

## **Mallinckrodt Plans Spin-Off of Specialty Generics Business to Shareholders**

- Transaction expected to create two differentiated pharmaceutical companies with scale –
  - One focused on innovative specialty pharmaceutical brands;
  - One with a portfolio of niche specialty generic products, active pharmaceutical ingredients (APIs), and non-promoted brands including the AMITIZA® product --
- Transaction expected to be completed in the second half of 2019 --
  - Spun-off company will assume the Mallinckrodt name;
  - Specialty Pharmaceutical Brands company will be renamed --

**STAINES-UPON-THAMES, United Kingdom – Dec. 6, 2018** - [Mallinckrodt plc](#) (NYSE: MNK), a leading global specialty pharmaceutical company, today announced plans to spin off a new company consisting of Mallinckrodt's Specialty Generics/Active Pharmaceutical Ingredients (Specialty Generics) business and AMITIZA® (lubiprostone) to Mallinckrodt shareholders, subject to final Board approval. The separation is expected to create two independent, appropriately capitalized, publicly traded companies – one focused on innovative specialty pharmaceutical brands, the other concentrated primarily in niche specialty generic products and API manufacturing – each positioned to optimize future success as they pursue independent growth strategies.

The planned separation is expected to be executed through a pro-rata distribution of common stock to Mallinckrodt's shareholders that is generally tax-free for U.S. federal income tax purposes. The spin-off is projected to be completed in the second half of 2019 or sooner. It is anticipated that the spun-off company will be listed on the New York Stock Exchange (NYSE) and will assume the Mallinckrodt name and ticker symbol (MNK).

The 'remaining' independent Specialty Pharmaceutical Brands company, whose goal is to improve outcomes for underserved patients with severe and critical conditions, will continue to focus on its portfolio of innovative marketed and development products. **Mark Trudeau**, current **President and Chief Executive Officer**, will lead the business. The remaining company will be renamed at a later date.

**Angus Russell, Mallinckrodt's Chairman of the Board**, said, "Over the past five years, Mallinckrodt has transformed its business through a series of strategic transactions – acquiring a portfolio of marketed and development stage pharmaceutical brands that can drive growth, and divesting non-core assets that could be better maximized by others. In 2016 the Board began to explore a range of strategic alternatives for the company's Specialty Generics business, and believes there is a strong rationale and opportunity to create two new, appropriately capitalized, independent companies that have the potential to unlock and increase value over the long term. We expect this separation will result in greater strategic focus, allowing each business to more effectively enhance returns by commercializing new and current product offerings; drive innovation by allocating resources to the areas of highest opportunity; and pursue growth and investment strategies more directly aligned with each company's respective goals."

**Mark Trudeau** said, "Today's announcement is another important step forward in our journey to become an innovation-driven, pure-play, specialty pharmaceutical brands growth company. We believe this separation will further enhance our strategic focus and strengthen our balance sheet. It should also provide us with additional liquidity to support investments in our in-line brands and development portfolio and strategically allocate capital."

Trudeau added, "The spin-off of the Specialty Generics business creates an exciting new company which we believe will be well positioned to grow. Operating independently will allow this new company to more rapidly capitalize on its growth opportunities to enhance value."

## PROFILE OF THE NEW SPECIALTY GENERICS COMPANY

For the twelve months ended September 28, 2018, the collective net sales from the new Specialty Generics company exceeded \$850 million on an as reported basis inclusive of the AMITIZA product since February 14, 2018.

With approximately 1,600 employees, the newly spun company will include a leading acetaminophen business, a portfolio of both API and generic finished dose forms of controlled substances and other drugs, a niche specialty generics development portfolio, and a strong U.S. manufacturing footprint. The inclusion of the AMITIZA product in the non-promoted assets to be spun off brings added manufacturing facilities and employees in Japan, and diversifies revenues further. Marketed in the U.S. and Japan by alliance partners, Mallinckrodt recognizes net sales from commercial partnership arrangements in the form of AMITIZA product sales, royalties and milestones. The new Specialty Generics company will be positioned financially to grow its ANDA<sup>1</sup> pipeline and expects to launch as many as five new products in 2019. The company will be headquartered in the St. Louis, Missouri area.

**Matthew Harbaugh**, currently Mallinckrodt's Executive Vice President and Chief Financial Officer (CFO) and President of the Specialty Generics business, is expected to become President and Chief Executive Officer of the new company upon completion of the spin off.

Harbaugh will step down as Mallinckrodt's CFO, effective immediately, to focus exclusively on preparing for separation, but will continue to serve as President of the Specialty Generics business and report to Trudeau. A search for Harbaugh's successor is underway. During this process, **George Kegler**, Mallinckrodt's Vice President of Finance, will serve as interim CFO. Announcements of the Board of Directors for the Specialty Generics business are expected at a later date.

**Harbaugh** said, "Mallinckrodt has a more than 150-year legacy of operations in St. Louis and a proud history of supplying the highest quality products to customers. As an independent, U.S.-based company, I am confident that we will be well positioned to advance our R&D<sup>2</sup> capabilities and continue to maintain our category leadership in controlled substances."

"Matt has been involved in the Specialty Generics business for over a decade," said Trudeau. "We're very pleased to have someone with his leadership experience take the helm."

## PROFILE OF THE SPECIALTY PHARMACEUTICAL BRANDS COMPANY

With net sales in excess of \$2.3 billion<sup>3</sup> (inclusive of a \$1 billion hospital portfolio and a robust innovative pipeline), the Specialty Pharmaceutical Brands company is expected to gain additional liquidity and financial flexibility from the transaction to enable continued strategic transformation and growth.

As reported on Nov. 6, Mallinckrodt's third quarter 2018 results showed strong customer demand for its branded hospital products – including **INOmax**<sup>®</sup> (nitric oxide) gas, for inhalation, **OFIRMEV**<sup>®</sup> (acetaminophen) injection and the **Therakos**<sup>®</sup> immunotherapy platform – and improved performance for **H.P. Acthar**<sup>®</sup> Gel (repository corticotropin injection). Solid execution combined with tight expense control helped support increased R&D investments in the company's innovative pipeline. Operational excellence and continued strong commercial execution throughout 2018 have also been the catalysts for Mallinckrodt to raise its guidance for adjusted diluted earnings per share in each of the last two quarters.

The company expects to achieve a number of key milestones for its pharmaceutical brands in coming quarters. It anticipates top-line results from both the completed rheumatoid arthritis clinical trial and multiple sclerosis registry for H.P. Acthar Gel as early as the first half of 2019. Additionally, in the second half of 2019, the company is targeting completion of enrollment in Phase 4 trials in uveitis and lupus for the drug, and anticipates completing enrollment in the H.P. Acthar Gel Phase 2 trial in amyotrophic lateral

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<sup>1</sup> Abbreviated New Drug Application

<sup>2</sup> Research and Development

<sup>3</sup> Reflects last twelve months ended September 28, 2018 on an as reported basis

sclerosis as well. Top-line results from the company's development program for **CPP-1X/sulindac** are anticipated in the first quarter of 2019, and the pivotal trial results for both **StrataGraft**<sup>®</sup> viable engineered skin tissue and **terlipressin** are expected to be available in the second half of the year.

Following the spin-off, ordinary shares of the renamed Specialty Pharmaceutical Brands company will continue to trade on the NYSE. The company will maintain its global headquarters in Staines-upon-Thames, United Kingdom, and its principal U.S. office in Bedminster, N.J. The company also plans to maintain other facilities throughout the United States and in Australia, Canada, Ireland, Japan, Luxembourg and Switzerland.

### **NEXT STEPS IN THE SEPARATION PROCESS**

With the pursuit of strategic alternatives for the Specialty Generics business actively underway for more than two years, important progress has already been made in key areas that the company believes will simplify and support a relatively short separation process. Completion of the separation transaction will be subject to certain conditions, including final Board approval, an opinion from tax counsel regarding the treatment of the spin-off as generally tax-free for U.S. federal income tax purposes to Mallinckrodt shareholders, and the U.S. Securities and Exchange Commission (SEC) declaring the Form 10 registration statement effective. There can be no assurance regarding the final allocation of assets between the two companies, the ultimate timing of the proposed separation, or that the spin-off will be completed.

### **CONFERENCE CALL AND WEBCAST**

Mallinckrodt will hold a conference call on Thursday, Dec. 6, 2018, beginning at 8:00 a.m. U.S. Eastern Time. This call can be accessed in three ways:

- At the Mallinckrodt website: <http://www.mallinckrodt.com/investors>.
- By telephone: For both listen-only participants and those who wish to take part in the question-and-answer portion of the call, the telephone dial-in number in the U.S. is (877) 359-9508. For participants outside the U.S., the dial-in number is (224) 357-2393. Callers will need to provide the Conference ID of 5349569.
- Through an audio replay: A replay of the call will be available beginning at 11:00 a.m. Eastern Time on Thursday, Dec. 6, 2018, and ending at 11:59 p.m. Eastern Time on Thursday, Dec. 20, 2018. Dial-in numbers for U.S.-based participants are (855) 859-2056 or (800) 585-8367. Participants outside the U.S. should use the replay dial-in number of (404) 537-3406. All callers will be required to provide the Conference ID of 5349569.

### **ADVISORS**

Goldman, Sachs & Co. is acting as financial advisor on the spin-off and Wachtell, Lipton, Rosen & Katz is acting as legal advisor.

### **ABOUT THE SPECIALTY GENERICS DISPOSAL GROUP**

In light of this announcement, and in accordance with the accounting literature pertaining to discontinued operations, it is expected that the Specialty Generics Disposal Group, which is currently reflected in discontinued operations, will be brought back into Mallinckrodt's continuing operations in conjunction with its next quarterly earnings announcement and within its 2018 Form 10-K to be filed in February 2019.

## **ABOUT AMITIZA**

AMITIZA (lubiprostone), a leading global product in the branded constipation market, is approved by the U.S. Food and Drug Administration for treatment of chronic idiopathic constipation in adults, irritable bowel syndrome with constipation in women 18 years of age and older, and opioid-induced constipation in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation. The AMITIZA product is a chloride channel activator which increases fluid secretion and motility of the intestine, facilitating passage of stool.

## **ABOUT MALLINCKRODT**

Mallinckrodt is a global business that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics and gastrointestinal products. To learn more about Mallinckrodt, visit [www.mallinckrodt.com](http://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 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.

## **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 the company believes or anticipates 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 proposed spin-off of the Specialty Generics business inclusive of Mallinckrodt's AMITIZA product, including the costs associated with the contemplated separation and spin-off, the expected benefits of the transaction, and the expected timeframe to complete such a transaction; 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 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; 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 December 29, 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.

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