



Mallinckrodt Strategic Acquisition

InfaCare

August 4, 2017



Forward-looking statements

Statements in this document that are not strictly historical, including statements regarding the proposed acquisition of InfaCare Pharmaceutical Corporation, the expected timetable for completing the transaction, future financial condition and operating results, economic, business, competitive and/or regulatory factors affecting Mallinckrodt's and InfaCare's businesses and any other statements regarding events or developments that we 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 InfaCare operate;
- InfaCare'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 InfaCare's product;
- The parties' ability to satisfy the acquisition agreement conditions (including required regulatory approvals) and complete the InfaCare acquisition on the anticipated timeline or at all;
- Mallinckrodt's ability to realize anticipated growth, synergies and cost savings from acquisitions (including the InfaCare 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 InfaCare acquisition);
- Mallinckrodt's ability to successfully develop or commercialize new products;
- Mallinckrodt's 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;

Forward-looking statements (continued)

- Cost containment efforts of customers, purchasing groups, third-party payers and governmental organizations;
- 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 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2017. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt does 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.

Key transaction highlights

DEAL CONSIDERATION

- Upfront payment: \$80 million
- Additional payments: Up to \$345 million dependent on regulatory and sales milestones

FINANCIAL IMPACT

- Expected to be dilutive by \$0.15 to \$0.20 of adjusted diluted earnings per share for remainder of fiscal 2017, with dilution modestly higher in fiscal 2018

TIMING

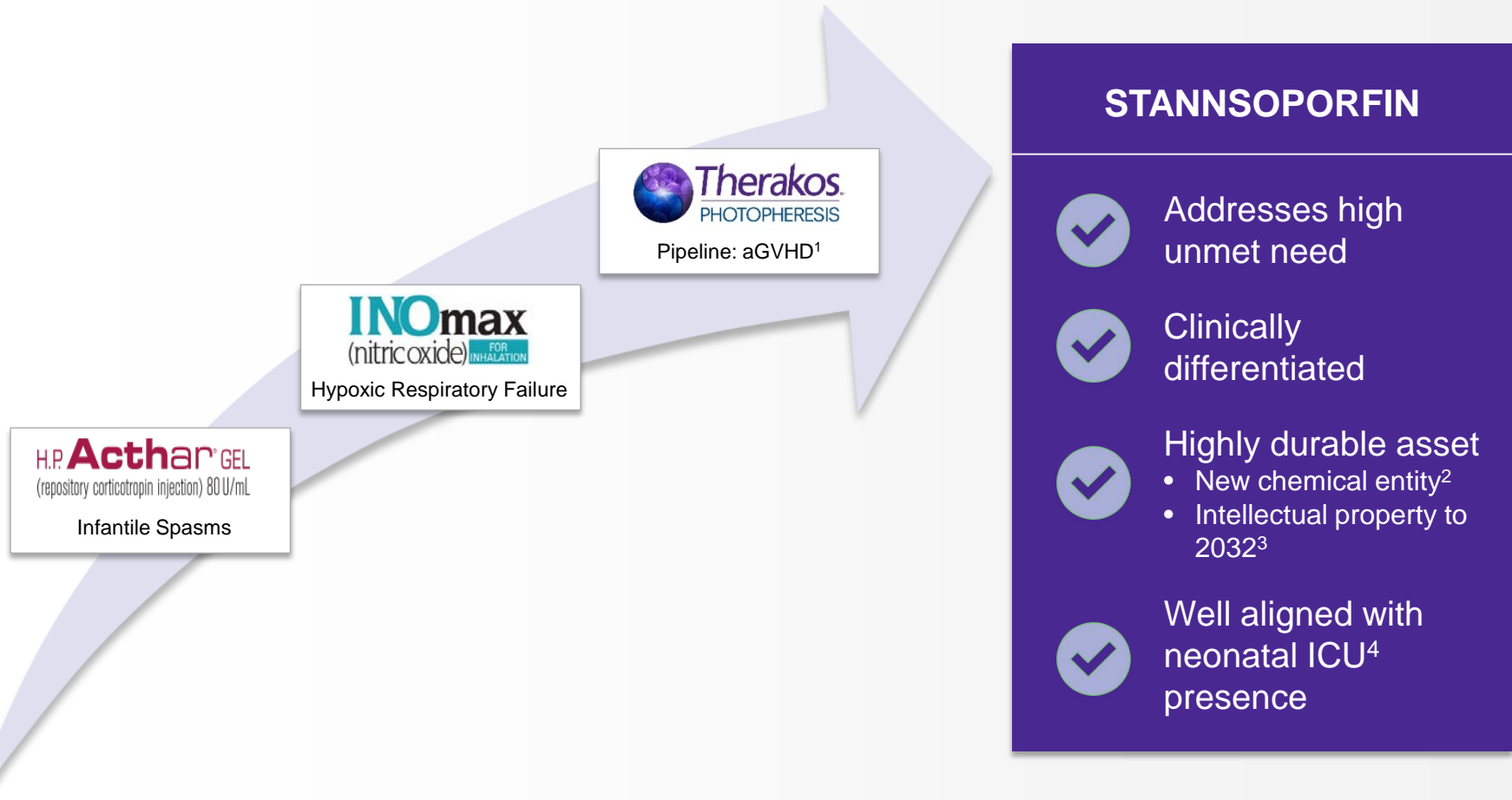
- Close expected by second half of 2017, subject to customary closing conditions, including the expiration or termination of the waiting period under the Hart Scott Rodino Antitrust Improvements Act

PRODUCT LAUNCH

- Expected in late 2018 in the U.S.; no additional clinical studies required for FDA approval

Sources: Management projections

Stannosporfin acquisition expands Mallinckrodt's offerings to improve the lives of babies and children



¹ Acute Graft Versus Host Disease

² Adis Insight

³ U.S. Patent and Trade Office

⁴ ICU = intensive care unit

Severe jaundice can threaten the lives of infants

DISEASE OVERVIEW^{1,2}

- **Jaundice** in infants is common and usually self-limiting
- Jaundice caused by excess bilirubin in blood (hyperbilirubinemia); bilirubin is formed during normal breakdown of hemoglobin (hemolysis)
- In some newborns hemolysis occurs at a greater rate, potentially reaching **severe bilirubin levels**
- In the brain bilirubin can cause **acute encephalopathy** syndrome
 - **Symptoms include** poor feeding, shrill cry, muscle rigidity, markedly arched back with neck hyperextended backwards, seizures, and stupor or coma. **Complications** may include hearing loss or death
 - Unresolved, can progress to **kernicterus**, rare condition associated with severe and permanent brain damage
- AAP³ guidelines⁴ recommend assessing all newborns for **hyperbilirubinemia** risk prior to discharge from hospital



CURRENT TREATMENT OPTIONS

- ▶ Phototherapy is standard of care to reduce bilirubin levels; may not address severe cases
- ▶ In some severe cases, HCPs⁵ must resort to invasive options, including blood exchange transfusion or, less often, IVIG⁶
- ▶ No treatments currently indicated for severe condition; high unmet need for severe and refractory patients

1 <http://www.mayoclinic.org/diseases-conditions/infant-jaundice/basics/complications/con-20019637> Accessed July 20, 2017

2 <https://medlineplus.gov/ency/article/007309.htm> Accessed July 20, 2017

3 AAP = American Academy of Pediatrics

4 <http://pediatrics.aappublications.org/content/114/1/297>

5 HCPs = Healthcare Professionals

6 IVIG = Intravenous immunoglobulin

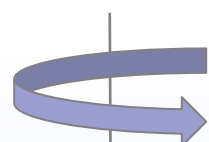
Stannsoporfin reduces severe jaundice potential through novel mechanism of action

Bilirubin forms from breakdown of hemoglobin in red blood cells

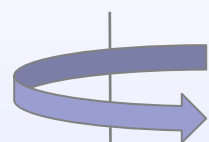
Hemoglobin



Heme



Biliverdin



Bilirubin

Heme is a component of hemoglobin

Heme oxygenase enzyme catalyzes heme breakdown to produce biliverdin

Biliverdin reductase enzyme acts on biliverdin to create bilirubin

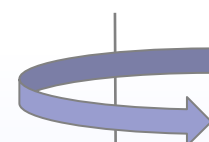
Stannsoporfin reduces bilirubin production by inhibiting heme oxygenase

STANNSOPORFIN

Hemoglobin



Heme



Biliverdin



Bilirubin

Heme Oxygenase

Source: Mallinckrodt's evaluation of clinical trials

Stannsoporfin provides unique therapeutic benefits vs. other treatment options

Demonstrates robust effect in inhibiting bilirubin production via novel mechanism of action; other treatment options focus on increased bilirubin removal which is less effective in severe jaundice

- **Reduces potential** of advancing to bilirubin levels requiring more intrusive therapies
- **Potentially decreases incidence** of readmission
- **May lower risks associated with other treatments** (e.g., bilirubin rebound) and prolonged/severe bilirubin elevation, which can impact central nervous system development
- **Exhibits favorable** safety/tolerability profile
- **Administered conveniently** by single, intramuscular injection vs. more invasive, complex and lengthy treatment options beyond phototherapy



Stannsoporfin is expected to significantly improve lives of infants

Source: Mallinckrodt's evaluation of clinical trials

Mallinckrodt estimates global¹ market of ~150k-275k severe jaundice patient treatments annually

Stannosporfin U.S. opportunity is ~45% of identified global market

Total annual U.S. term births^{2,3}

~3.7mm

Term births in U.S. with jaundice (due to elevated bilirubin levels)⁴

~750k

Term babies at risk of developing severe hyperbilirubinemia; includes two segments:

- Pre-discharge babies with elevated bilirubin levels despite phototherapy⁵
- Babies re-admitted (post discharge) due to elevated bilirubin levels⁶

Pre-discharge

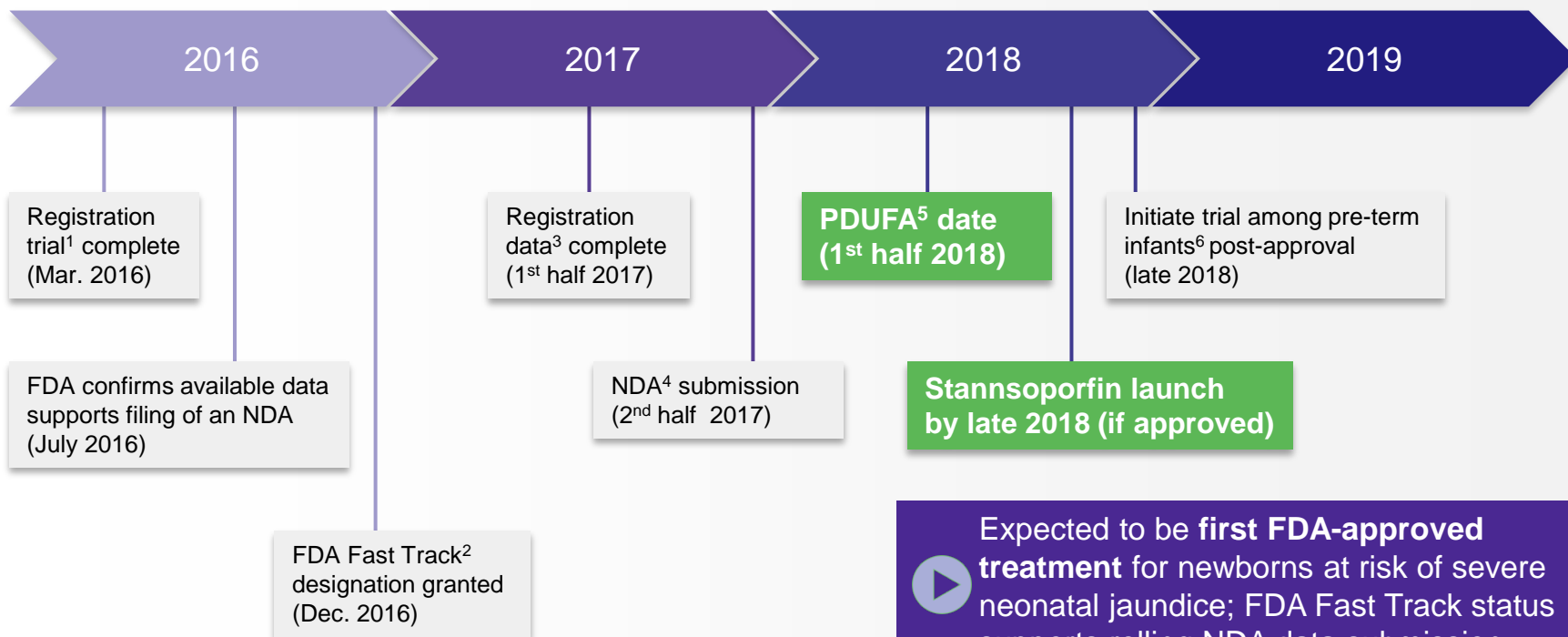
Post-discharge

~70k-125k target patient treatments

Estimated annual costs to the U.S. healthcare system for treating severe infantile jaundice are ~\$5k/patient, or about ~\$500mm^{4,5,6} per year

Stannsoporfin U.S. launch anticipated by late 2018

KEY REGULATORY MILESTONES



1 Registration trial is a Phase 2(b) study (JASMINE 204); completed treatment phase by Mar. 2016

2 <https://www.fda.gov/forpatients/approvals/fast/ucm405399.htm>

3 Completed gathering follow-up safety data for registration trial required for NDA submission

4 NDA = New Drug Application

5 PDUFA = Prescription Drug User Fee Act

6 Conducting trials among pre-term infants at less than 35 weeks gestational age is part of FDA's pediatric requirement

Added Sources: Mallinckrodt's assessment of regulatory timelines and clinical trials; Minutes of InfaCare meeting with FDA; Management projections

Expected to be **first FDA-approved treatment** for newborns at risk of severe neonatal jaundice; FDA Fast Track status supports rolling NDA data submission

NDA filing in progress, with FDA agreement to accept totality of data, including two Phase 2(b) trials (one pivotal); **no additional trials necessary**, reflecting medical need; challenges also in conducting trials in these fragile infants

Mallinckrodt can maximize the value of stannosoporphin

STANNSOPORFIN ADDS VALUE TO MALLINCKRODT

- Addresses high unmet need in severe neonatal jaundice
- Deepens presence in neonatal care; strongly aligned with existing commercial infrastructure and clinical capabilities
- Broadens specialty brands portfolio with durable, clinically differentiated asset
- Brings global rights, with initial focus in U.S.



MALLINCKRODT ADDS VALUE TO STANNSOPORFIN

- Provides commercialization and launch support to optimize patient access and clinical impact
- Brings existing strong expertise in neonatal centers through INOMAX
- Enhances research capabilities, leveraging existing infrastructure (e.g., clinical operations, medical affairs, HEOR¹)
- Offers opportunity to expand to ex-U.S. markets, will explore regulatory pathways for approvals

¹ HEOR = Health Economics Outcomes Research

Stannsoporfin is an excellent addition to Mallinckrodt's portfolio

ADDRESSES HIGH UNMET NEEDS

- Expected first treatment indicated for severe condition, easy to administer
- Reduces need for less effective treatment options, possibly decreases incidence of readmission
- Exhibits favorable safety/tolerability profile

CLINICALLY DIFFERENTIATED

- Highly effective, novel mechanism of action inhibits bilirubin production, unlike other treatment options
- May decrease serious risks related to other treatments and prolonged/severe bilirubin elevation

HIGHLY DURABLE ASSET

- New chemical entity
- Valid intellectual property until 2032

WELL ALIGNED WITH NEONATAL ICU FOCUS

- Deepens Mallinckrodt's presence in neonatal care
- Fully leverages strong existing commercial infrastructure and clinical capabilities