG

#### No new safety signals were identified, and no SAEs were reported as related to F14 treatment

### **UZEDY**<sup>®</sup>

Monthly and every-two months subcutaneous risperidone for treatment of schizophrenia

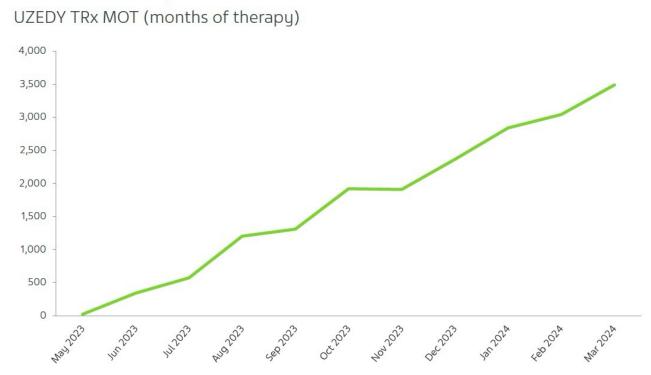
## Strong sales ramp up

### UZEDY<sup>®</sup> Launch Building Momentum



#### Reaffirming 2024 revenues outlook of ~\$80M

# Extraction reservation that UZEDY Prescription Growth



- Differentiated clinical profile we believe to be attractive to patients and HCPs
- Broad access in Fee-for-Service
  Medicaid
- Strong commercial effort to drive awareness, trial and adoption
- Sales coverage of hospitals, acute treatment centers and community mental health centers

12 | Source: IQVIA NPA (TRx normalized into patient months of therapy equivalent volume based on dosing regimen), large LTC supplier stopped sending IQVIA TRx / NRx / NBRx data starting 7/7/23



#### **Medincell revenue from UZEDY®**

## Mid- to high-single digit royalties on net sales Up to \$105m of commercial milestones

# UZEDY<sup>®</sup> Strong differentiation thanks to BEPO<sup>®</sup>



#### **Subcutaneous injection** (vs. Intramuscular)

No reconstitution needed

Immediate onset of action

(vs. oral supplementation or second injection needed)

Same effect regardless of location of injection

# UZEDY<sup>®</sup> Key outcomes from clinical studies



#### Significant reduction in risk of relapse<sup>1</sup>

80% reduction in the risk of relapse with UZEDY® q1m compared vs. placebo

#### Improvements in PANSS scores<sup>2</sup>

PANSS scores change favoring UZEDY® (-4.10) over placebo (+1.11) at the end of treatment

#### Improved quality of life in long-term safety study<sup>3</sup>

- Improved or stable long-term quality of life up to 56 weeks of therapy
- Patients remaining relapse free up to 56 weeks were 98% q1m

1. Data on file. Teva Neuroscience, Inc; UZEDY<sup>™</sup> (risperidone) extended-release injectable suspension current Prescribing Information. Parsippany, NJ: Teva Neuroscience, Inc 2. For exploratory analysis. No determination of statistical significance can be made and no conclusions should be drawn; ITT, intent-totreat; LS. leastsquares; PAN SS, Positive and Negative Syndrome Scale.. 3. Shine study, Kane JM et al. Presented at the Neuroscience Education Institute Congress; November 9–12, 2023; Colorado Springs, Colorado. Poster 59;



#### mdc-TJK

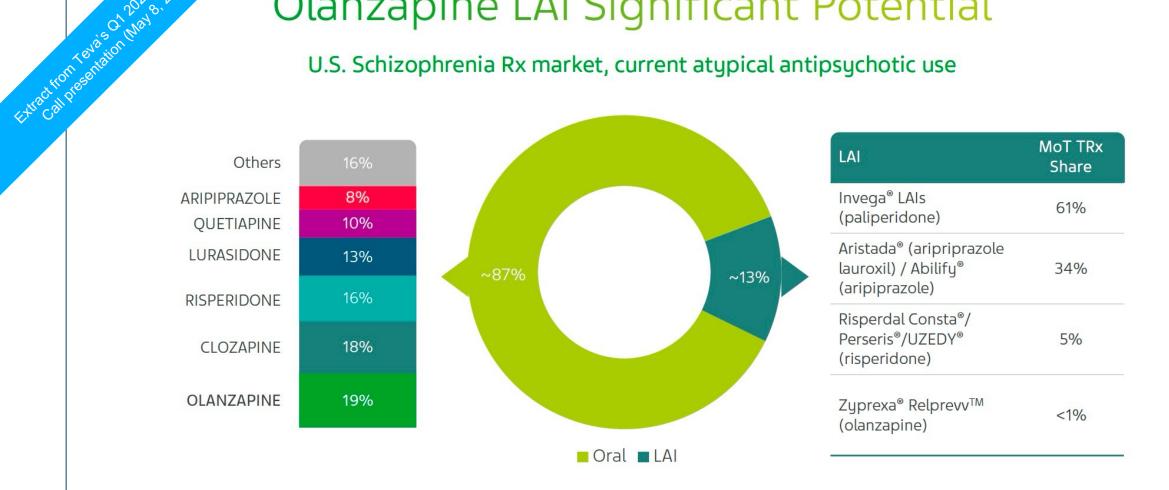
Once-monthly subcutaneous long-acting injection of the atypical antipsychotic olanzapine

# Positive Phase 3 efficacy results No PDSS to date



#### **Olanzapine LAI Significant Potential**

U.S. Schizophrenia Rx market, current atypical antipsychotic use



Current Atypical Antipsychotic Use: IQVIA NPA Feb'24 MAT; (LAI TRx normalized into patient months of therapy equivalent volume based on dosing regimen), Oral atypical TRx share: company analysis

6 | Global peak sales source: Evaluate pharma complete data extract for LAI antipsychotics Trademarks mentioned are the property of their respective owners



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#### **UZEDY<sup>®</sup>**, a best-in-class in a well-established market

Janssen (Johnson & Johnson) very successful at building a risperidone LAIs franchise



**ORAL RISPERIDONE** 

PEAK SALES (2005) \$3.5bn

**2024 SALES** 

\$4.5bn (>3bn in US)

Oral risperidone: \$500m

<sup>1</sup>Metabolite of risperidone

#### mdc-TJK, a potential first-in-class thanks to a favorable safety profile

Olanzapine LAI from Eli Lilly did not grab potential because of an FDA black box against the risk of **post-injection** delirium and sedation syndrome (PDSS)



# The risk of PDSS limits the use of the only other existing olanzapine LAI

PDSS: Sudden and unexpected onset of delirium or sedation after injection

<0.1% of injections and ≈2% of patients

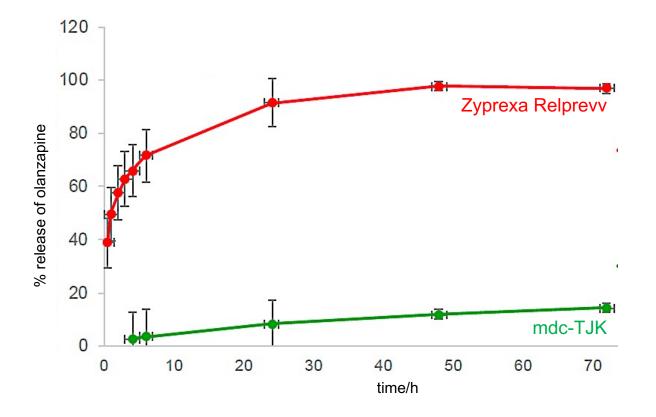
Risk remain for each injection

#### **FDA Blackbox and monitoring requirement**

- Restricted distribution program
- Patients must stay at healthcare facility for 3 hours after each injection



### mdc-TJK is not susceptible to PDSS thanks to subcutaneous injection and advanced controlled release (I)

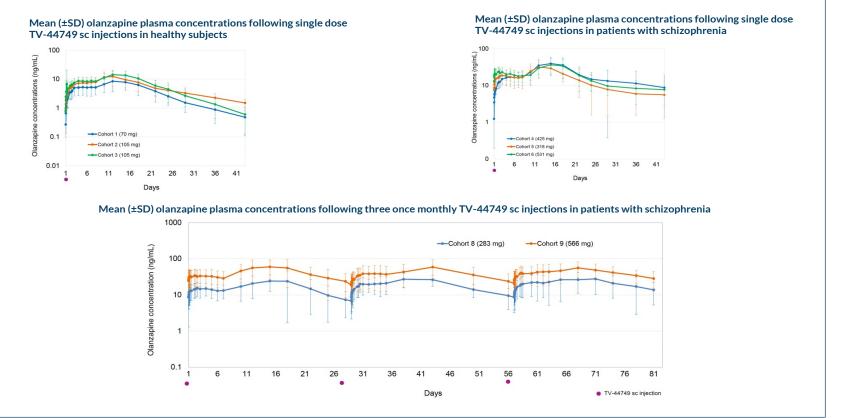


#### **In-vitro evidence**

Releate of olanzapine from Zyprexa Relprevv<sup>1</sup> and mdc-TJK in human plasma, 37°C, 100 rpm (30 mg dose), orbitalshaking water bath

Extract from Teva's Q2 earnings call presentation <sup>1</sup> Zyprexa Relprevv is a trademark of Eli Lilly and Company

### mdc-TJK is not susceptible to PDSS thanks to subcutaneous injection and advanced controlled release (II)



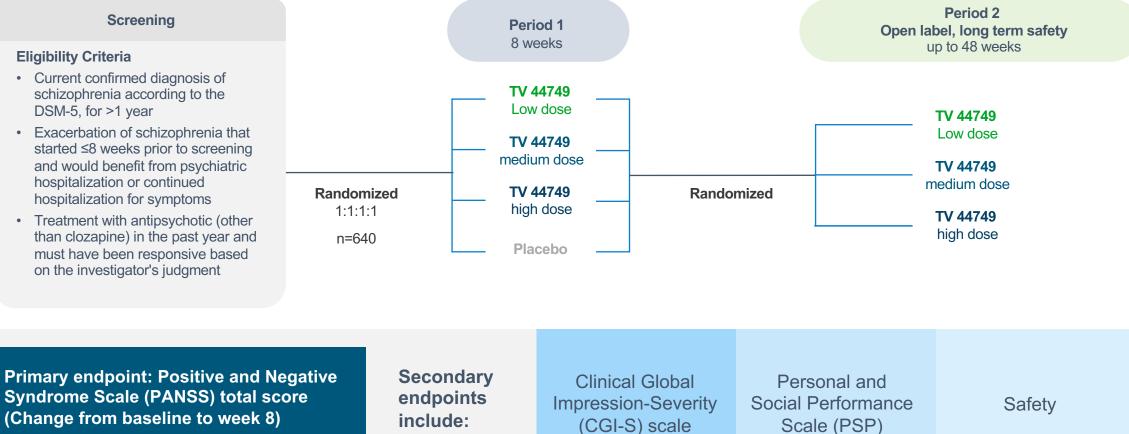
Phase 1 data

## mdc-TJK, SOLARIS, pivotal phase 3 study

#### **Eligibility Criteria**

Screening

- Current confirmed diagnosis of schizophrenia according to the DSM-5, for >1 year
- Exacerbation of schizophrenia that started ≤8 weeks prior to screening and would benefit from psychiatric hospitalization or continued hospitalization for symptoms
- Treatment with antipsychotic (other than clozapine) in the past year and must have been responsive based on the investigator's judgment

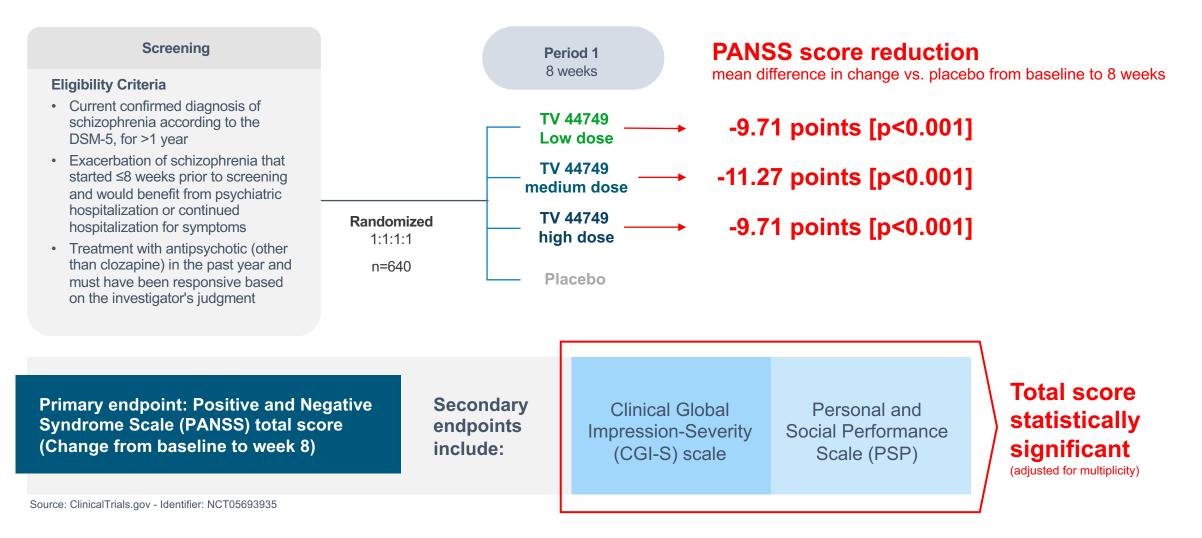


Syndrome Scale (PANSS) total score (Change from baseline to week 8)

Source: ClinicalTrials.gov - Identifier: NCT05693935

include:

## mdc-TJK, SOLARIS top line efficacy data



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## **No PDSS to date** 80% of ca. 3600 required injections



### mdc-TJK: Accelerating Phase 3 trial

## Phase 3 recruitment finalized 9 months ahead of schedule

## Full submission safety database to be available in H2 2024



#### **Medincell revenue from mdc-TJK**

#### **\$12m out of \$17m of development milestones left**

## Mid- to high-single digit royalties on net sales

## **Up to \$105m of commercial milestones**

#### **Partnering**

### Collaboration with AbbVie (April 2024)



# Strategic co-development and licensing agreement with AbbVie

#### **Up to 6 Long-Acting Injectable therapies**

- Multiple therapeutic areas and indications
- First program candidate selected; formulation activities underway

Medincell to conduct formulation and preclinical activities

#### AbbVie to conduct clinical development

AbbVie responsible for commercialization globally

#### **Financial metrics**

## **\$35 million upfront payment**

## up to **\$1.9 billion**

#### in potential commercial and development milestones

(up to \$315 million for each program)

## Tiered

## mid-single to low-double digit royalties

## What's next for 2024?





## Annual results June 25, 2024





