



Mallinckrodt Strategic Acquisition

Ocera Therapeutics, Inc.

November 2, 2017



Forward-looking statements

Statements in this document that are not strictly historical, including statements regarding the proposed acquisition of Ocera Therapeutics, the expected timetable for completing the transaction, future financial condition and operating results, economic, business, market opportunity, competitive and/or regulatory factors affecting Mallinckrodt's and Ocera's businesses and any other statements regarding events or developments that the companies believe or anticipate will or may occur in the future, may be "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, and involve a number of risks and uncertainties. There are a number of important factors that could cause actual events to differ materially from those suggested or indicated by such forward-looking statements and you should not place undue reliance on any such forward-looking statements.

These factors include risks and uncertainties related to, among other things:

- General economic conditions and conditions affecting the industries in which Mallinckrodt and Ocera operate;
- Ocera's ability to obtain regulatory approval to market its product or the timing of such approval process;
- The commercial success of Mallinckrodt's products and of Ocera's product;
- The parties' ability to satisfy the acquisition agreement conditions and complete the Ocera acquisition on the anticipated timeline or at all;
- Mallinckrodt's ability to realize anticipated growth, synergies and cost savings from acquisitions (including the Ocera acquisition);
- Conditions that could necessitate an evaluation of Mallinckrodt's goodwill and/or intangible assets for possible impairment;
- Changes in laws and regulations;
- Mallinckrodt's ability to successfully integrate acquisitions of operations, technology, products and businesses generally and to realize anticipated growth, synergies and cost savings (including with respect to the Ocera acquisition);
- Mallinckrodt's and Mallinckrodt's licensors' ability to successfully develop or commercialize new products;
- Mallinckrodt's and Mallinckrodt's licensors' ability to protect intellectual property rights;
- Mallinckrodt's ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration;
- Customer concentration;
- Mallinckrodt's reliance on certain individual products that are material to its financial performance;
- Cost containment efforts of customers, purchasing groups, third-party payers and governmental organizations;

Forward-looking statements (continued)

- The reimbursement practices of a small number of public or private insurers;
- Pricing pressure on certain of Mallinckrodt's products due to legal changes or changes in insurers' reimbursement practices resulting from recent increased public scrutiny of healthcare and pharmaceutical costs;
- Limited clinical trial data for H.P. Acthar® Gel;
- Complex reporting and payment obligations under healthcare rebate programs;
- Mallinckrodt's ability to navigate price fluctuations;
- Future changes to U.S. and foreign tax laws;
- Mallinckrodt's ability to achieve expected benefits from restructuring activities;
- Complex manufacturing processes;
- Competition;
- Product liability losses and other litigation liability;
- Ongoing governmental investigations;
- Material health, safety and environmental liabilities;
- Retention of key personnel;
- Conducting business internationally;
- The effectiveness of information technology infrastructure; and
- Cybersecurity and data leakage risks.

These and other factors are identified and described in more detail in the "Risk Factors" section of Mallinckrodt's Annual Report on Form 10-K for the fiscal year ended September 30, 2016, as well as such sections of Ocera's Annual Report on Form 10-K for the fiscal year ended December 31, 2016. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt and Ocera do not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law.



Additional Information and Notice to Investors

This communication is for informational purposes only and does not constitute an offer to purchase nor a solicitation of an offer to sell any securities of Ocera Therapeutics. The tender offer for the shares of Ocera Therapeutics common stock described in this communication has not yet commenced. The solicitation and offer to purchase shares of Ocera Therapeutics common stock will only be made pursuant to a tender offer statement on Schedule TO and related exhibits, including the offer to purchase, letter of transmittal, and other related documents. Upon commencement of the tender offer, Mallinckrodt plc and its wholly-owned subsidiaries, MAK LLC and MEH Acquisition Co., will file with the SEC a tender offer statement on Schedule TO and related exhibits, including the offer to purchase, letter of transmittal, and other related documents. In addition, Ocera will file with the SEC a tender offer solicitation/recommendation statement on Schedule 14D-9 with respect to the tender offer. These documents will contain important information, including the terms and conditions of the tender offer. Investors and security holders are urged to read each of these documents and any amendments to these documents carefully when they are available prior to making any decisions with respect to the tender offer. Investors and security holders will be able to obtain free copies of these materials (when available) and other documents filed with the SEC through the web site maintained by the SEC at www.sec.gov. Copies of the documents filed by Mallinckrodt plc, MAK LLC and MEH Acquisition Co. with the SEC will also be available free of charge on the Investor Relations section of its website at www.mallinckrodt.com and copies of the documents filed by Ocera with the SEC will be available free of charge on Ocera's website at ocerainc.com.

Transaction highlights – acquisition of Ocera and OCR-002 (ornithine phenylacetate) developmental asset

DEAL CONSIDERATION

- Mallinckrodt to commence cash tender offer to purchase Ocera Therapeutics for \$1.52 per share, plus Contingent Value Right; company has global rights to OCR-002 and all related assets
- Upfront payment: Approximately \$42 million; additional payments: up to \$75 million dependent on development and sales milestones

TIMING

- Close expected Q4 2017, subject to customary closing conditions

FINANCIAL IMPACT

- Assuming a 2017 close, company expects dilution to adjusted diluted earnings per share of approximately \$0.25 to \$0.35 annually beginning in 2018
- Assuming approval of intravenous (IV) and oral formulations, expected peak sales of >\$500 million

DEVELOPMENT STATUS

- IV formulation (for acute hepatic encephalopathy) now in Phase 2, expected U.S. approval 2022
- Oral formulation (for recurrent hepatic encephalopathy) now in Phase 2, expected U.S. approval 2024
- Granted U.S. FDA¹ Orphan Drug designation and Fast Track status, as well as granted EMA² Orphan Drug designation

Ocera acquisition builds on Mallinckrodt's commitment to develop therapies for serious and critical diseases

Product	PreClinical	Phase 1	Phase 2	Phase 3	Registration	Indication
UVADEX® (methoxsalen) sterile solution (Therakos)	[Progress bar]					Chronic GVHD ¹ (Japan)
STANNSOPORFIN heme oxygenase inhibitor	[Progress bar]					Neonatal Hyperbilirubinemia
XENON gas for inhalation	[Progress bar]					Post Cardiac Arrest
STRATAGRAFT® regenerative skin tissue	[Progress bar]					Severe Burns, DPT ²
TERLIPRESSIN	[Progress bar]					HRS ³ Type-1
UVADEX (methoxsalen) sterile solution (Therakos)	[Progress bar]					Acute GVHD (U.S.)
H.P. ACTHAR® GEL (repository corticotropin injection)	[Progress bar]					ALS ⁴
STRATAGRAFT regenerative skin tissue	[Progress bar]					Severe Burns, FT ⁵
OCR-002 (ornithine phenylacetate) intravenous	[Progress bar]					Hepatic Encephalopathy
OCR-002 (ornithine phenylacetate) oral	[Progress bar]					Hepatic Encephalopathy
EXPRESSGRAFT™ Anti-Infective (Cathelicidin)	[Progress bar]					DFU ⁶
MNK-1411 (cosyntropin injection)	[Progress bar]					DMD ⁷
EXPRESSGRAFT (VEGF ⁸)	[Progress bar]					Pro-Angiogenic
EXPRESSGRAFT (IL-12 ⁹)	[Progress bar]					Anti-Tumor
INOMAX® (nitric oxide) gas, for inhalation	[Progress bar]					Transplant Organ Perfusate
MP-3964 (TLR9 ¹⁰ antagonist)	[Progress bar]					Transplant Organ Perfusate & AP ¹¹

OCR-002

- ✓ Addresses high unmet need in hepatic encephalopathy
- ✓ Novel ammonia scavenger mechanism
- ✓ IV and oral formulations
- ✓ Strong clinical and commercial alignment with terlipressin
- ✓ Advances MNK emerging focus in hepatic/renal conditions

1 Graft vs Host Disease

2 Deep Partial Thickness

3 Hepatorenal Syndrome

4 Amyotrophic Lateral Sclerosis

5 Full Thickness

6 Diabetic Foot Ulcers

7 Duchenne Muscular Dystrophy

8 Vascular Endothelial Growth Factor

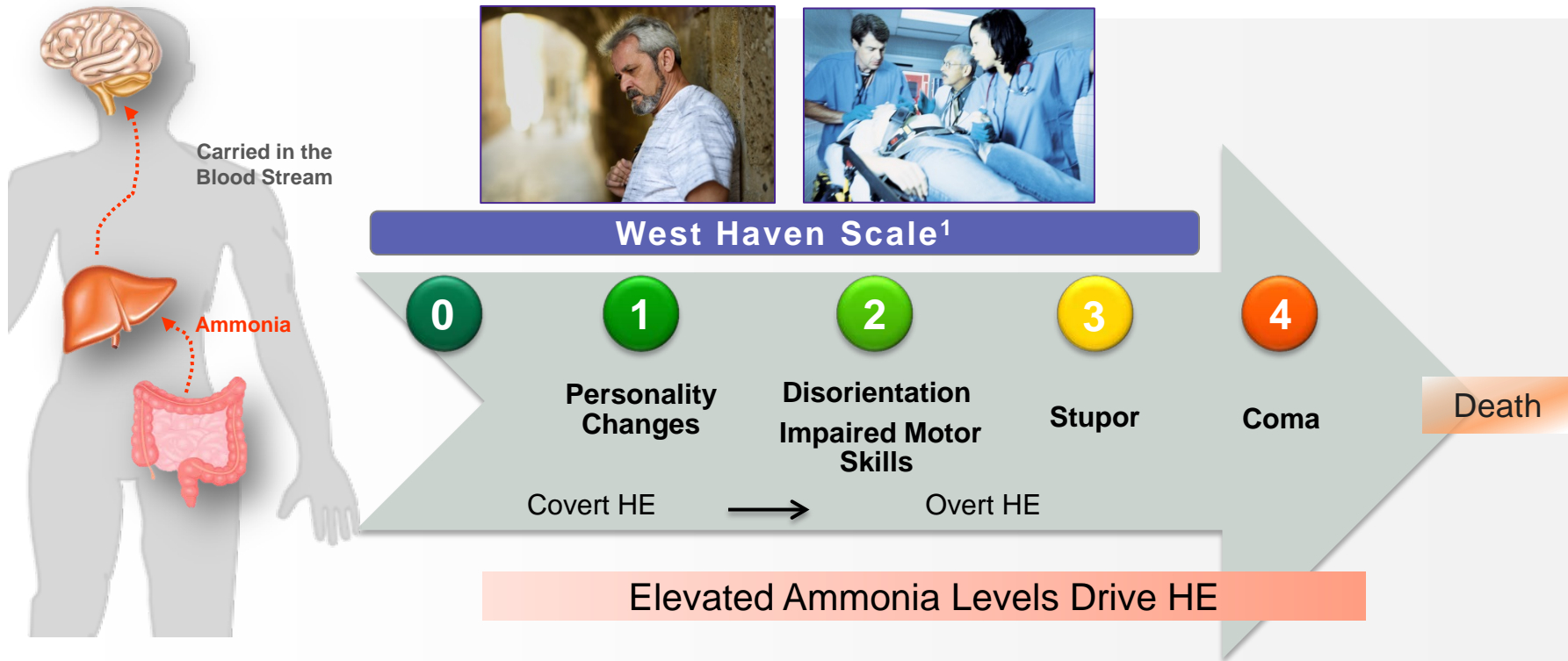
9 Interleukin

10 Toll-like Receptor

11 Acute Pancreatitis

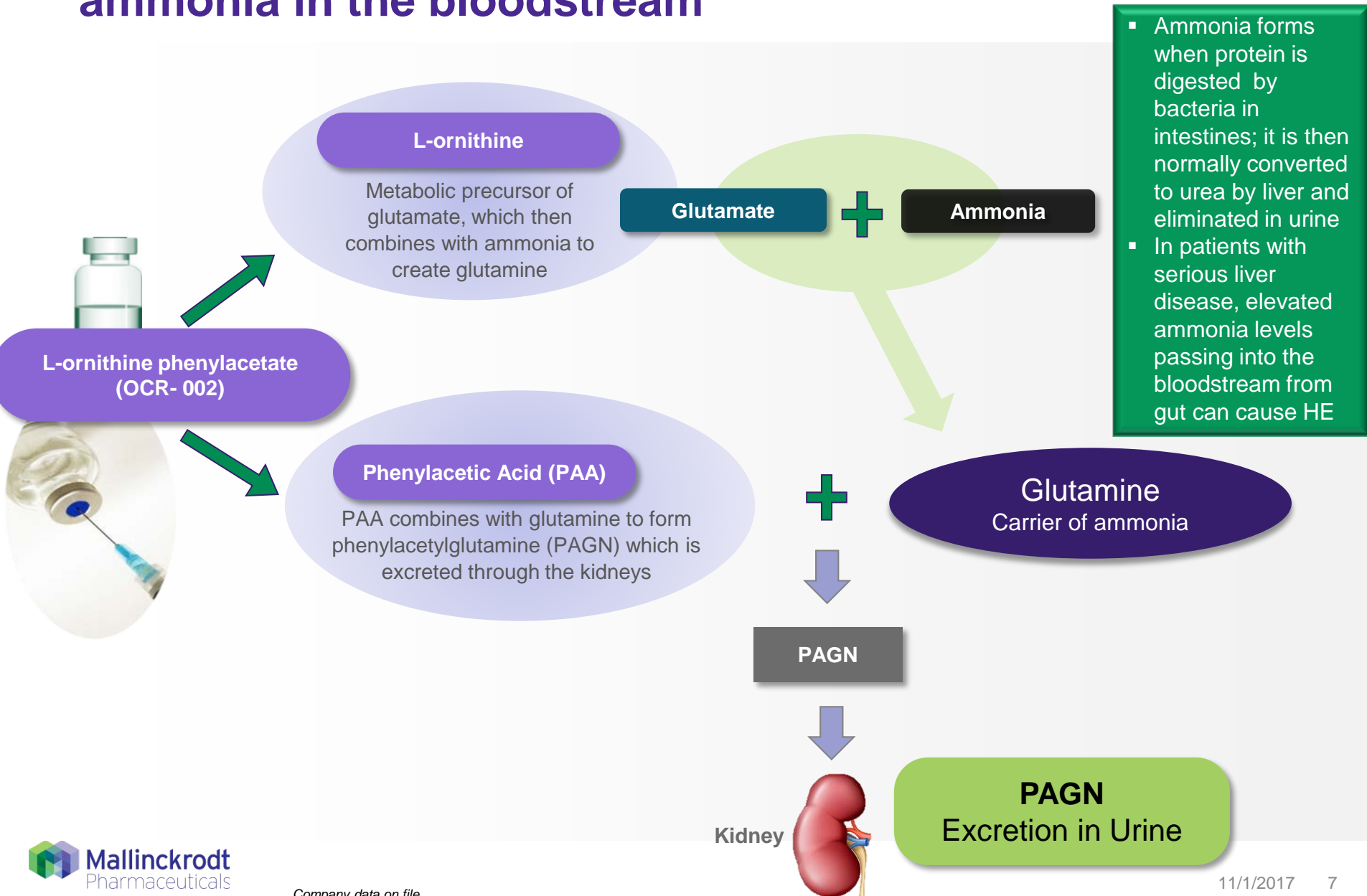
Pending close of transaction

Hepatic encephalopathy (HE) is associated with elevated ammonia levels stemming from serious liver disease

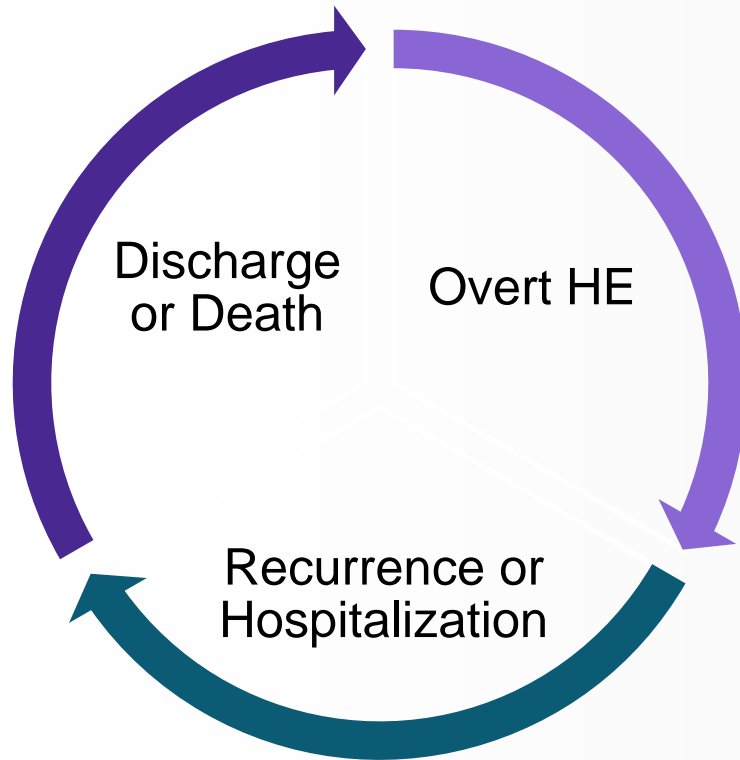


- HE is a continuum of transient, usually reversible neurological and psychiatric dysfunction, associated with elevated ammonia levels^{2,3}
- Symptoms range from mildly altered mental status to deep coma, sometimes death¹
- Goal of HE treatment is aimed at lowering blood ammonia levels³
- Once a patient suffers an acute HE episode, prevention of recurrent HE is critical and requires ongoing therapy

OCR-002's novel mechanism of action helps eliminate ammonia in the bloodstream



OCR-002 goal: break vicious cycle of HE



HE is Chronic, Debilitating and Costly

- 30-50%: Cirrhosis patients may have HE¹
- 25%: Patients' first acute episodes occur within five years of HE diagnosis
- 40-50%: Patients with acute episodes have recurrence within one year; frequency increases with severity²
- ~15%: Mortality associated with HE on average; can be greater in more severe patients³
- \$5-7 billion^{3,4}: Estimated total HE associated costs to U.S. health system
- Persistent and frequent acute HE has long-term neurocognitive impairment and increases risk for liver transplant¹

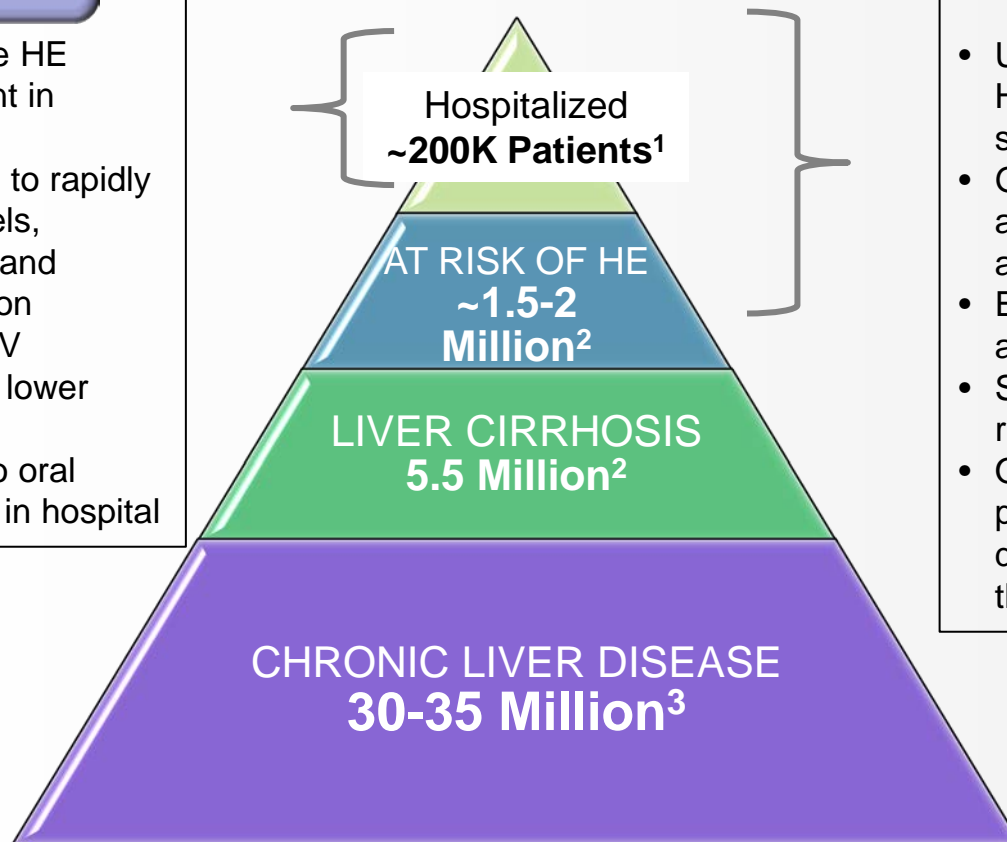
OCR-002 has potential to both treat acute HE and prevent recurrent HE, which today is largely untreated

IV for acute treatment

- Used to treat severe HE patients who present in hospital or ICU
- Goal of treatment is to rapidly lower ammonia levels, improve symptoms and reduce hospitalization
- No FDA-approved IV treatment to rapidly lower ammonia levels
- Opportunity for IV to oral OCR-002 transition in hospital

Oral for recurrent treatment

- Used to prevent recurrence of HE in hospital or outpatient setting
- Goal of treatment is to stabilize ammonia levels once lowered, and prevent rehospitalization
- Expected to provide step-down and continuity of care with IV
- Should enable patients to remain stable at home
- Only small number of at-risk patients are currently treated due to limitations of existing therapies



INTERNATIONAL MARKET:

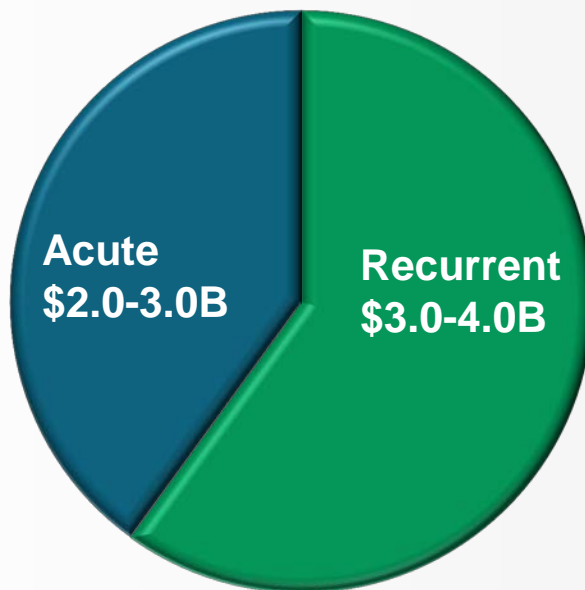
- Worldwide rights to OCR-002
- Europe and Japan annual HE market estimates: 150k-200k patients⁴

OCR-002 addresses significant unmet medical need and provides commercial opportunity

\$5.0-7.0 Billion U.S. Market Potential Opportunity^{1,2}

IV for acute treatment

- Hospital setting
- 200k hospitalizations annually³
- ~\$30,000-\$60,000/hospitalization stay including HE treatments^{1,2}
- No FDA-approved IV treatment to rapidly lower ammonia levels
- Opportunity for IV to oral transition in hospital



Oral for recurrent treatment

- Hospital or outpatient setting
- Goal to prevent rehospitalization of patients at risk for recurrence
- ~40-50% recurrence rate within first year of acute event; likelihood of recurrence increases with severity⁴
- Only 50-60% of high-risk patients are receiving current standard of care and fewer stay on therapy due to poor compliance⁵

OCR-002 is positively differentiated from current treatments for hepatic encephalopathy (HE)

	Formulation	HE Label	Method of Action	Potential Benefits	Key Side Effects	Current Sales
OCR-002	IV	Acute HE	Ammonia scavenger, actively eliminates ammonia in bloodstream and excretes through kidneys	Rapid improvement in symptoms; reduction in hospital stay	Minimal side effects observed to date ¹	N/A
	Oral	Recurrent HE				
Lactulose	Oral, nasogastric or enema	HE ²	Laxative, passively reduces ammonia through bowel movements		Difficult to administer in acute setting Poor compliance due to severe diarrhea and GI ³ issues	~\$40MM ⁴ Generic
Rifaximin	Oral	Recurrent HE ⁵	Antibiotic, passively reduces ammonia by affecting gut flora; excretes ammonia through bowel movements		Peripheral edema, nausea, dizziness, broad GI issues Restricted for patients with severe liver issues	~\$600MM ⁶ 2% CAGR

In Development

While some drugs are in pre-clinical and Phase 1 development for HE, none are specifically targeting ammonia nor are there IV formulations in development to rapidly lower ammonia levels directly

¹ Company data on file; Rifaximin label

² Approved in 1976

³ GI = Gastrointestinal

⁴ Quintiles/IMS data

⁵ Approved in 2010

⁶ Estimated sales from HE indication based on SEC filings, forward looking growth estimates based on analysts' forecasts

Mallinckrodt has opportunity to create value by investing and refining OCR-002 clinical program

Though STOP HE Phase 2 trial¹ did not meet primary endpoint, it achieved secondary endpoints, yielding promising clinical insights

- **Ammonia levels correlated with HE severity** and ammonia reduction correlated with clinical improvement
- **OCR-002 lowered ammonia faster and led to faster clinical improvement** compared to placebo + standard of care in patients with confirmed hyperammonemia at baseline
- **OCR-002 patients had higher response rate** at 48 hours vs. placebo + standard of care; **those responders left hospital ~1.5 days earlier**
- **OCR-002 was safe and well-tolerated**

Trial design and execution issues contributed to primary endpoint results

- **Inadequate dosing regimen**
- **Delays in starting treatment** after admission
- **Placebo group heterogeneity** (e.g., different standards of care used)

Anticipated MNK path forward

- **MNK will invest to establish dosing ranges prior to initiating Phase 3 program**
- **Continued engagement with FDA; confirm regulatory pathway; gain approval and launch**

Mallinckrodt can maximize value of OCR-002 to address high unmet patient need

OCR-002 can add value to Mallinckrodt:

- Addresses high unmet need in acute and recurrent hepatic encephalopathy
- Enhances portfolio to treat severe and critical diseases related to hepatic and renal conditions, aligns well with terlipressin development asset
- Broadens specialty brands portfolio with durable, clinically differentiated asset
- Brings global rights, with initial focus in U.S.

Mallinckrodt can add value to OCR-002:

- Development, regulatory expertise to gain product approval
- Commercialization and launch support to optimize patient access and clinical impact
- Clinical and commercial presence in hospital critical care (IV), specialist (oral) settings
- Enhanced research capabilities and infrastructure (e.g., clinical operations, medical affairs, HEOR¹)
- Operations and manufacturing expertise to enhance formulation development
- Opportunity to expand to ex-U.S. markets; will explore regulatory pathways for approvals



OCR-002 has robust, durable intellectual property, exclusivity protection

ORPHAN DRUG EXCLUSIVITY

- Seven years exclusivity from date of first product approval, expected in 2022

METHOD OF USE

- Expires in 2025, with potential for patent term extension¹

COMPOSITION OF MATTER

- Expires in January 2031, with potential for patent term extension¹

Exclusivity
Patents
Durability
Innovation
IP

OCR-002 aligns with MNK strategic vision as patient-centric, innovation driven specialty pharmaceutical growth company focusing on severe and critical conditions

ADDRESSES HIGH UNMET NEEDS

- In U.S., ~200,000 patients hospitalized with acute HE annually, and 1.5 million at risk for recurrent HE
- If approved, expected to become first treatment broadly indicated for HE in patients with acute and chronic liver disease

CLINICALLY DIFFERENTIATED

- Novel mechanism of action – no other products remove ammonia in bloodstream and excrete through kidneys
- Only IV formulation to treat acute HE
- Superior side effect profile compared to current standard of care

HIGHLY DURABLE ASSET

- FDA granted Orphan Drug designation and Fast Track status, as well as Orphan Drug designation by EMA¹
- Intellectual property and patent estate that extends to at least 2030

WELL ALIGNED WITH TERLIPRESSIN, HEPATIC/RENAL FOCUS

- Deepens Mallinckrodt's focus on treating hepatic and renal conditions
- Strong commercial and clinical synergy potential with terlipressin development asset