



# **Mallinckrodt Strategic Acquisition Stratatech Corporation**

**August 10, 2016**

# Forward-Looking Statements

*Statements in this document that are not strictly historical, including statements regarding future financial condition and operating results, economic, business, competitive and/or regulatory factors affecting Mallinckrodt'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:*

- ▶ The parties' ability to satisfy the conditions to the Stratatech Corporation acquisition and complete the acquisition on the anticipated timeline or at all;*
- ▶ General economic conditions and conditions affecting the industries in which Mallinckrodt operates;*
- ▶ The commercial success of Mallinckrodt's products;*
- ▶ Mallinckrodt's ability to realize anticipated growth, synergies and cost savings from acquisitions;*
- ▶ 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;*
- ▶ 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;*

# Forward-Looking Statements (Continued)

- ▶ *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;*
- ▶ *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<sup>®</sup> 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;*
- ▶ *Product liability losses and other litigation liability;*
- ▶ *Ongoing governmental investigations;*
- ▶ *Material health, safety and environmental liabilities;*
- ▶ *Retention of key personnel;*
- ▶ *Conducting business internationally; and*
- ▶ *The effectiveness of information technology infrastructure.*

## Forward-Looking Statements (Continued)

*These and other factors are identified and described in more detail in the "Risk Factors" sections of Mallinckrodt's Annual Report on Form 10-K for the fiscal year ended September 25, 2015 and Quarterly Report on Form 10-Q for the fiscal quarter ended June 24, 2016. 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.*

# Mallinckrodt to acquire Stratatech, diversifying hospital pipeline

## Company details

- Privately held, development-stage company, founded 2002
  - World-class, cell-based regenerative medicine capabilities
  - State-of-the-art clinical development and commercial manufacturing focused on the severe burn market
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## Financial impact

- Strength of overall business will offset slight dilution to company's near- and longer-term adjusted diluted earnings per share
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## Timing

- Close expected second half of calendar 2016, subject to customary conditions

# Unique skin-substitute technology platform has potential to alter burn- and wound-treatment paradigm

## StrataGraft® (Phase 3)

- Potentially first biological “off-the-shelf” skin substitute for treatment of severe burns<sup>1</sup>
- Innovative proprietary technology produces living tissues designed to mimic key attributes of human skin
- To be filed under BLA<sup>2</sup>, if approved 2020 would convey regulatory data exclusivity until 2032
- FDA<sup>3</sup> Orphan Product Status awarded 2012

## Technology platform – additional new product potential

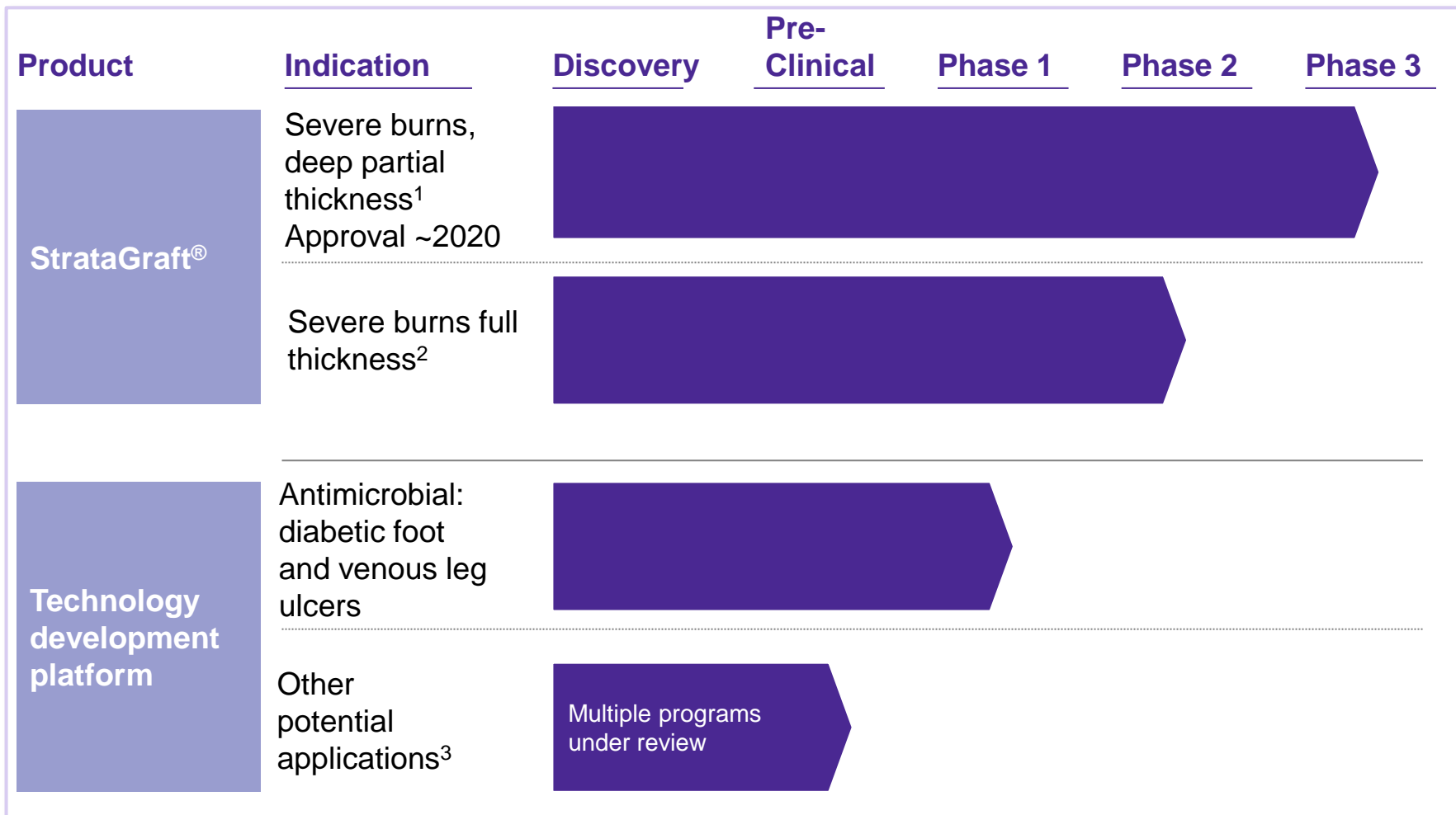
- Genetically enhanced tissue, applied topically, that produces elevated levels of natural wound healing and antimicrobial factors
- Platform expected to be highly durable with difficult-to-replicate technology

1 Phase 3 for deep partial-thickness indication and in Phase 2 for full thickness

2 Biologics License Application

3 U.S. Food and Drug Administration

# Deepens, diversifies Mallinckrodt hospital pipeline, provides long-term growth drivers



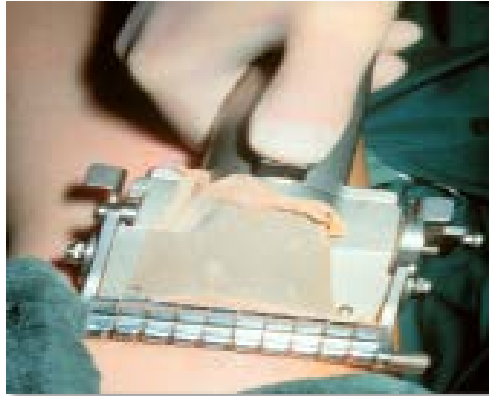
1 Second-degree burns: Impacts the second layer of skin (dermis)

2 Third-degree burns: Burns that extend into the bottom layer of skin (subcutaneous tissue), muscle, or bone and often cause significant scarring

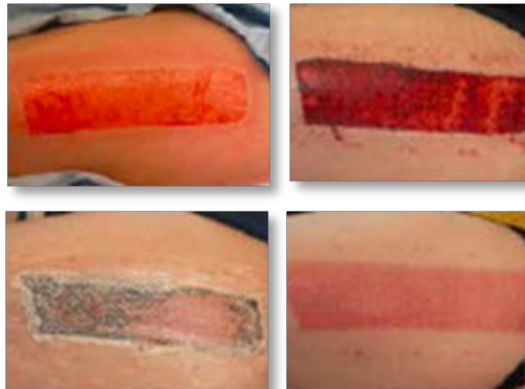
3 Pre-clinical applications include broader wound care indications, treatments for antineoplastic application such as preventing, inhibiting or halting malignant cells

# StrataGraft is designed to address significant unmet needs of ~10,000 U.S. burn patients annually

Human Skin Autografting: current standard of care for 2<sup>nd</sup>/3<sup>rd</sup> degree burns



Harvest skin with dermatome



Donor sites

- Most current severe burn management procedures require autograft
- Autograft has significant negative patient impact:
  - Painful harvesting of donor skin creates a new wound
  - Causes extensive scarring
  - Multiplies channels/opportunities for infection risk
- Frequently results in multiple treatments/surgeries; hospitalizations of highly variable, unknown length



# Differentiated therapy to address the severe burn market



StrataGraft (3 months)



Autograft (3 months)

## StrataGraft designed to:

- Reduce need for painful donor site, decreasing short- and long-term care
- Result in fast coverage and closure
- Reduce rate of contracture and scarring
- Simplify surgical procedure and shorten surgical time
- Reduce need for multiple surgeries and corresponding costs

# StrataGraft's Phase 2 results<sup>1</sup> in DPT<sup>2</sup> burns demonstrate ability to eliminate need for autografting by Day 28

	<b>Efficacy<sup>3</sup></b> Patients requiring autograft by Day 28	<b>Safety<sup>3</sup></b> Patients with 100% wound closure at 3 months
<b>StrataGraft</b>	0%	93% <sup>4</sup>
<b>Autograft</b>	100%	100%



- ✓ **Efficacy achieved with a single application applied “off-the-shelf”**
- ✓ **DNA analysis verified no evidence of StrataGraft cells at 3 months**
- ✓ **Superior cosmetic outcome to autografting**

<sup>1</sup>Stratatech data on file.

<sup>2</sup> DPT: Deep Partial Thickness

<sup>3</sup> Reflects percent of total patients in the study (n=30)

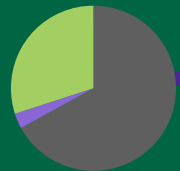
<sup>4</sup> A patient who did not meet inclusion criteria, had a StrataGraft site 50% closed at 3 months due to reopening of the wound after a protocol violation.

# Severe burn market is marked by high unmet patient need

## Acute Burn U.S. Market

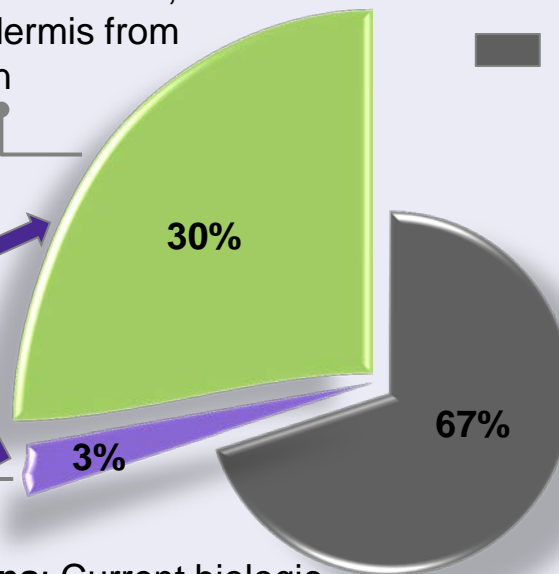
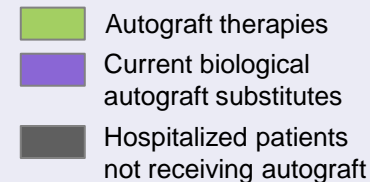
Burn patients treated (~450K)

In burn centers (~30K<sup>1</sup>)



## Contemporary in-burn centers standard of burn care

**Severe burns<sup>2</sup>:** Human skin, animal-derived dermis, processed dermis from donated skin



**Severe burns:** Current biologic off-the-shelf autograft substitutes not available

**Less severe burns:** with broad range of therapies – not a target for Stratatech products

U.S. severe burn market:  
10,000 patients, ~\$300 million

<sup>1</sup> Total of ~40,000 patients hospitalized annually, with 30,000 at hospital burn centers, 10,000 of whom are treated for severe burns

<sup>2</sup> Severe burns: second- and third-degree burns as previously identified

Data Source: American Burn Association



# MNK provides proven commercialization and full launch support to maximize Stratatech's success

## The acquisition:

- Expands pipeline and research capabilities within MNK established development infrastructure (e.g., clinical operations, medical affairs, HEOR<sup>1</sup>)
  - Extends company's orphan drug focus
  - Provides excellent example of MNK's *Acquire to Invest* strategy
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- Leverages leadership position in U.S. hospital space
    - Existing commercial presence in burn centers
    - Established relationships with hospital networks, insurance companies, group purchasing organizations
  - Strengthens surgical offerings to further improve patient outcomes