MALLINCKRODT TO ACQUIRE STRATATECH CORPORATION, A REGENERATIVE MEDICINE COMPANY FOCUSED ON PROPRIETARY THERAPEUTIC HUMAN SKIN SUBSTITUTE PRODUCTS

-- Acquisition further diversifies Mallinckrodt's hospital portfolio pipeline --

-- StrataGraft®, Phase 3 investigational product in development for treatment of severe burns, is a regenerative living tissue designed to mimic key attributes of human skin and reduce the need for painful autograft --

-- To be submitted under FDA Biologic License Application (BLA); if approved, StrataGraft would carry regulatory exclusivity through 2032; received FDA orphan designation in 2012--

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

CHESTERFIELD, United Kingdom, August 10, 2016 /PR Newswire/ - Mallinckrodt plc (NYSE: MNK), a leading global specialty pharmaceutical company, today announced that it has entered into a merger agreement with Stratatech Corporation, a privately held regenerative medicine company focused on the development of unique, proprietary skin substitute products. Developmental products include StrataGraft regenerative skin tissue and a technology platform for genetically enhanced skin tissues. Financial terms of the transaction were not disclosed.

Stratatech's Leading-Edge, Innovative Technology Development Platform

If approved, StrataGraft could be the first biological "off-the-shelf" skin substitute product for treatment of severe burns – Stratatech's proprietary tissue engineering technology produces living tissues designed to mimic human skin and promote tissue regeneration. The current standard of care for second- and third-degree burns requires autograft, the painful harvesting of a patient's tissue from an uninjured area to graft into another burned area. Severe burns can frequently cause extensive scarring, create multiple channels for infection risk and may result in multiple surgeries, all of which lead to hospitalizations of highly variable, unspecified length[1].

The technology platform provides potential for new products through genetically enhanced tissues, applied topically, that produce elevated levels of natural wound healing and antimicrobial factors. Phase 1 development is underway in diabetic foot and venous leg ulcers, with other potential applications under consideration.

"The addition of this highly durable, cutting-edge development portfolio and technology platform to our hospital growth business is an excellent example of Mallinckrodt's A*cquire to Invest* strategy," said **Mark Trudeau, Chief Executive Officer and President of Mallinckrodt**. "We believe Stratatech's technology has the potential to transform the standard of treatment for wound care. Additionally, the acquisition will bring world-class Stratatech researchers with deep expertise in cell-based, differentiated regenerative medicine to Mallinckrodt's research team."

[1] American Burn Association 2009 White Paper "Surgical Management of the Burn Wound and Use of Skin Substitutes"

"Stratatech brings dedicated scientific and development know-how to Mallinckrodt, along with a broad, innovative progenitor keratinocyte[2] technology platform," said **Lynn Allen-Hoffmann, Chief Executive Officer of Stratatech**. "In our next phase of development, the unique cell line used to produce living tissue in StrataGraft can also be genetically modified to potentially increase production of a variety of factors to support and promote wound healing, such as antimicrobial and vascular endothelial growth factors. This could offer utility in a number of skin injury settings beyond burns."

StrataGraft Development and Severe Burn Market

StrataGraft is an investigational product in Phase 3 development for treatment of severe, deep partial thickness burns[3], with a U.S. Food and Drug Administration (FDA) approval decision anticipated by 2020. Phase 2 development of StrataGraft is underway for treatment of severe, full thickness burns[4]. In 2012, the FDA granted StrataGraft orphan product status, and the product is being developed as a biologic to be filed under a BLA that would confer regulatory protection until 2032.

Stratatech is currently executing two contracts which support advanced development including manufacturing, clinical studies and eventual product procurement by the U.S. Department of Health and Human Services, Office of Assistant Secretary for Preparedness and Response, and the Biomedical Advanced Research and Development Authority (BARDA). Under the terms and conditions of the contract with BARDA, Mallinckrodt is required to continue seamless execution of all contractual obligations. Stratatech also has independent contracts with the U.S. Department of Defense covering other aspects of product development.

In the U.S., approximately 10,000 patients annually are hospitalized for treatment of severe burns, and the U.S. market for skin graft products used in this application is estimated at approximately $300 million. Additional opportunities exist internationally, and the acquisition includes worldwide product rights.

Dilution Consideration and Closing

The strength of Mallinckrodt's overall business is expected to offset slight dilution to the company's near- and longer-term adjusted diluted earnings per share. Guidance on the impact of the acquisition to the company's GAAP[5] diluted earnings per share has not been provided due to the inherent difficulty of forecasting the timing or amount of items that would be included in calculating such impact. Subject to customary terms and conditions, the company anticipates the transaction will close in the second half of calendar 2016.

If approved, Mallinckrodt expects the products to be commercialized by the company's existing hospital-focused organization, enhanced by Mallinckrodt's strong relationships with hospital networks, insurance companies and group purchasing organizations to more quickly expand patient access to this unique treatment option.

ABOUT MALLINCKRODT

[2] A keratinocyte is the predominant cell type in the epidermis, the outermost layer of the skin
[3] Second-degree burns: Burns that impact the dermis
[4] Third-degree burns: Burns that extend into subcutaneous tissue, muscle, or bone and often cause much scarring
[5] Generally accepted accounting principles

Mallinckrodt is a global business that develops, manufactures, markets and distributes specialty pharmaceutical and biopharmaceutical products and therapies, as well as nuclear imaging products. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology and pulmonology; immunotherapy and neonatal respiratory critical care therapies; analgesics and hemostasis products; and central nervous system drugs. The company's core strengths include the acquisition and management of highly regulated raw materials and specialized chemistry, formulation and manufacturing capabilities. The company's Specialty Brands segment includes branded medicines; its Specialty Generics segment includes specialty generic drugs, active pharmaceutical ingredients and external manufacturing; and the Nuclear Imaging segment includes nuclear imaging agents. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

Mallinckrodt uses its website as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. It also uses its website to expedite public access to time-critical information regarding the company in advance of or in lieu of distributing a press release or a filing with the U.S. Securities and Exchange Commission (SEC) disclosing the same information. Therefore, investors should look to the Investor Relations page of the website for important and time-critical information. Visitors to the website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of the website.

NON-GAAP FINANCIAL MEASURES

This press release references adjusted diluted earnings per share, which is considered a "non-GAAP" financial measure under applicable SEC rules and regulations.

Adjusted diluted earnings per share represent adjusted net income divided by the number of diluted shares. Adjusted net income represents amounts, prepared in accordance with accounting principles generally accepted in the U.S. (GAAP), adjusted for certain items (on an after-tax basis) that management believes are not reflective of the operational performance of the business. Adjustments to GAAP amounts include restructuring and related charges, net; amortization and impairment charges; discontinued operations; acquisition-related expenses, significant legal and environmental charges and other items identified by the company.

The company has provided these adjusted financial measures because they are used by management, along with financial measures in accordance with GAAP, to evaluate the company's operating performance. In addition, the company believes that they will be used by certain investors to measure Mallinckrodt's operating results. Management believes that presenting these adjusted measures provides useful information about the company's performance across reporting periods on a consistent basis by excluding items that the company does not believe are indicative of its core operating performance.

These adjusted measures should be considered supplemental to and not a substitute for financial information prepared in accordance with GAAP. The company's definition of these adjusted measures may differ from similarly titled measures used by others.

Because adjusted financial measures exclude the effect of items that will increase or decrease the company's reported results of operations, management strongly encourages investors to review the company's consolidated financial statements and publicly filed reports in their entirety.

Cautionary Statements Related to 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; 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® 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; and the effectiveness of information technology infrastructure.

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.

CONTACTS

Investor Relations
Coleman N. Lannum, CFA

Senior Vice President, Investor Strategy and IRO
314-654-6649
cole.lannum@mallinckrodt.com

Daniel J. Speciale, CPA
Director, Investor Relations
314-654-3638
daniel.speciale@mallinckrodt.com

Media
Rhonda Sciarra
Senior Communications Manager
314-654-8618
rhonda.sciarra@mallinckrodt.com

Meredith Fischer
Senior Vice President, Communications and Public Affairs
314-654-3318
meredith.fischer@mallinckrodt.com