Mallinckrodt plc Form S-4/A March 04, 2014 Table of Contents

As filed with the Securities and Exchange Commission on March 4, 2014

Registration No. 333-193395

# **UNITED STATES**

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **AMENDMENT NO. 1**

ТО

# FORM S-4

# **REGISTRATION STATEMENT**

# **UNDER**

# THE SECURITIES ACT OF 1933

MALLINCKRODT INTERNATIONAL FINANCE S.A.

MALLINCKRODT PUBLIC LIMITED COMPANY (Exact name of registrant as specified in its charter)

(Exact name of registrant as specified in its charter)

Luxembourg (State or other jurisdiction of

incorporation or organization)

2834 (Primary Standard Industrial

**Classification Number**)

98-1094609 (I.R.S. Employer

**Identification Number**)

42-44 Avenue de la Gare

L-1610 Luxembourg

+352 28 48 78 10 61 (Address, including zip code, and telephone number, including

area code, of registrant s principal executive offices)

Ireland (State or other jurisdiction of

incorporation or organization)

2834 (Primary Standard Industrial

**Classification Number**)

98-1088325 (I.R.S. Employer

**Identification Number**)

Damastown, Mulhuddart

**Dublin 15, Ireland** 

+353 1 880-8180 (Address, including zip code, and telephone number, including

area code, of registrant s principal executive offices)

Peter G. Edwards, Esq.

**Senior Vice President and General Counsel** 

Mallinckrodt

675 James S. McDonnell Blvd.

Hazelwood, Missouri 63042

**United States** 

(314) 654-2000

(Name, Address, including Zip Code, and Telephone Number, including Area Code, of Agent for Service)

# With copies to:

# Adam O. Emmerich, Esq.

# Benjamin M. Roth, Esq.

# Wachtell, Lipton, Rosen & Katz 51 West 52nd Street New York, New York 10019

## **United States**

Approximate date of commencement of the proposed sale of the securities to the public: As soon as practicable after this Registration Statement is declared effective.

If the securities being registered on this Form are being offered in connection with the formation of a holding company and there is compliance with General Instruction G, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, as amended, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filerAccelerated filer"Non-accelerated filerx(Do not check if a smaller reporting company)Smaller reporting company"If applicable, place an X in the box to designate the appropriate rule provision relied upon in conducting this<br/>transaction:transaction:"

Exchange Act Rule 13e-4(i) (Cross-Border Issue Tender Offer) "

Exchange Act Rule 14d-1(d) (Cross-Border Third-Party Tender Offer) "

The Registrants hereby amend this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrants shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

#### **SUBJECT TO COMPLETION. DATED MARCH 4, 2014**

#### PROSPECTUS

#### MALLINCKRODT INTERNATIONAL FINANCE S.A.

#### **EXCHANGE OFFER FOR**

#### \$300,000,000 3.500% SENIOR NOTES DUE 2018

#### FOR

#### A LIKE PRINCIPAL AMOUNT OF OUTSTANDING

#### 3.500% SENIOR NOTES DUE 2018

#### AND

#### \$600,000,000 4.750% SENIOR NOTES DUE 2023

#### FOR

#### A LIKE PRINCIPAL AMOUNT OF OUTSTANDING

#### 4.750% SENIOR NOTES DUE 2023

Mallinckrodt International Finance S.A. (the Issuer ) is offering, upon the terms and subject to the conditions set forth in this prospectus and the accompanying letter of transmittal, to exchange an aggregate principal amount of up to \$300 million of outstanding 3.500% Senior Notes due 2018 (the outstanding 2018 notes ) and an aggregate principal amount of up to \$600 million of outstanding 4.750% Senior Notes due 2023 (the outstanding 2023 notes and, together with the outstanding 2018 notes, the outstanding notes ), each of which were issued in a private placement, for an equal principal amount of 3.500% Senior Notes due 2018 (the registered 2018 notes ) and 4.750% Senior Notes due 2023 (the registered 2023 notes and, together with the registered 2018 notes ) and 4.750% Senior Notes due 2023 (the registered 2023 notes and, together with the registered 2018 notes ) and 4.750% Senior Notes due 2023 (the registered 2023 notes and, together with the registered 2018 notes ). The terms of the exchange offer. We refer to outstanding notes and the exchange notes collectively as the notes. The terms of the exchange notes will be substantially identical in all material respects to the terms of the outstanding notes, and the Issuer will issue the exchange notes under the same Indenture (as defined

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below) as the outstanding notes. The Issuer issued the outstanding notes in connection with the separation of the Pharmaceuticals business of Covidien plc (Covidien) from Covidien s other businesses (the separation). As part of the separation, the assets and liabilities associated with the Pharmaceuticals business were transferred to Mallinckrodt plc, an Irish public limited company, and Mallinckrodt plc issued its ordinary shares to holders of Covidien ordinary shares on a pro rata basis on June 28, 2013 (such issuance, the distribution). The Issuer became a 100% owned subsidiary of Mallinckrodt plc as part of the separation. The outstanding notes were issued in accordance with the terms of the Indenture dated April 11, 2013 among the Issuer, Covidien International Finance S.A. and Deutsche Bank Trust Company Americas, as amended by the Supplemental Indenture dated June 28, 2013 among the Issuer, Mallinckrodt plc and Deutsche Bank Trust Company Americas (together, the Indenture).

## The exchange offer expires at 5:00 p.m., New York City time, on

#### , 2014, unless extended.

## Terms of the Exchange Offer

The Issuer will issue exchange notes for all outstanding notes that are validly tendered and not withdrawn prior to the expiration of the exchange offer.

You may withdraw tendered outstanding notes at any time prior to the expiration of the exchange offer.

The terms of the exchange notes are substantially identical in all material respects (including principal amount, interest rate, maturity and redemption rights) to the terms of the outstanding notes for which they may be exchanged, except that the exchange notes generally will not be subject to transfer restrictions or be entitled to registration rights and the exchange notes will not have the right to earn additional interest under circumstances relating to our registration obligations.

Mallinckrodt plc, an Irish public limited company and the parent of the Issuer, will guarantee the Issuer s obligations under the exchange notes, including the payment of principal of, premium, if any, and interest on the exchange notes. This guarantee of the exchange notes will be an unsecured and unsubordinated obligation of Mallinckrodt plc. See Description of Notes Guarantee.

The exchange of outstanding notes for exchange notes pursuant to the exchange offer generally should not constitute a taxable exchange for U.S. federal income tax purposes. See Material United States Federal Income Tax Considerations.

There is no existing market for the exchange notes, and we do not intend to apply to list the exchange notes on any securities exchange or market.

# See <u>Risk Factors</u> beginning on page 17 for a discussion of the factors you should consider in connection with the exchange offer.

# NEITHER THE U.S. SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

Each broker-dealer that receives exchange notes for its own account pursuant to this exchange offer must acknowledge that it will deliver a prospectus in connection with any resale of the exchange notes. The accompanying letter of transmittal relating to the exchange offer states that by so acknowledging and delivering a prospectus, a broker-dealer will not be deemed to admit that it is an underwriter within the meaning of the Securities Act. This prospectus, as it may be amended or supplemented from time to time, may be used by a broker-dealer in connection with resales of exchange notes received in exchange for outstanding notes where such outstanding notes were acquired by such broker-dealer as a result of market-making activities or other trading activities. See Plan of Distribution.

## The date of this prospectus is , 2014.

You should rely only on the information contained in this prospectus prepared by or on behalf of us to which we have referred you. We have not authorized anyone to provide you with information different from, or inconsistent with, the information contained in this prospectus. We are not making an offer to sell these securities in any jurisdiction where such offer or sale is not permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery.

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#### **Presentation of Information**

On June 28, 2013, Covidien completed the separation of its Pharmaceuticals business from its other businesses (the separation ), including the transfer of the assets and liabilities associated with the Pharmaceuticals business to Mallinckrodt plc and the creation, as a result of the distribution (as defined below), of an independent, publicly-traded company, Mallinckrodt plc, which now holds the assets and liabilities formerly associated with Covidien s Pharmaceuticals business. As used in this prospectus, unless the context otherwise requires, references to the Issuer

and MIFSA refer to Mallinckrodt International Finance S.A., a Luxembourg public limited liability company (*société anonyme*) incorporated under the laws of the Grand Duchy of Luxembourg, having its registered office at 44, avenue de la Gare, L-1610 Luxembourg and being registered with the Luxembourg Trade and Companies Register under the number B 172865, and a 100% owned subsidiary

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of Mallinckrodt plc. Unless the context otherwise requires, references to Mallinckrodt plc, Mallinckrodt public limited company. Mallinckrodt Pharmaceuticals, Mallinckrodt, our. our Company and the Company refe we, us, Mallinckrodt plc, an Irish public limited company, and its consolidated subsidiaries. Unless the context otherwise requires, references to Mallinckrodt s historical business and operations prior to the completion of the separation on June 28, 2013 refer to the business and operations of Covidien s Pharmaceuticals business as it was historically managed as part of Covidien and its subsidiaries. Unless the context otherwise requires, references in this prospectus to Covidien refer to Covidien plc, an Irish public limited company, and its consolidated subsidiaries, including the Pharmaceuticals business prior to completion of the separation. References to the distribution refer to the dividend on Covidien ordinary shares that was satisfied by Mallinckrodt s issuance of its ordinary shares to the persons entitled to receive the dividend on June 28, 2013. References to the initial purchasers refer to J.P. Morgan Securities LLC, Goldman, Sachs & Co., Citigroup Global Markets Inc., Deutsche Bank Securities Inc., Barclays Capital Inc., BMO Capital Markets Corp., Mizuho Securities USA Inc., PNC Capital Markets LLC, The Williams Capital Group, L.P. and Wells Fargo Securities, LLC. Except as otherwise indicated, references in this prospectus to fiscal 2014, fiscal 2013, fiscal 2012, fiscal 2011, fiscal 2010 and fiscal 2009 are to Mallinckrodt s fiscal years ended September 26, 2014, September 27, 2013, September 28, 2012, September 30, 2011, September 24, 2010 and September 25, 2009, respectively. References to dollars or \$ refer to United States dollars.

## **Trademarks and Trade Names**

Mallinckrodt owns or has rights to use trademarks and trade names that it uses in conjunction with the operation of its business. One of the more important trademarks that it owns or has rights to use that appears in this prospectus is

Mallinckrodt, which is a registered trademark or the subject of pending trademark applications in the United States and other jurisdictions. Solely for convenience, the Company only uses the of symbols the first time any trademark or trade name is mentioned. Such references are not intended to indicate in any way that the Company will not assert, to the fullest extent permitted under applicable law, its rights to its trademarks and trade names. Each trademark or trade name of any other company appearing in this prospectus is, to the Company s knowledge, owned by such other company.

#### **Notice to Investors**

This document is not a prospectus within the meaning of Part 5 of the Investment Funds, Companies and Miscellaneous Provisions Act 2005 of Ireland (as amended) or the Prospectus Directive. No offer of shares to the public is made, or will be made, that requires the publication of a prospectus pursuant to Irish prospectus law (within the meaning of Part 5 of the Investment Funds, Companies and Miscellaneous Provisions Act 2005 of Ireland, as amended) or the Prospectus Directive. This document has not been approved or reviewed by or registered with the Central Bank of Ireland or any other competent authority or regulatory authority in the European Economic Area. This document does not constitute investment advice or the provision of investment services within the meaning of the European Communities (Markets in Capital Instruments) Regulations 2007 of Ireland (as amended) or the Markets in Financial Instruments Directive (2004/39/EC). None of the Issuer, Covidien plc and Mallinckrodt plc is an authorized investment firm within the meaning of the European Communities (Markets in Financial Instruments Directive (2004/39/EC). None of the Issuer, Covidien plc and Mallinckrodt plc is an authorized investment firm within the meaning of the European Communities (Markets Financial Instruments) Regulations 2007 of Ireland (as amended) or the Markets in Financial Instruments Directive (2004/39/EC). None of the Issuer, Covidien plc and Mallinckrodt plc is an authorized investment firm within the meaning of the European Communities (Markets Financial Instruments) Regulations 2007 of Ireland (as amended) or the Markets in Financial Instruments Directive (2004/39/EC) and the recipients of this document should seek independent legal and financial advice in determining their actions in respect of or pursuant to this document.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-4 (Registration No. 333-193395) under the Securities Act with respect to the exchange notes. This prospectus is a part of the registration statement and does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. For further information about us and the exchange notes, you should refer to the registration statement, including its exhibits and schedules. This prospectus summarizes material provisions of contracts and other documents to which we refer you. Since the prospectus may not contain all of the information that you may find important, you should review the full text of these contracts and other documents. We have included or incorporated by reference copies of these documents as exhibits to our registration statement.

We are subject to the information and reporting requirements of the Exchange Act and, in accordance with the Exchange Act, we will file periodic reports, proxy statements and other information with the SEC. Our filings with the SEC are available to the public on the SEC s website at www.sec.gov. Those filings are also available to the public on our corporate web site at www.mallinckrodt.com. The information we file with the SEC or contained on our corporate web site or any other web site that we may maintain is not part of this prospectus, any prospectus supplement or the registration statement of which this prospectus is a part. You may also read and copy, at SEC prescribed rates, any document we file with the SEC, including the registration statement (and its exhibits) of which this prospectus is a part, at the SEC s Public Reference Room located at 100 F Street, N.E., Washington D.C. 20549. You can call the SEC at 1-800-SEC-0330 to obtain information on the operation of the Public Reference Room.

For so long as any of the notes are restricted securities within the meaning of Rule 144(a)(3) under the Securities Act, we will, during any period in which we are not subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act, provide to the holder or beneficial owner of such restricted securities or to any prospective purchaser of such restricted securities designated by such holder or beneficial owner, in each case upon written request of such holder, beneficial owner or prospective purchaser, the information required to be provided by Rule 144A(d)(4) under the Securities Act.

You should rely only upon the information provided in this prospectus. We have not authorized anyone to provide you with different information. You should not assume that the information in this prospectus is accurate as of any date other than the date of this prospectus.

## CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

The Company has made forward-looking statements in this prospectus that are based on management s beliefs and assumptions and on information currently available to management. Forward-looking statements include, but are not limited to, information concerning the Company s possible or assumed future results of operations, business strategies, financing plans, competitive position, potential growth opportunities, potential operating performance improvements, the effects of competition and the effects of future legislation or regulations. Forward-looking statements include all statements that are not historical facts and can be identified by the use of forward-looking terminology such as the words believe, expect, intend, project, anticipate, estimate, predict, potential, plan, continue, negative of these terms or similar expressions.

Forward-looking statements involve risks, uncertainties and assumptions. Actual results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any forward-looking statements.

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The factors included in Risk Factors could cause the Company s results to differ materially from those expressed in forward-looking statements. There may be other risks and uncertainties that the Company is unable to predict at this time or that the Company currently does not expect to have a material adverse effect on its business.

These forward-looking statements are made as of the date of this prospectus. The Company expressly disclaims any obligation to update these forward-looking statements other than as required by law.

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# **PROSPECTUS SUMMARY**

The following is a summary of the information discussed in this prospectus. This summary may not contain all of the details concerning the exchange offer or other information that may be important to you. To better understand the exchange offer and our business and financial position, you should carefully review this entire prospectus and the documents incorporated by reference, including the Risk Factors beginning on page 17.

## **Our Company**

We are a global company that develops, manufactures, markets and distributes both branded and generic specialty pharmaceuticals, active pharmaceutical ingredients ( API ) and diagnostic imaging agents. Our products are found in almost every hospital, standalone diagnostic imaging center or pharmacy in the United States ( U.S. ) and we have a commercial presence in approximately 70 countries. We believe our extensive commercial reach and formulation expertise, coupled with our ability to navigate the highly regulated and technical nature of our business, have created compelling competitive advantages that we anticipate will sustain future revenue growth.

We conduct our business in the following two segments:

*Specialty Pharmaceuticals* produces and markets branded and generic pharmaceuticals and API, comprised of medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients; and

*Global Medical Imaging* develops, manufactures and markets contrast media and delivery systems ( CMDS ) and radiopharmaceuticals (nuclear medicine).

For further information on our products and segments, refer to Business Our Businesses and Product Strategies.

# **Our Competitive Strengths**

We believe we have the following strengths:

*Expertise in the acquisition and importation of highly regulated raw materials, and strong regulatory relationships.* We have expertise in the acquisition and importation of highly regulated raw materials, such as opioids, other controlled substances and radioisotopes. For example, in calendar 2012, we believe we received almost 40% of the U.S. Drug Enforcement Administration s ( DEA ) total annual quota for controlled substances that we manufacture. In calendar 2012, our Generics business had an approximate 30% market share of DEA Schedules II and III opioid, oral solid doses, based on IMS Health data. The acquisition of certain raw materials and the processing of them into finished products requires a close collaboration with a wide variety of regulatory authorities including the DEA, U.S. Food and Drug Administration ( FDA ), U.S. Nuclear Regulatory Commission ( NRC ), European Medicines Agency and Irish Medicines Board, among many others. We have a long history of working closely with regulatory agencies to ensure ongoing, reliable access to these highly regulated materials.

*Specialized chemistry, development and formulation expertise which supports a product pipeline.* We have specialized chemistry expertise in the formulation of new drug combinations and reformulation of existing drugs into a wide range of products, such as tablets, capsules, oral liquids, injectable and intrathecal products. In late 2009, we completed a significant upgrade to our formulation pilot plant in Webster Groves, Missouri. This expansion greatly enhanced our pharmaceutical formulation capability, which has resulted in a significant increase in both branded and generic formulations that have been approved by the FDA, or that are in various stages of pre-clinical development, clinical development or regulatory review.

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A broad portfolio of generic products and controlled substance API for pain and a pipeline of branded pharmaceutical pain products. Our Generics and API businesses have a strong position in the controlled substance generics market. We believe our Generics and API businesses offer the broadest product line of opioid and other controlled substances available (primarily DEA Schedules II and III), and we focus in a number of therapeutic areas with high barriers to entry, limited competition and long product life-cycles. Our strong market position is a result of the following:

Formulation and manufacturing expertise in controlled substances and complex generics;

Our commitment to investment in our research and development ( R&D ) infrastructure and capabilities has resulted in a pipeline of generic and branded controlled substances, many of which are long-acting or hard to formulate products, which are under development or pending approval by the FDA. For example, in the fourth quarter of fiscal 2013, the FDA accepted for filing and granted priority review to our New Drug Application ( NDA ) for the drug filed as MNK-795, which the FDA has granted conditional approval for the brand name XARTEMIS XR (oxycodone HCl and acetaminophen) Extended-Release Tablets ( Xartemis XR ). PENNSA®Ddiclofenac sodium topical solution) 2% w/w ( Pennsaid 2% ), originally filed as MNK-395, was approved by the FDA in January 2014 and launched in February 2014. In addition, on December 28, 2012, we became the first company to receive approval from the FDA to manufacture and market in the U.S. a generic version of CONCERTA® (methylphenidate HCl) Extended-Release Tablets (a registered trademark of Alza Corporation) ( Concerta ), a branded pharmaceutical for the treatment of attention deficit hyperactivity disorder ( ADHD );

Our strong position in controlled substance API and vertical integration from opioid raw materials to finished dosage forms; and

U.S. importation restrictions of controlled substance API and finished products.

*Solid market position in diagnostic imaging agents.* We believe that we are one of the top three participants globally in nuclear radiopharmaceutical products. We are one of only two manufacturers of technetium-99m (Tc-99m) generators (marketed under the brand name Ultra-Technekow DTE) in North America, one of only three in Europe and the only one on either continent that has its own molybdenum-99 (Mo-99) processing facility, which provides cost and raw material supply advantages. In CMDS, we offer a fully integrated line of contrast media, pre-filled syringes and proprietary power injectors. Our leading contrast media product, Optiray (Ioversol Injection) (Optiray), has been on the market for over 25 years and is differentiated in part by being offered in pre-filled syringes that fit our proprietary power injectors, which enhances clinician safety and reduces risks in medication management.

*Distinctive high-quality manufacturing and distribution skills with vertical integration where there are competitive advantages.* Our manufacturing and supply chain capabilities enable highly efficient controlled substance tableting, packaging and distribution. Our investments include one of the world s largest DEA Schedule C-II vault storage capacities for raw materials, intermediates and finished dosages. In our Global

Medical Imaging segment, we have the capability to process Mo-99 for use in our Ultra-Technekow DTE generators and to manufacture cyclotron-derived isotopes such as thallium-201, indium-111, gallium-67, germanium-68 and iodine-123. In addition, we produce the large-volume terminally sterilized pre-filled plastic syringes that fit into our power injectors. Where appropriate, we have also pursued selective vertical integration initiatives to ensure our manufacturing and supply chain benefit from cost and productivity efficiencies, such as using several of our API products to provide the raw materials for some of our generic products.

*Global commercial reach.* Our Global Medical Imaging segment operates throughout the world and its direct and indirect marketing and selling capabilities are tailored to business and geographic needs. We

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have unique capabilities in complex markets that are not easy to enter, navigate or operate in, and there are very few companies that have the experience and expertise in manufacturing, regulatory and distribution to effectively manage controlled substances on a global scale. Our Global Medical Imaging segment has a commercial presence in approximately 70 countries that has positioned us for growth in select markets.

Strong management team with extensive industry experience. We benefit from having a management team with extensive experience in small, medium and large life sciences firms. Mark Trudeau, our President and Chief Executive Officer, has more than 29 years of experience in the pharmaceuticals industry. Prior to joining Covidien s Pharmaceuticals business in January 2012, Mr. Trudeau served as Chief Executive Officer of Bayer Healthcare LLC USA, the U.S. healthcare business of Bayer AG, and as President of Bayer HealthCare Pharmaceuticals U.S. Region. Mr. Trudeau also served on the Board of the Pharmaceutical Researchers and Manufacturers of America, the National Pharmaceutical Council and as a Trustee of the HealthCare Institute of New Jersey. Matthew Harbaugh, our Senior Vice President and Chief Financial Officer, joined Covidien s Pharmaceuticals business in 2007 and has over 20 years of financial experience, mostly in the life sciences field. Additional members of the senior management team include Peter Edwards, our Senior Vice President and General Counsel; Hugh O Neill, our Senior Vice President and President of U.S. Specialty Pharmaceuticals; Steve Merrick, our Senior Vice President and President, Commercial Operations, International; Gary Phillips, our Senior Vice President and Chief Strategy Officer; Mario Saltarelli, our Senior Vice President and Chief Science Officer; Ian Watkins, our Senior Vice President and Chief Human Resources Officer; Meredith Fischer, our Senior Vice President, Communications and Public Affairs; and Sandra Hatten, our Senior Vice President, Quality and Regulatory Compliance; all of whom have industry experience.

#### **Our Strategy**

Our strategy is to enhance growth and build shareholder value by expanding our core businesses, expanding our product portfolio in pain management, selectively pursuing growth opportunities in adjacent markets through acquisitions and driving our profitability.

We are committed to the following goals:

*Grow sales in our Specialty Pharmaceuticals segment faster than the market.* We believe that our R&D investments in our Specialty Pharmaceuticals segment have positioned us to grow sales at a faster rate than the overall market growth rate.

*Expand core product portfolio with new branded and generic products.* We intend to continue to focus on marketing our pain drugs (such as extended-release opioids and topical anti-inflammatories) and the drugs and pipeline we acquired from our acquisition of CNS Therapeutics, Inc. (CNS Therapeutics) (such as GABLOFEN<sup>®</sup> (baclofen injection) (Gablofen). We also have a pipeline of branded pain management products that we intend to develop and bring to market. In addition, we believe that we can continue to expand our generic product portfolio of controlled substances, particularly in the pain market and the ADHD segment of the controlled substance market, especially those products that are difficult to formulate.

*Grow into new, adjacent areas through acquisitions and targeted partnerships.* Our business development objectives are focused on targeted business opportunities that will capitalize on our core strengths in controlled substances and formulations in both Brands and Generics and also near adjacent therapeutic areas.

*Drive our profitability*. We intend to continue to drive profitability through managing our Global Medical Imaging segment for cash and with continued implementation of restructuring initiatives. In August 2013, our board of directors approved \$100 million to \$125 million in restructuring initiatives over the following three years. We continue to execute on various initiatives that will allow us to achieve greater efficiencies, improve our competitiveness and drive profitability across both segments.

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#### **Risk Factors**

An investment in the notes is subject to a number of risks. Please read the information in the section captioned Risk Factors for a more thorough description of these and other risks. These risks include, but are not limited to:

Risks related to the exchange offer, such as:

If you choose not to exchange your outstanding notes in the exchange offer, the transfer restrictions currently applicable to your outstanding notes will remain in force and the market price of your outstanding notes could decline.

Your ability to transfer the notes may be limited by the absence of an active trading market, and an active trading market may not develop for the notes.

Risks related to the notes, such as:

MIFSA s indebtedness could adversely affect its financial condition and prevent it from fulfilling its obligations under the notes.

We may not be able to generate sufficient cash to service all of our indebtedness, including the notes, and may be forced to take other actions to satisfy our obligations under our indebtedness, which may not be successful.

Despite our current level of indebtedness, Mallinckrodt plc and its subsidiaries may still be able to incur more debt.

Risks related to our pending acquisition of Cadence Pharmaceuticals, Inc.

Risks related to our business, such as:

The DEA regulates the availability of controlled substances that are API, drug products under development and marketed drug products. At times, the procurement and manufacturing quotas granted by the DEA may be insufficient to meet our commercial and R&D needs.

The manufacture of our products is highly exacting and complex, and our business could suffer if we, or our suppliers, encounter manufacturing or supply problems.

The global supply of fission-produced Mo-99 is limited. Our inability to obtain and/or to timely transport Mo-99 to our Tc-99m generator production facilities could prevent us from delivering our Ultra-Technekow DTE Tc-99m generators to our customers in the required quantities, within the required timeframe, or at all, which could result in order cancellations and decreased revenues or increased costs if we procure supply from other sources.

In response to the U.S. National Security Administration s Global Threat Initiative, we are in the process of converting our Mo-99 production operation in the Netherlands from high enriched uraniu (HEU) targets to low enriched uranium (LEU) targets. There can be no assurance that we will be successful in completing this conversion.

Our customer concentration may materially adversely affect our financial condition and results of operations.

Risks related to the separation.

Risks related to tax matters.

Risks related to Mallinckrodt plc s and MIFSA s jurisdictions of incorporation.

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# **The Separation**

Mallinckrodt plc was incorporated in Ireland on January 9, 2013 for the purpose of holding Covidien s Pharmaceuticals business following the separation. Immediately prior to the distribution on June 28, 2013, Covidien transferred its Pharmaceuticals business to Mallinckrodt plc in return for which Mallinckrodt plc issued shares to Covidien ordinary shareholders, pro rata to their respective holdings. Prior to the transfer by Covidien to Mallinckrodt plc of the Pharmaceuticals business, Mallinckrodt plc had no business operations. Immediately following the distribution, the persons who received Mallinckrodt plc ordinary shares in the distribution owned all of Mallinckrodt plc s outstanding ordinary shares.

The description and other information in this prospectus regarding the separation is included in this prospectus solely for informational purposes. Nothing in this prospectus should be construed as an offer to sell, or the solicitation of an offer to buy, any of Mallinckrodt plc s or Covidien s ordinary shares.

In connection with the separation, Mallinckrodt plc and Covidien entered into a separation and distribution agreement (the separation and distribution agreement ) and various other agreements, including a transition services agreement, a tax matters agreement and an employee matters agreement. These agreements provide a framework for our relationship with Covidien after the separation and provide for the allocation between us and Covidien of Covidien s assets, employees, liabilities and obligations (including its property, employee benefits, environmental liabilities and tax liabilities) attributable to periods prior to, at and after our separation from Covidien. For additional information regarding the separation and distribution agreement and other transaction agreements, see Risk Factors Risks Related to the Separation.

Prior to the offering of the outstanding notes, MIFSA entered into a 5-year revolving credit facility with a borrowing capacity of up to \$250 million (the credit facility ). Mallinckrodt plc guaranteed the credit facility upon completion of the distribution. Indebtedness under the credit facility is treated as an unsecured and unsubordinated obligation of MIFSA and, since the completion of the distribution, Mallinckrodt plc, and ranks pari passu in right of payment with the outstanding notes. Borrowings under the credit facility will bear interest at LIBOR plus 2.375% per annum (subject to adjustment based upon a ratings-based pricing grid). The credit facility provides for customary fees, including facility fees and other fees. See Description of Certain Indebtedness and Description of Notes.

# Recent Developments Our Pending Acquisition of Cadence Pharmaceuticals, Inc.

# The Offer and the Merger

On February 10, 2014, Mallinckrodt plc entered into an Agreement and Plan of Merger (the Merger Agreement ) with Madison Merger Sub, Inc., a Delaware corporation and an indirect wholly owned subsidiary of Mallinckrodt plc (Merger Sub), and Cadence Pharmaceuticals, Inc., a Delaware corporation (Cadence), pursuant to which Merger Sub agreed, on the terms and subject to the conditions set forth therein, to commence a tender offer (the Offer) to acquire all of the outstanding shares of common stock, \$0.0001 par value per share, of Cadence at a purchase price of \$14.00 per share in cash (the Offer Price), subject to any required withholding of taxes and without interest, and, following the completion of the Offer merge with and into Cadence (the Merger), with Cadence surviving the Merger as an indirect wholly owned subsidiary of Mallinckrodt plc. The Offer was commenced on February 19, 2014, the date on which Mallinckrodt plc and Merger Sub filed a Schedule TO relating to the Offer with the Securities and Exchange Commission (SEC).

The Merger will be governed by Section 251(h) of the General Corporation Law of the State of Delaware, with no stockholder vote required to consummate the Merger. At the effective time of the Merger, each outstanding share of

Cadence common stock, other than shares owned by stockholders who have validly exercised their appraisal rights under Delaware law and shares owned by Mallinckrodt plc, Merger Sub, any subsidiary of Mallinckrodt plc or held in Cadence s treasury (which shares will be cancelled), will be converted

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into the right to receive cash in an amount equal to the Offer Price, subject to any required withholding of taxes and without interest.

Our pending acquisition of Cadence is subject to a number of risks. Please see Risk Factors Risks Related to Our Pending Acquisition of Cadence Pharmaceuticals, Inc. for a more detailed discussion.

## Conditions to the Offer and the Merger

Merger Sub s obligation to accept shares tendered in the Offer is subject to customary conditions, including, among other things, (i) the absence of a termination of the Merger Agreement in accordance with its terms, (ii) that the number of shares of Cadence common stock validly tendered in accordance with the terms of the Offer and not validly withdrawn equal, when added to any shares owned by Mallinckrodt plc or Merger Sub, at least one more share than one-half of the outstanding shares of Cadence common stock, (iii) the expiration or early termination of any applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder (the HSR Condition ), (iv) that no governmental authority shall have enacted any law or order which makes the Offer or the Merger illegal or otherwise prohibits the consummation of the Offer or the Merger, (v) the absence of certain material adverse effects and (vi) the delivery of certain financial information.

The Merger is subject to the following closing conditions: (x) Merger Sub must have accepted for payment all shares validly tendered and not validly withdrawn pursuant to the Offer and (y) no governmental authority having enacted any law or order which makes the Merger illegal or otherwise prohibits the consummation of the Merger.

#### Representations and Warranties; Covenants

Cadence has made customary representations and warranties to Mallinckrodt plc and Merger Sub in the Merger Agreement. Cadence has also agreed to customary covenants, including, among other things, covenants (i) not to solicit alternative proposals from third parties for a transaction with respect to Cadence and (ii) to conduct its business in the ordinary course during the period between the execution of the Merger Agreement and the closing of the Merger.

Each of Mallinckrodt plc and Merger Sub has made customary representations and warranties to Cadence in the Merger Agreement. In addition, the Merger Agreement contains customary covenants of Mallinckrodt plc and Merger Sub, including, among other things, a covenant of Mallinckrodt plc to use its reasonable best efforts to obtain the proceeds of the debt financing required to consummate the transactions.

## Termination and Termination Fees

The Merger Agreement contains customary termination rights for both Mallinckrodt plc and Cadence, including, among others, for failure to consummate the Offer on or before June 10, 2014 (which date may be extended to August 10, 2014 if the HSR Condition is not satisfied by such date and, if both Mallinckrodt plc and Cadence mutually agree (acting reasonably), such date may be further extended to September 10, 2014 if the HSR Condition is reasonably capable of being satisfied by such date).

Upon termination of the Merger Agreement under specified circumstances, including a termination by Cadence to enter into an agreement for an alternative transaction that constitutes a superior proposal (as defined in the Merger Agreement), Cadence has agreed to pay Mallinckrodt plc a termination fee of \$20.2 million.

The foregoing summary of the Merger Agreement and the transactions contemplated thereby does not purport to be complete and is qualified in its entirety by the full text of the Merger Agreement filed as Exhibit 2.2 to the registration statement of which this prospectus forms a part, and which is incorporated herein by reference.

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# **Debt Financing**

Mallinckrodt plc has received a commitment letter, dated as of February 10, 2014 (as amended, supplemented or otherwise modified from time to time, the Debt Commitment Letter ), from Deutsche Bank AG New York Branch (DBNY) and Deutsche Bank Securities Inc. (DBSI and, together with DBNY, the Agents) pursuant to which DBNY made loan commitments for the purpose of financing a portion of the funds required to complete the Offer and the Merger and the refinancing of certain indebtedness of Mallinckrodt and Cadence (such commitments, the Debt Financing). Mallinckrodt plc also entered into an agreement, dated as of February 20, 2014 (the Joinder Agreement), with each of Barclays Bank PLC (Barclays), Citigroup Global Markets Inc. (CGMI), Wells Fargo Bank, National Association (WF Bank and, together with Barclays, CGMI and DBNY, the Debt Financing Sources) and Wells Fargo Securities LLC (WF Securities). Pursuant to the Joinder Agreement, Mallinckrodt plc appointed each of Barclays, CGMI and WF Securities to act (and each of such entities agreed to act), together with DBSI, as a joint lead arranger for the Debt Financing.

Pursuant to the Debt Commitment Letter, the Debt Financing Sources have committed to provide or arrange, subject to the terms and conditions of the Debt Commitment Letter, a senior secured term loan facility in the aggregate principal amount of \$1.3 billion (the Term Loan Facility) and a senior secured revolving credit facility with commitments in the aggregate principal amount of \$250 million (the Revolving Credit Facility and, together with the Term Loan Facility, the Senior Secured Credit Facilities).

We estimate that the total amount of funds required to consummate the Offer and the Merger, to provide funding for the payment in respect of outstanding in-the-money options and restricted stock units of Cadence and to repay or refinance certain indebtedness of Mallinckrodt and Cadence is approximately \$1.4 billion, plus related fees and expenses. We anticipate funding such cash requirements with a combination of the proceeds from the Debt Financing and cash on hand. As of February 11, 2014, Mallinckrodt plc had approximately \$350 million of cash and cash equivalents.

Funding of the Debt Financing is subject to the satisfaction of various customary conditions. We expect to use the proceeds of the Debt Financing on the date on which such conditions are satisfied to pay a portion of the merger consideration and transaction costs related to the Merger.

# **Corporate Information**

Our principal executive offices are located at Damastown, Mulhuddart, Dublin 15, Ireland. Our telephone number at this location is +353 (1) 880-8180. Our U.S. headquarters is located at 675 James S. McDonnell Boulevard, Hazelwood, Missouri 63042. Our telephone number at this location is (314) 654-2000. Our website is www.mallinckrodt.com. The information and other content contained on our website is not incorporated by reference in this prospectus. You should not consider information and other content contained on our website to be a part of this prospectus.

# SUMMARY TERMS OF THE EXCHANGE OFFER

The following is a brief summary of the terms of the exchange offer. For a more complete description of the exchange offer, see Exchange Offer.

General	On April 11, 2013, MIFSA issued an aggregate of \$300,000,000 principal amount of 3.500% Senior Notes due 2018 and an aggregate of \$600,000,000 principal amount of 4.750% Senior Notes due 2023 in a private offering in connection with the separation. In connection with the private offering, MIFSA entered into a registration rights agreement with the initial purchasers in which MIFSA agreed, among other things, to deliver this prospectus to you and to complete the exchange offer within 365 days after the date of issuance of the outstanding notes.
The Exchange Offer	MIFSA is offering to exchange an aggregate principal amount of up to \$300,000,000 of outstanding 3.500% Senior Notes due 2018 (the outstanding 2018 notes ) and an aggregate of \$600,000,000 principal amount of 4.750% Senior Notes due 2023 (the outstanding 2023 notes and, together with the outstanding 2018 notes, the outstanding notes ) for an equal principal amount of 3.500% Senior Notes due 2018 (the registered 2018 notes ) and 4.750% Senior Notes due 2023 (the registered 2023 notes and, together with the registered 2018 notes, the exchange notes ), respectively, each of whose sale will be registered under the U.S. Securities Act of 1933, as amended (the Securities Act ). We refer to the foregoing transactions collectively as the exchange offer. We refer to the 2018 notes and the outstanding 2023 notes and the registered 2018 notes collectively as the 2018 notes and the exchange notes and the outstanding 2023 notes and the registered 2018 notes and the registered 2018 notes and the exchange offer. We refer to the outstanding 2018 notes and the registered 2018 notes and the registered 2018 notes collectively as the exchange offer. We refer to the outstanding 2018 notes and the registered 2018 notes collectively as the exchange notes collectively as the 2023 notes and the registered 2023 notes and the registered 2023 notes and the exchange notes and the exchange notes.
Expiration of the Exchange Offer; Withdrawal of Tender	The exchange offer will expire at 5:00 p.m., New York City time, on , 2014, unless extended. MIFSA does not currently intend to extend the expiration of the exchange offer. You may withdraw your tender of outstanding notes in the exchange offer at any time before the expiration of the exchange offer. Any outstanding notes not accepted for exchange for any reason will be returned without expense to you promptly after the expiration or termination of the exchange offer.
Conditions to the Exchange Offer	The exchange offer is not conditioned upon any minimum aggregate principal amount of outstanding notes being tendered for exchange. The exchange offer is subject to customary conditions, which we may waive. See Exchange Offer Conditions for more information regarding the conditions to the exchange offer.

**Procedures for Tendering Notes** 

To tender outstanding notes you must deliver a letter of transmittal and deliver the outstanding notes to the exchange agent. Delivery of the outstanding notes may be made by book-entry transfer to the

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exchange agent s account at the Depository Trust Company (DTC). If you hold your notes in book-entry form through DTC, then in lieu of the procedure for physical delivery of a letter of transmittal and delivery of outstanding notes, you may follow the procedures for the DTC s Automated Tender Offer Program (ATOP).

Specifically, to accept the exchange offer by delivery of a letter of transmittal and outstanding notes:

you must complete, sign and date the letter of transmittal, or a facsimile of the letter of transmittal, have the signature on the letter of transmittal guaranteed if the letter of transmittal so requires and deliver the letter of transmittal or facsimile to the exchange agent, including all the required documents, prior to the expiration of the exchange offer; and

either:

the exchange agent must receive the outstanding notes along with the letter of transmittal; or

the exchange agent must receive, before expiration of the exchange offer, timely confirmation of book-entry transfer of outstanding notes into the exchange agent s account at DTC, according to the procedure for book-entry transfer described in Exchange Offer Methods of Delivering Outstanding Notes Book-Entry Transfer ; or

you must comply with the guaranteed delivery procedures described in Exchange Offer Methods of Delivering Outstanding Notes Guaranteed Delivery Procedures.

If you hold your outstanding notes in book-entry form through DTC, in lieu of the above procedures:

you may instruct DTC, in accordance with the ATOP system, to transmit on your behalf a computer-generated message to the exchange agent in which the holder of the outstanding notes acknowledges and agrees to be bound by the terms of the letter of transmittal, which computer-generated message must be received by the exchange agent

prior to 5:00 p.m., New York City time, on the expiration date; and

the exchange agent must receive, before expiration of the exchange offer, timely confirmation of book-entry transfer of outstanding notes into the exchange agent s account at DTC, according to the procedure for book-entry transfer described in Exchange Offer Methods of Delivering Outstanding Notes Book-Entry Transfer.

Special Procedures for Beneficial Owners If you are a beneficial owner whose outstanding notes are registered in the name of a broker, dealer, commercial bank, trust company or other nominee, and you want to tender outstanding notes in the exchange offer, you should contact the registered owner promptly and

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	instruct the registered holder to tender on your behalf. If you wish to tender on your own behalf, you must, before completing and executing the letter of transmittal and delivering your outstanding notes, either make appropriate arrangements to register ownership of the outstanding notes in your name or obtain a properly completed bond power from the registered holder. See Exchange Offer Procedures for Tendering.
Guaranteed Delivery Procedures	If you wish to tender your outstanding notes, and time will not permit your required documents to reach the exchange agent by the expiration of the exchange offer, or the procedure for book-entry transfer cannot be completed on time, you may tender your outstanding notes under the procedures described under Exchange Offer Methods of Delivering Outstanding Notes Guaranteed Delivery Procedures.
Consequences of Failure to Exchange	Any outstanding notes that are not tendered in the exchange offer, or that are not accepted in the exchange, will remain subject to the restrictions on transfer set forth in the Indenture and described in the Offering Memorandum dated April 8, 2013 (the Offering Memorandum ). Since the outstanding notes have not been registered under the U.S. federal securities laws, you will not be able to offer or sell the outstanding notes except under an exemption from the requirements of the Securities Act or unless the outstanding notes are registered under the Securities Act. Upon the completion of the exchange offer, we will have no further obligations, except under limited circumstances, to provide for registration of the outstanding notes under the U.S. federal securities laws. See Exchange Offer Consequences of Failure to Tender.
Material United States Federal Income Tax Considerations	The exchange of outstanding notes for exchange notes pursuant to the exchange offer generally should not constitute a taxable exchange for U.S. federal income tax purposes. See Material United States Federal Income Tax Considerations.
Transferability	Under existing interpretations of the Securities Act by the staff of the SEC contained in several no-action letters to third parties, and subject to the immediately following sentence, we believe that the exchange notes will generally be freely transferable by holders after the exchange offer without further compliance with the registration and prospectus delivery requirements of the Securities Act (subject to certain representations required to be made by each holder of outstanding notes, as set forth under Exchange Offer Procedures for Tendering ). However, any holder of outstanding notes who:

is one of Mallinckrodt plc s or MIFSA s affiliates (as defined in Rule 405 under the Securities Act),

does not acquire the exchange notes in the ordinary course of business,

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distributes, intends to distribute, or has an arrangement or understanding with any person to distribute the exchange notes as part of the exchange offer, or

is a broker-dealer who purchased outstanding notes from MIFSA in the initial offering of the outstanding notes for resale pursuant to Rule 144A or any other available exemption under the Securities Act,

will not be able to rely on the interpretations of the staff of the SEC, will not be permitted to tender outstanding notes in the exchange offer and, in the absence of any exemption, must comply with the registration and prospectus delivery requirements of the Securities Act in connection with any resale of the exchange notes.

Our belief that transfers of exchange notes would be permitted without registration or prospectus delivery under the conditions described above is based on SEC interpretations given to other, unrelated issuers in similar exchange offers. We cannot assure you that the SEC would make a similar interpretation with respect to our exchange offer. We will not be responsible for or indemnify you against any liability you may incur under the Securities Act.

Each broker-dealer that receives exchange notes for its own account under the exchange offer in exchange for outstanding notes that were acquired by the broker-dealer as a result of market-making or other trading activity must acknowledge that it will deliver a prospectus in connection with any resale of the exchange notes. See Plan of Distribution.

We will not receive any cash proceeds from the issuance of the exchange notes pursuant to the exchange offer.

Deutsche Bank Trust Company Americas is the exchange agent for the exchange offer. The address and telephone number of the exchange agent are set forth under Exchange Offer Exchange Agent.

**Use of Proceeds** 

**Exchange Agent** 

## THE NOTES

The following summary contains basic information about the notes and is not intended to be complete. For a more complete understanding of the notes and the guarantee, please refer to the section entitled Description of Notes included elsewhere in this prospectus. The terms of the exchange notes are substantially identical in all material respects to the terms of the outstanding notes, except that the exchange notes will not contain terms with respect to transfer restrictions or additional interest upon a failure to fulfill certain of our obligations under the registration rights agreement and the exchange notes will have a different CUSIP. The exchange notes will evidence the same debt as the outstanding notes. The exchange notes will be governed by the same Indenture under which the outstanding notes were issued.

In this section, (i) MIFSA or the Issuer refers only to Mallinckrodt International Finance S.A., and not any of its subsidiaries or affiliates and (ii) Mallinckrodt plc refers only to Mallinckrodt plc, and not any of its subsidiaries or affiliates.

Issuer	Mallinckrodt International Finance S.A.
Guarantee	Mallinckrodt plc will guarantee the exchange notes on an unsecured and unsubordinated basis.
Exchange Notes Offered	\$300,000,000 aggregate principal amount of 3.500% Senior Notes due 2018.
	\$600,000,000 aggregate principal amount of 4.750% Senior Notes due 2023.
Maturity Dates	2018 notes: April 15, 2018.
	2023 notes: April 15, 2023.
Interest Rates	2018 notes: 3.500% per annum.
	2023 notes: 4.750% per annum.
Interest Payment Dates	April 15 and October 15, commencing April 15, 2014. No interest will be paid on outstanding notes following their acceptance for exchange.

## Ranking

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The notes will be MIFSA s unsecured and unsubordinated obligations and will rank (i) equally in right of payment with all of MIFSA s other existing and future unsecured and unsubordinated obligations and (ii) senior to any obligations of MIFSA that are expressly subordinated by their terms to the notes. The notes will be (i) effectively subordinated to any of MIFSA s existing and future secured debt, to the extent of the value of the assets securing such debt, and (ii) structurally subordinated to all of the existing and future liabilities (including trade payables) of MIFSA s subsidiaries that do not guarantee the notes.

The Mallinckrodt plc guarantee will be Mallinckrodt plc s unsecured and unsubordinated obligation and will rank (i) equally in right of payment with all of Mallinckrodt plc s other existing and future

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	unsecured and unsubordinated obligations and (ii) senior to any obligations of Mallinckrodt plc that are expressly subordinated by their terms to the notes. Such guarantee will be (i) effectively subordinated to any of Mallinckrodt plc s existing and future secured debt, to the extent of the value of the assets securing such debt, and (ii) structurally subordinated to all of the existing and future liabilities (including trade payables) of Mallinckrodt plc s subsidiaries that do not guarantee the notes.
	See Description of Notes Ranking.
Optional Redemption	MIFSA may redeem some or all of the notes at any time at the redemption prices described under the caption Description of Notes Optional Redemption.
Change of Control	If a change of control triggering event occurs with respect to a series of notes, MIFSA will be required to make an offer to repurchase such notes in cash from the holders at a price equal to 101% of their aggregate principal amount thereof, plus accrued and unpaid interest to, but not including, the date of repurchase. See Description of Notes Repurchase Upon Change of Control Triggering Event.
Certain Covenants	The indenture governing the notes contains covenants limiting:
	the ability of MIFSA and its restricted subsidiaries and Mallinckrodt plc to incur certain liens;
	the ability of MIFSA and its restricted subsidiaries and Mallinckrodt plc to enter into sale and lease-back transactions; and
	the ability of MIFSA and Mallinckrodt plc to merge or consolidate with any other person or sell or convey all or substantially all of its assets to any person.
	See Description of Notes Negative Covenants.
Trustee, Registrar, Paying Agent and Transfer Agent	Deutsche Bank Trust Company Americas

Form and Denominations

**Further Issuances** 

The notes will be issued only in registered form in denominations of \$2,000 and integral multiples of \$1,000 in excess thereof. Each series of notes will be represented by one or more global notes registered in the name of The Depository Trust Company.

MIFSA may issue additional notes of each series ranking equally and ratably with the notes initially offered in this offering and having the same interest rate, maturity and other terms of such series (except for the issue date, the issue price, the initial interest payment date and rights under the registration rights agreement). Such additional notes will be treated as a single class of such series for all purposes of the indenture, including for purposes of voting and redemptions. See Description of Notes Issuance of Additional Notes.

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No Prior Market	The exchange notes will generally be freely transferable (subject to certain restrictions discussed in Exchange Offer ) but will be a new issue of securities for which there will not initially be a market. Accordingly, there can be no assurance as to the development or liquidity of any market for the exchange notes. The initial purchasers in the private offering of the outstanding notes have advised us that they currently intend to make a market for the exchange notes, as permitted by applicable laws and regulations. However, they are not obligated to do so and may discontinue any such market making activities at any time without notice. We do not intend to apply for a listing of the exchange notes on any securities exchange or automated dealer quotation system.
Use of Proceeds	We will not receive any proceeds from the exchange offer. See Use of Proceeds.
Governing Law	The indenture and each series of notes are governed by and construed in accordance with the laws of the State of New York without regard to conflicts of law principles.
Risk Factors	In evaluating an investment in the exchange notes, prospective investors should carefully consider, along with the other information in this prospectus, the specific factors set forth under Risk Factors for risks involved with an investment in the exchange notes.

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#### SUMMARY HISTORICAL CONSOLIDATED AND COMBINED FINANCIAL DATA

The following table sets forth summary historical financial data for the periods indicated below. The summary income statement data for the three months ended December 27, 2013 and December 28, 2012 and the summary balance sheet data at December 27, 2013 have been derived from our unaudited condensed consolidated and combined financial statements included elsewhere in this prospectus. The summary income statement data for each of the fiscal years in the three-year period ended September 27, 2013 and the summary balance sheet data as of September 27, 2013 and September 28, 2012 have been derived from our audited consolidated and combined financial statements, which are included elsewhere in this prospectus. The summary balance sheet data as of September 30, 2011 has been derived from our audited combined financial statements that are not included in this prospectus. The summary financial data should be read in conjunction with our consolidated and combined financial statements and accompanying notes and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus.

The combined financial statements for periods prior to the separation on June 28, 2013 have been prepared by Covidien to present the historical operating assets, liabilities and related results of operations of its Pharmaceuticals business. The combined financial statements include all assets and liabilities related to the operation of the business and which were subject to oversight and review by management of the Pharmaceuticals business prior to the separation. The combined financial statements do not include certain corporate non-operating assets and liabilities, principally related to changes in the internal capital structure resulting from the internal reorganization of our legal entities to facilitate the separation. These non-operating assets and liabilities do not represent standalone businesses and primarily relate to intercompany transactions. The Company s combined financial statements for the periods prior to the separation on June 28, 2013, including for the nine months ended June 28, 2013 that is included in the fiscal 2013 results and the three months ended December 28, 2012, may not be indicative of our future performance and do not necessarily reflect the results of operations, financial position and cash flows that would have been had it operated as an independent, publicly-traded company for the entirety of the periods presented.

#### **Non-GAAP Financial Measures**

Adjusted EBITDA represents GAAP net income before net interest, income taxes, depreciation and amortization, adjusted to exclude certain items. These items, if applicable, include discontinued operations; other income, net; separation costs; restructuring charges, net; immediately expensed up-front and milestone payments; acquisition-related costs; and non-cash impairment charges. We have provided this non-GAAP financial measure because it is used by management, along with financial measures in accordance with GAAP, to evaluate our operating performance. In addition, we believe it will be used by certain investors to measure our operating results. Management believes that presenting Adjusted EBITDA provides useful information about our performance across reporting periods on a consistent basis by excluding items that we do not believe are indicative of our core operating performance.

Adjusted EBITDA has the following limitations:

it does not reflect our cash expenditures, or future requirements, for capital expenditures or contractual commitments;

it does not reflect changes in, or cash requirements for, our working capital needs;

it does not reflect interest expense or the cash requirements necessary to service interest or principal payments;

it is not adjusted for all non-cash income or expense items that are reflected in our statements of cash flows; and

other companies in our industry may calculate this measure differently than we do, limiting its usefulness as a comparative measure.

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Because of these limitations, Adjusted EBITDA should be considered supplemental to and not a substitute for net income or any other performance measures derived in accordance with GAAP. See our consolidated and combined financial statements included elsewhere in this prospectus for our GAAP results.

	Three Moi December 27,	Fiscal Year <sup>(1)</sup>					
(Dollars in Millions)	2013 <sup>(2)</sup>	2012 <sup>(3)</sup>	<b>2013</b> <sup>(4)</sup>	2	<b>2012</b> <sup>(5)</sup>		<b>2011</b> <sup>(6)</sup>
Consolidated and Combined							
Statement of Income Data:							
Net sales	\$540.2	\$504.0	\$2,204.5	\$	2,056.2	\$	2,021.8
Gross profit	255.6	233.5	1,024.9		964.8		914.9
Operating income <sup>(7)</sup>	73.1	36.8	144.8		235.2		240.7
Income from continuing operations							
before income taxes	63.0	36.9	126.4		236.1		243.2
Income from continuing operations	46.4	19.8	57.8		141.3		157.0
Other Financial Data:							
Adjusted EBITDA <sup>(8)</sup>	N/A	N/A	\$ 396.7	\$	402.8	\$	371.8

	December 27, 2013	D	ecember 28, 2012	September 27, 2013	, Sep	tember 28, 2012	Sep	tember 30, 2011
Consolidated and Combined Balance Sheet Data:								
Total assets	\$3,569.4	\$	3,083.2	\$3,556.6	\$	2,898.9	\$	2,832.2
Long-term debt	918.0		2.8	918.3		8.9		10.4
Shareholders equity	1,309.3		2,113.7	1,255.6		1,891.9		1,788.7

(1) Fiscal 2011 includes 53 weeks, while fiscal 2013 and 2012 each includes 52 weeks.

- (2) The three months ended December 27, 2013 includes \$2.2 million of separation costs and \$8.1 million of restructuring and related charges, net, of which \$0.1 million related to accelerated depreciation.
- (3) The three months ended December 28, 2012 includes \$12.0 million of separation costs and \$1.0 million of restructuring and related charges, net, of which \$0.8 million related to accelerated depreciation.
- (4) Fiscal 2013 includes \$74.2 million of separation costs and \$35.8 million of restructuring and related charges, net, of which \$2.6 million related to accelerated depreciation.
- (5) Fiscal 2012 includes \$25.5 million of separation costs and \$19.2 million of restructuring and related charges, net, of which \$8.0 million related to accelerated depreciation.
- (6) Fiscal 2011 includes \$2.9 million of separation costs and \$10.0 million of restructuring and related charges, net, of which \$1.6 million related to accelerated depreciation.
- (7) During fiscal 2013, 2012 and 2011, Covidien allocated general corporate expenses to us in the amount of \$39.6 million, \$49.2 million and \$56.3 million respectively. The three months ended December 28, 2012 includes \$11.9 million of allocated general corporate expenses. General corporate expenses include, but are not limited to, costs related to finance, legal, information technology, human resources, communications, employee benefits and incentives, insurance and stock-based compensation. Effective upon completion of the separation, we assumed

responsibility for all of these functions and related costs and our costs as a standalone entity are likely to be higher than those allocated to us from Covidien. No pro forma adjustments have been made to reflect the costs and expenses described in this paragraph.

(8) The following table provides a reconciliation of our net income to Adjusted EBITDA for the periods presented:

		Fiscal Year	
(Dollars in Millions)	2013	2012	2011
Net income	\$ 58.8	\$134.6	\$150.7
Adjustments:			
Interest expense, net	19.2	0.1	0.4
Provision for income taxes	68.6	94.8	86.2
Depreciation expense	104.1	103.6	92.8
Amortization expense	35.4	27.3	27.0
(Income) loss from discontinued operations, net of income taxes	(1.0)	6.7	6.3
Other income, net	(0.8)	(1.0)	(2.9)
Restructuring charges, net	33.2	11.2	8.4
Separation costs	74.2	25.5	2.9
Up-front and milestone payments	5.0		
Adjusted EBITDA	\$ 396.7	\$402.8	\$371.8

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#### **RISK FACTORS**

Any investment in the notes involves a high degree of risk. You should carefully consider the risks described below and all of the information contained in this prospectus before deciding whether to participate in the exchange offer. Our competitive position, business, financial condition, results of operations and cash flows can be affected by the factors set forth below, any one of which could cause our actual results to vary materially from recent results or from our anticipated future results. The risk factors generally have been separated into seven groups: risks related to the exchange offer, risks related to the notes, risks related to our pending acquisition of Cadence Pharmaceuticals, Inc., risks related to our business, risks related to the separation, risks related to tax matters and risks related to Mallinckrodt plc s and MIFSA s jurisdictions of incorporation.

#### **Risks Related to the Exchange Offer**

# If you choose not to exchange your outstanding notes in the exchange offer, the transfer restrictions currently applicable to your outstanding notes will remain in force and the market price of your outstanding notes could decline.

If you do not exchange your outstanding notes for exchange notes in the exchange offer, then you will continue to be subject to the transfer restrictions on the outstanding notes as set forth in the Offering Memorandum distributed in connection with the private offering of the outstanding notes. In general, the outstanding notes may not be offered or sold unless they are registered or exempt from registration under the Securities Act and applicable state securities laws. Except as required by the registration rights agreement, we do not intend to register resales of the outstanding notes under the Securities Act.

If you do not exchange your outstanding notes for exchange notes in the exchange offer and other holders of outstanding notes tender their outstanding notes in the exchange offer, the total principal amount of the outstanding notes remaining after the exchange offer will be less than it was prior to the exchange offer, which may have an adverse effect upon and increase the volatility of, the market price of the outstanding notes due to reduction in liquidity.

# Your ability to transfer the notes may be limited by the absence of an active trading market, and an active trading market may not develop for the notes.

The exchange notes are a new issue of securities for which there is no established trading market. We do not intend to have the exchange notes listed on a national securities exchange or to arrange for quotation on any automated quotation system. The initial purchasers have advised us that they intend to make a market in the exchange notes, as permitted by applicable laws and regulations; however, the initial purchasers are not obligated to make a market in the exchange notes, and they may discontinue their market-making activities at any time without notice. Therefore, we cannot assure you as to the development or liquidity of any trading market for the exchange notes. The liquidity of any market for the exchange notes will depend on a number of factors, including:

the number of holders of exchange notes;

our operating performance and financial condition;

the market for similar securities;

the interest of securities dealers in making a market in the exchange notes; and

prevailing interest rates.

Historically, the market for non-investment grade debt has been subject to disruptions that have caused substantial volatility in the prices of securities similar to the exchange notes. The market, if any, for the exchange notes may face similar disruptions that may adversely affect the prices at which you may sell your exchange notes. Therefore, you may not be able to sell your exchange notes at a particular time and the price that you receive when you sell may not be favorable.

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# You may not receive the exchange notes in the exchange offer if the exchange offer procedures are not properly followed.

MIFSA will issue the exchange notes in exchange for your outstanding notes only if you properly tender the outstanding notes before expiration of the exchange offer. Neither we nor the exchange agent are under any duty to give notification of defects or irregularities with respect to the tenders of the outstanding notes for exchange. If you are the beneficial holder of outstanding notes that are held through your broker, dealer, commercial bank, trust company or other nominee, and you wish to tender such notes in the exchange offer, you should promptly contact the person or entity through which your outstanding notes are held and instruct that person or entity to tender on your behalf.

# Broker-dealers may become subject to the registration and prospectus delivery requirements of the Securities Act and any profit on the resale of the exchange notes may be deemed to be underwriting compensation under the Securities Act.

Any broker-dealer that acquires exchange notes in the exchange offer for its own account in exchange for outstanding notes which it acquired through market-making or other trading activities must acknowledge that it will comply with the registration and prospectus delivery requirements of the Securities Act in connection with any resale transaction by that broker-dealer. Any profit on the resale of the exchange notes and any commission or concessions received by a broker-dealer may be deemed to be underwriting compensation under the Securities Act.

#### **Risks Related to the Notes**

# MIFSA s indebtedness could adversely affect its financial condition and prevent it from fulfilling its obligations under the notes.

MIFSA has indebtedness, which could adversely affect its ability to fulfill its obligations under the notes and have a negative impact on its financing options and liquidity position. As of December 27, 2013, we had \$919.4 million of total debt. We expect to incur additional indebtedness in connection with our pending acquisition of Cadence. See

Risks Related to Our Pending Acquisition of Cadence Pharmaceuticals, Inc. We may also incur other additional indebtedness in the future.

Subject to the limits contained in the credit agreement that governs the credit facility, the indenture that governs the notes and our other debt instruments, we may be able to incur additional debt from time to time to finance working capital, capital expenditures, investments or acquisitions, or for other purposes. If we do so, the risks related to our high level of debt could intensify.

Our indebtedness may impose restrictions on us that could have material adverse consequences by:

limiting our ability to obtain additional financing to fund future working capital, capital expenditures, acquisitions or other general corporate requirements;

requiring a substantial portion of our cash flows to be dedicated to debt service payments instead of other purposes, thereby reducing the amount of cash flows available for working capital, capital expenditures, acquisitions and other general corporate purposes; increasing our vulnerability to general adverse economic and industry conditions;

limiting our flexibility in planning for and reacting to changes in the industry in which we compete; and

placing us at a competitive disadvantage to other, less leveraged competitors. In addition, the indenture that governs the notes and the credit agreement governing the credit facility contain restrictive covenants that limit our ability to engage in activities that may be in our long-term best interest. Our failure to comply with those covenants could result in an event of default which, if not cured or waived, could result in the acceleration of our debt.

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# We may not be able to generate sufficient cash to service all of our indebtedness, including the notes, and may be forced to take other actions to satisfy our obligations under our indebtedness, which may not be successful.

Our ability to make scheduled payments on or refinance our debt obligations, including the notes, depends on our financial condition and operating performance, which are subject to prevailing economic and competitive conditions and to certain financial, business, legislative, regulatory and other factors beyond our control. We may be unable to maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness, including the notes.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we could face liquidity problems and could be forced to reduce or delay investments and capital expenditures or to dispose of material assets or operations, seek additional debt or equity capital or restructure or refinance our indebtedness, including the notes. We may not be able to effect any such alternative measures on commercially reasonable terms or at all and, even if successful, those alternative actions may not allow us to meet our scheduled debt service obligations.

In addition, MIFSA conducts its operations through its subsidiaries, none of which are guarantors of the notes. Accordingly, repayment of MIFSA s indebtedness, including the notes, is dependent on the generation of cash flow by MIFSA s subsidiaries and their ability to make such cash available to MIFSA, by distribution, debt repayment or otherwise. MIFSA s subsidiaries do not have any obligation to pay amounts due on the notes or MIFSA s other indebtedness or to make funds available for that purpose. MIFSA s subsidiaries may not be able to, or may not be permitted to, make distributions to enable MIFSA to make payments in respect of MIFSA s indebtedness, including the notes. Each subsidiary is a distinct legal entity, and, under certain circumstances, legal and contractual restrictions may limit MIFSA s ability to obtain cash from its subsidiaries. In the event that MIFSA does not receive distributions from its subsidiaries, MIFSA may be unable to make required principal and interest payments on its indebtedness, including the notes.

Our inability to generate sufficient cash flows to satisfy our debt obligations, or to refinance our indebtedness on commercially reasonable terms or at all, would materially and adversely affect our financial position and results of operations and our ability to satisfy our obligations under the notes.

If we cannot make scheduled payments on our debt, we will be in default and holders of either series of notes could declare all outstanding principal and interest under such series of notes to be due and payable, the lenders under the credit facility could terminate their commitments to loan money, our secured lenders, if any, could foreclose against the assets securing their borrowings and we could be forced into bankruptcy or liquidation. All of these events could result in your losing your investment in the notes.

# Despite our current level of indebtedness, Mallinckrodt plc and its subsidiaries may still be able to incur more debt. This could further exacerbate the risks to our financial condition described above.

Mallinckrodt plc and its subsidiaries may be able to incur significant additional indebtedness in the future. In particular, we expect to incur significant additional indebtedness in connection with our pending acquisition of Cadence that will rank equally in right of payment with the notes. See Risks Related to Our Pending Acquisition of Cadence Pharmaceuticals, Inc. If we incur any additional indebtedness that ranks equally with the notes, subject to collateral arrangements, the holders of that debt will be entitled to share ratably with you in any proceeds distributed in connection with any insolvency, liquidation, reorganization, dissolution or other winding up of our company. This may have the effect of reducing the amount of proceeds paid to you. If new debt is added to our current debt levels, the related risks that we now face could intensify. See Description of Certain Indebtedness and Description of Notes.

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#### The terms of the credit agreement that governs the credit facility and the indenture that governs the notes restrict our current and future operations, particularly our ability to respond to changes or to pursue our business strategies.

The indenture that governs the notes and the credit agreement governing the credit facility contain a number of restrictive covenants that impose significant operating and financial restrictions on us and may limit our ability to engage in acts that may be in our long-term best interest, including limitations or restrictions on our ability to:

incur additional non-guarantor indebtedness;

pay dividends or make other distributions on or repurchase or redeem our capital stock;

incur liens;

enter into transactions with affiliates;

enter into agreements restricting the Issuer s subsidiaries ability to pay dividends;

enter into sale and leaseback transactions; and

consolidate, merge or sell all or substantially all of our assets or all or substantially all of the assets of the Specialty Pharmaceuticals segment or the Global Medical Imaging segment. As a result of these restrictions, we may be:

limited in how we conduct our business;

unable to raise additional debt or equity financing to operate during general economic or business downturns; or

unable to compete effectively, execute our growth strategy or take advantage of new business opportunities. In addition, the restrictive covenants in the credit agreement that govern the credit facility require us to maintain specified financial ratios. Our ability to meet those financial ratios can be affected by events beyond our control.

A breach of the covenants under the indenture that governs the notes or under the credit agreement that governs the credit facility could result in an event of default under the applicable indebtedness. Such a default may allow the creditors to accelerate the related debt and may result in the acceleration of any other debt to which a

cross-acceleration or cross-default provision applies. In addition, an event of default under the credit agreement that governs the credit facility would permit the lenders under the credit facility to terminate all commitments to extend further credit under the credit facility. In the event our lenders or noteholders accelerate the repayment of our borrowings, the Issuer and Mallinckrodt may not have sufficient assets to repay that indebtedness.

# The notes rank equally in right of payment with the Issuer s indebtedness under the credit facility and are effectively subordinated to the Issuer s secured indebtedness to the extent of the value of the property securing that indebtedness.

The notes are not secured by any of the Issuer s or Mallinckrodt s assets. As a result, the notes and the guarantee rank equally in right of payment with the Issuer s and Mallinckrodt s indebtedness under the credit facility. As of December 27, 2013, we have total unused availability under the credit facility of approximately \$250 million. In addition, we may incur secured debt in the future, which will be effectively senior to the Issuer s obligations under the notes and credit facility, to the extent of the value of the property securing that indebtedness. The effect of this effective subordination of the notes and credit facility is that upon a default in payment on, or the acceleration of, any of our secured indebtedness, or in the event of bankruptcy, insolvency,

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liquidation, dissolution or reorganization of our company or of that other secured debt, the proceeds from the sale of assets securing our secured indebtedness will be available to pay obligations on the notes and credit agreement only after all indebtedness under our secured debt has been paid in full. As a result, the holders of the notes may receive less, ratably, than the holders of secured debt in the event of the Issuer s or Mallinckrodt s bankruptcy, insolvency, liquidation, dissolution or reorganization.

We expect the indebtedness that we anticipate incurring in connection with our pending acquisition of Cadence to be secured by certain of our assets. See Risks related to Our Pending Acquisition of Cadence Pharmaceuticals, Inc.

#### The notes are structurally subordinated to all obligations of the Issuer s existing and future subsidiaries.

MIFSA s subsidiaries have no obligation, contingent or otherwise, to pay amounts due under the notes or to make any funds available to pay those amounts, whether by dividend, distribution, loan or other payment. The notes are structurally subordinated to all indebtedness and other obligations of any subsidiary of MIFSA such that in the event of insolvency, liquidation, reorganization, dissolution or other winding up of any such subsidiary, all of that subsidiary s creditors (including trade creditors and preferred stockholders, if any) are entitled to payment in full out of that subsidiary s assets before MIFSA is entitled to any payment.

We expect the indebtedness that we anticipate incurring in connection with our pending acquisition of Cadence to be guaranteed by certain of MIFSA s subsidiaries. See Risks related to Our Pending Acquisition of Cadence Pharmaceuticals, Inc.

In addition, the indenture that governs the notes permits these subsidiaries to incur additional indebtedness and does not contain any limitation on the amount of other liabilities, such as trade payables, that may be incurred by these subsidiaries. See Description of Notes Negative Covenants.

#### MIFSA may not be able to repurchase the notes upon a change of control.

Upon the occurrence of specific change of control events, we are required to offer to repurchase all outstanding notes at 101% of their principal amount, plus accrued and unpaid interest to, but not including, the date of repurchase. Additionally, under the credit facility, the occurrence of one or more certain change of control events may constitute an event of default that permits the lenders to accelerate the obligations under the credit facility and terminate their commitments to lend thereunder. The source of funds for any repurchase of the notes and repayment of borrowings under the credit facility would be MIFSA s available cash or cash generated from Mallinckrodt s operations or other sources, including borrowings, sales of assets or sales of equity. MIFSA may not be able to repurchase the notes upon a change of control and repay other indebtedness that will become due. MIFSA may require additional financing from third parties to fund any such repurchases, and MIFSA may be unable to obtain financing on satisfactory terms or at all. Further, MIFSA s ability to repurchase the notes may be limited by law. In order to avoid the obligations to repurchase the notes and events of default and potential breaches of the credit agreement governing the credit facility, we may have to avoid certain change of control transactions that would otherwise be beneficial to us.

In addition, some important corporate events, such as leveraged recapitalizations, may not, under the indenture that governs the notes, constitute a change of control that would require the issuer to repurchase the notes, even though those corporate events could increase the level of our indebtedness or otherwise adversely affect our capital structure, credit ratings or the value of the notes. See Description of Notes Repurchase Upon Change of Control Triggering Event.

### Holders of the notes may not be able to determine when a sale of substantially all of our assets has occurred.

The covenants restricting consolidations, mergers or sales of all or substantially all assets in the indenture that governs the notes include a phrase relating to the sale of all or substantially all of Mallinckrodt plc s and

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MIFSA s assets. See Description of Notes Limitations on Consolidations, Mergers and Sales of Assets. There is no precise established definition of the phrase substantially all under applicable law. Accordingly, the ability of a holder of notes to enforce these covenants as a result of a sale of less than all our assets to another person may be uncertain.

Federal and state fraudulent transfer laws may permit a court to void the notes and/or the guarantees, and if that occurs, you may not receive any payments on the notes.

Federal and state fraudulent transfer and conveyance statutes may apply to the issuance of the notes and the incurrence of the guarantees of the notes. Under federal bankruptcy law and comparable provisions of state fraudulent transfer or conveyance laws, which may vary from state to state, the notes or the guarantees thereof could be voided as a fraudulent transfer or conveyance if the Issuer or any of the guarantors, as applicable, (a) issued the notes or incurred the guarantees with the intent of hindering, delaying or defrauding creditors or (b) received less than reasonably equivalent value or fair consideration in return for either issuing the notes or incurring the guarantees and, in the case of (b) only, one of the following is also true at the time thereof:

the Issuer or any of the guarantors, as applicable, were insolvent or rendered insolvent by reason of the issuance of the notes or the incurrence of the guarantees;

the issuance of the notes or the incurrence of the guarantees left the Issuer or any of the guarantors, as applicable, with an unreasonably small amount of capital or assets to carry on the business;

the Issuer or any of the guarantors intended to, or believed that the Issuer or such guarantor would, incur debts beyond the Issuer s or the guarantor s ability to pay as they mature; or

the Issuer or any of the guarantors were a defendant in an action for money damages, or had a judgment for money damages docketed against the Issuer or the guarantor if, in either case, the judgment is unsatisfied after final judgment.

A court may find that a guarantor did not receive reasonably equivalent value or fair consideration for its guarantee to the extent the guarantor did not obtain a reasonably equivalent benefit directly or indirectly from the issuance of the notes.

We cannot be certain as to the standards a court would use to determine whether or not the Issuer or the guarantors were insolvent at the relevant time or, regardless of the standard that a court uses, whether the notes or the guarantees would be subordinated to the Issuer s or any of the guarantors other debt. In general, however, a court would deem an entity insolvent if:

the sum of its debts, including contingent and unliquidated liabilities, was greater than the fair saleable value of all of its assets;

the present fair saleable value of its assets was less than the amount that would be required to pay its probable liability on its existing debts, including contingent liabilities, as they become absolute and mature; or

it could not pay its debts as they became due.

If a court were to find that the issuance of the notes or the incurrence of a guarantee was a fraudulent transfer or conveyance, the court could void the payment obligations under the notes or that guarantee and could require the holders of the notes to repay any amounts received with respect to that guarantee. In the event of a finding that a fraudulent transfer or conveyance occurred, you may not receive any repayment on the notes. Further, the avoidance of the notes or the guarantees could result in an event of default with respect to the Issuer s and Mallinckrodt s other debt that could result in acceleration of that debt.

Finally, as a court of equity, a bankruptcy court could subordinate the claims in respect of the notes to other claims against us under the principle of equitable subordination if the court determines that (1) the holder of notes engaged in some type of inequitable conduct, (2) the inequitable conduct resulted in injury to our other creditors or conferred an unfair advantage upon the holders of notes and (3) equitable subordination is not inconsistent with the provisions of the bankruptcy code.

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# A lowering or withdrawal of the ratings assigned to our debt securities by rating agencies may increase our future borrowing costs and reduce our access to capital.

Our debt currently has an investment grade rating from S&P and a non-investment grade rating from Moody s. We expect that following the Merger our debt will have a non-investment grade rating from both S&P and Moody s, and any rating assigned could be lowered or withdrawn entirely by a rating agency if, in that rating agency s judgment, future circumstances relating to the basis of the rating, such as adverse changes, so warrant. Consequently, real or anticipated changes in our credit ratings will generally affect the market value of the notes. Credit ratings are not recommendations to purchase, hold or sell the notes. Additionally, credit ratings may not reflect the potential effect of risks relating to the structure or marketing of the notes.

Any future lowering of our ratings (including in connection with the transactions related to the Merger) likely would make it more difficult or more expensive for us to obtain additional debt financing. If any credit rating assigned to the notes is subsequently lowered or withdrawn for any reason (including in connection with the transactions related to the Merger), you may not be able to resell your notes without a discount.

# Challenges in the commercial and credit environment may materially adversely affect our ability to issue debt on acceptable terms and our future access to capital.

Our ability to issue debt or enter into other financing arrangements on acceptable terms could be materially adversely affected if there is a material decline in the demand for our products or in the solvency of our customers or suppliers, or if other significantly unfavorable changes in economic conditions occur. In addition, volatility in the world financial markets could increase borrowing costs or affect our ability to access the capital markets, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

# We may need additional financing in the future to meet our capital needs or to make acquisitions, and such financing may not be available on favorable or acceptable terms.

We may need to seek additional financing for general corporate purposes. For example, we may need to increase our investment in R&D activities or need funds to make acquisitions. We may be unable to obtain any desired additional financing on terms that are favorable or acceptable to us. Depending on market conditions, adequate funds may not be available to us on acceptable terms and we may be unable to fund our expansion, successfully develop or enhance products, or respond to competitive pressures, any of which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

### Risks Related to Our Pending Acquisition of Cadence Pharmaceuticals, Inc.

# The failure to successfully integrate Cadence s business and operations in the expected time frame may adversely affect the combined company s future results.

We believe that the acquisition of Cadence will result in certain benefits, including certain cost synergies and operational efficiencies. However, to realize these anticipated benefits, the businesses of Mallinckrodt and Cadence must be successfully combined. The success of the Merger will depend on the combined company s ability to realize these anticipated benefits from combining the businesses of Mallinckrodt and Cadence. The combined company may fail to realize the anticipated benefits of the Merger for a variety of reasons, including the following:

failure to successfully manage relationships with customers, distributors, licensors and suppliers;

failure to leverage the increased scale of the combined company quickly and effectively;

potential difficulties integrating and harmonizing financial reporting systems;

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the loss of key employees; and

failure to effectively coordinate sales and marketing efforts to communicate the capabilities of the combined company.

The actual integration may result in additional and unforeseen expenses or delays. If the combined company is not able to successfully integrate Cadence s business and operations, or if there are delays in combining the businesses, the anticipated benefits of the Merger may not be realized fully or at all or may take longer to realize than expected.

#### Failure to complete the Merger could negatively impact our future business and financial results.

If the Merger is not completed, our ongoing business may be adversely affected and we will be subject to a number of risks, including the following:

we will be required to pay certain costs relating to the Merger, such as legal, accounting, financial advisor and printing fees whether or not the Merger is completed; and

matters relating to the Merger (including integration planning) may require substantial commitments of time and resources by our management, which could otherwise have been devoted to other opportunities that may have been beneficial to us,

in each case, without realizing any of the benefits of having completed the Merger. If the Merger is not completed, these risks may materialize and may adversely affect our business, financial condition, results of operations and cash flows.

Our indebtedness following the completion of the Merger will be substantially greater than our indebtedness prior to the transaction. This increased level of indebtedness could adversely affect us, including by decreasing our business flexibility and increasing our borrowing costs.

After the Merger, we will have a significant amount of indebtedness. Our high level of debt could have important consequences to the holders of the notes, including:

making it more difficult for us to satisfy our obligations with respect to the notes and our other debt;

limiting our ability to obtain additional financing to fund future working capital, capital expenditures, acquisitions or other general corporate requirements;

requiring a substantial portion of our cash flows to be dedicated to debt service payments instead of other purposes, thereby reducing the amount of cash flows available for working capital, capital expenditures, acquisitions and other general corporate purposes;

increasing our vulnerability to general adverse economic and industry conditions;

exposing us to the risk of increased interest rates as certain of our borrowings, including borrowings under the credit facilities, are at variable rates of interest;

limiting our flexibility in planning for and reacting to changes in the industry in which we compete;

placing us at a competitive disadvantage to other, less leveraged competitors; and

increasing our cost of borrowing.

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#### We expect that the terms of the credit agreement that will govern the Senior Secured Credit Facilities will restrict our current and future operations, particularly our ability to respond to changes or to pursue our business strategies.

We expect that the credit agreement governing the Senior Secured Credit Facilities will contain a number of restrictive covenants that impose significant operating and financial restrictions on us and may limit our ability to engage in acts that may be in our long-term best interest, including limitations or restrictions on our ability to:

incur additional indebtedness;

pay dividends or make other distributions on or repurchase or redeem our capital stock;

prepay, redeem or repurchase certain debt;

make loans and investments;

sell assets;

incur liens;

enter into transactions with affiliates;

enter into agreements restricting the ability of the subsidiaries of Mallinckrodt plc to pay dividends; and

consolidate, merge or sell all or substantially all of our assets. As a result of these restrictions, we may be:

limited in how we conduct our business;

unable to raise additional debt or equity financing to operate during general economic or business downturns; or

unable to compete effectively, execute our growth strategy or take advantage of new business opportunities.

In addition, the credit agreement that will govern the Revolving Credit Facility will require us to maintain a maximum total net leverage ratio under certain circumstances. Our ability to meet such financial ratio can be affected by events beyond our control.

A breach of the covenants under the credit agreement that will govern the Senior Secured Credit Facilities could result in an event of default under the notes. Such a default may allow the creditors to accelerate the Senior Secured Credit Facilities and may result in the acceleration of any other debt to which a cross-acceleration or cross-default provision applies, including the notes. In addition, an event of default under the credit agreement that will govern the Senior Secured Credit Facilities would permit the lenders under our Senior Secured Credit Facilities to terminate all commitments to extend further credit under our Senior Secured Credit Facilities. Furthermore, if we were unable to repay the amounts due and payable under the Senior Secured Credit Facilities, those lenders could proceed against the collateral granted to them to secure that indebtedness. In the event our creditors accelerate the repayment of our borrowings, we may not have sufficient assets to repay that indebtedness.

# Cadence s business and the commercial and financial success of our acquisition of Cadence depend on the commercial success of Cadence s only product, OFIRMEV.

Cadence s success, and consequently the success of our acquisition of Cadence, depends on the continued success of the commercialization of its only product, OFIRMEV, which was approved by the FDA in November 2010 for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever in adults and children two years of age and older.

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Cadence launched OFIRMEV in January 2011, but our ability to maintain and increase revenues from sales of OFIRMEV following the completion of our acquisition of Cadence will depend on several factors, including:

our ability to increase market demand for OFIRMEV through our own marketing and sales activities, and any other arrangements to promote this product we may later establish;

our ability to maintain and defend the patent protection and regulatory exclusivity of OFIRMEV;

our ability to continue to procure a supply of OFIRMEV from its sole source third-party manufacturer in sufficient quantities and at acceptable quality and pricing levels in order to meet commercial demand;

the performance of Cadence s third-party manufacturer and our ability to ensure that the supply chain for OFIRMEV efficiently and consistently delivers OFIRMEV to our customers;

our ability to deploy and support a qualified sales force;

our ability to maintain fees and discounts payable to the wholesalers and distributors who distribute OFIRMEV, as well as to group purchasing organizations, at commercially reasonable levels;

whether the Federal Trade Commission (FTC), Department of Justice (DOJ) or third parties seek to challenge and are successful in challenging Cadence s settlement agreement with Paddock Laboratories, Inc., Perrigo Company and Paddock Laboratories, LLC (collectively, Perrigo) or its settlement agreement with Sandoz, Inc., Sandoz AG, Neogen International N.V. and APC Pharmaceuticals, LLC;

warnings or limitations that may be required to be added to OFIRMEV s FDA-approved labeling;

the occurrence of adverse side effects or inadequate therapeutic efficacy of OFIRMEV, and any resulting product liability claims or product recalls; and

our ability to achieve hospital formulary acceptance for OFIRMEV, and to the extent third-party payors separately cover and reimburse for OFIRMEV, the availability of adequate levels of reimbursement for OFIRMEV from third-party payors.

Following the completion of the Merger, any disruption in our ability to generate revenues from the sale of OFIRMEV or lack of success in its commercialization will have a substantial adverse impact on our business, financial condition, results of operations and cash flows.

# The patent rights that Cadence has in-licensed covering OFIRMEV are limited to a specific IV formulation of acetaminophen. As a result, the market opportunity for this product may be limited by the lack of patent protection for the active ingredient itself and other formulations of IV acetaminophen may be developed by competitors.

The active ingredient in OFIRMEV is acetaminophen. Patent protection is not available for the acetaminophen molecule itself in the territories licensed to Cadence, which include the U.S. and Canada. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredient as OFIRMEV so long as the competitors do not infringe any process or formulation patents that Cadence has in-licensed from Bristol-Myers Squibb Company (BMS) and its licensor, SCR Pharmatop S.A. (Pharmatop). Cadence is the exclusive licensee of two U.S. patents and two Canadian patents owned by Pharmatop, under BMS s license to these patents from Pharmatop. U.S. Patent No. 6,028,222, or the 222 patent (Canadian patent number 2,233,924), covers the formulation of OFIRMEV, and this patent expires in August 2017. U.S. Patent No. 6,992,218, or the 218 patent (Canadian patent number 2,415,403), covers the process used to manufacture OFIRMEV, and this patent expires in June 2021. Cadence plans to complete a pediatric clinical trial of OFIRMEV and, upon timely completion and the acceptance by the FDA of the data from this study, Cadence expects that OFIRMEV will be eligible for an additional six months of marketing exclusivity in the U.S.

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We are also aware of several U.S. and Canadian patents and patent applications directed to various potential injectable formulations of acetaminophen as well as methods of making and using these potential formulations. For example, Injectapap, a liquid formulation of acetaminophen for intramuscular injection, was approved by the FDA for the reduction of fever in adults in March 1986, although it was subsequently withdrawn from the market by McNeil Pharmaceutical in July 1986. The number of patents and patent applications directed to products in the same field as OFIRMEV indicates that competitors have sought to develop and may seek to market competing formulations that may not be covered by Cadence s licensed patents and patent applications. The commercial opportunity for OFIRMEV could be significantly harmed if competitors are able to develop alternative formulations of acetaminophen outside the scope of Cadence s in-licensed patents. We are also aware of a number of third-party patents in the U.S. that claim methods of making acetaminophen.

Five third-parties have challenged, and additional third parties may challenge, the patents covering OFIRMEV, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. If a third party files an NDA or ANDA for a generic drug product containing acetaminophen and relies in whole or in part on studies conducted by or for Cadence, the third party will be required to certify to the FDA that, in the opinion of that third party, the patent listed in the Orange Book for a branded product is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the third party s generic drug product. A third party certification that the new product will not infringe the Orange Book-listed patents for OFIRMEV, or that such patents are invalid, is called a Paragraph IV patent certification. If the third party submits a Paragraph IV patent certification to the FDA, a notice of the Paragraph IV patent certification must also be sent to Cadence once the third party s NDA or ANDA is accepted for filing by the FDA. A lawsuit may then be initiated to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of the receipt of notice of a Paragraph IV patent certification automatically prevents the FDA from approving the NDA or ANDA until the earlier of the expiration of a 30-month period, the expiration of the patents, the entry of a settlement order stating that the patents are invalid or not infringed, a decision in the infringement case that is favorable to the NDA or ANDA applicant, or such shorter or longer period as the court may order. If a patent infringement lawsuit is not initiated within the required 45-day period, the third-party s NDA or ANDA will not be subject to the 30-month stay.

For example, in August 2011, Cadence and Pharmatop filed suit in the United States District Court for the District of Delaware against Perrigo and Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc. (collectively, Exela). The lawsuit followed the notices that Cadence received in July 2011 from each of Perrigo and Exela concerning their filings of ANDAs containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In the lawsuit, Cadence alleged that Perrigo and Exela each infringed the 222 patent and the 218 patent by filing their respective ANDAs seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. The 222 and the 218 patents are listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The patent infringement lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Perrigo ANDA and the Exela ANDA until the earlier of the expiration of a 30-month period, the expiration of the

222 and 218 patents, the entry of a settlement order or consent decree stating that the 222 and 218 patents are invalid or not infringed, a decision in the case concerning infringement or validity that is favorable to Perrigo or Exela, or such shorter or longer period as the Court may order. Each of Perrigo and Exela filed an answer in the case that asserted, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims.

Cadence settled with Perrigo and the case against Perrigo was dismissed on November 30, 2012. In connection with the settlement and license agreements entered into in November 2012, Perrigo was granted the exclusive right of first refusal to negotiate an agreement with Cadence to market an authorized generic version of OFIRMEV in the U.S. in the event that Cadence elects to launch an authorized generic version of the product. The license agreement also provides that, if Cadence enters into an agreement for Perrigo to market an authorized

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generic version of OFIRMEV during the license period, Perrigo would purchase the product exclusively from Cadence. Cadence would receive product costs plus an administrative fee, as well as a royalty payment based on the net profits achieved by Perrigo from the sale of the authorized generic product. Additionally, Cadence granted Perrigo the non-exclusive right to market a generic IV acetaminophen product in the U.S. under Perrigo s ANDA after December 6, 2020, or earlier under certain circumstances. The FTC or the DOJ could seek to challenge Cadence s settlement with Perrigo, or a competitor, customer or other third-party could initiate a private action under antitrust or other laws challenging the settlement with Perrigo. Any such challenge could be both expensive and time consuming and may render the settlement agreement unenforceable.

A bench trial for the lawsuit with Exela was held in May 2013, with one additional trial date held in early July 2013. In November 2013, the court ruled in favor of Cadence and found that Exela s ANDA for a generic version of OFIRMEV infringed the 222 and 218 patents. An appeal of the decision in favor of Cadence was filed by Exela on December 20, 2013. It is not possible to predict the outcome of this appeal, and an adverse outcome could result in the launch of one or more generic versions of OFIRMEV before the expiration of the last of the listed patents in June 6, 2021 (or December 6, 2021 if pediatric exclusivity is granted), which could adversely affect our ability to successfully maximize the value of OFIRMEV if our acquisition of Cadence is completed, and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

In addition, in January 2013, Cadence filed suit in the United States District Court for the Southern District of California against Fresenius Kabi USA, LLC ( Fresenius ) following receipt of a December 2012 notice from Fresenius concerning its submission of an NDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In February 2013, Cadence filed suit in the United States District Court for the Southern District of California against Sandoz, Inc. ( Sandoz ) following receipt of a December 2012 notice from Sandoz concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In October 2013, Cadence filed a motion to amend its complaint against Sandoz to join Sandoz AG, Neogen International N.V., APC Pharmaceuticals, LLC, and DIACO S.p.A. (together with Sandoz, the Sandoz Parties ) to the lawsuit against Sandoz due to the involvement of each of these companies with the preparation of the Sandoz ANDA and related matters. In the lawsuits against Fresenius and the Sandoz Parties, which were coordinated for purposes of discovery and other pretrial proceedings in the Southern District of California, Cadence alleged that Fresenius and the Sandoz Parties each infringed the 222 patent and the 218 patent by filing an NDA, in the case of Fresenius, or an ANDA, in the case of the Sandoz Parties, seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. Both Fresenius and the Sandoz Parties filed answers in the Southern District of California asserting, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims. Both the Fresenius and Sandoz lawsuits were filed within 45 days of receipt of the respective notice letters, thereby triggering a stay of FDA approval of the Fresenius NDA and the Sandoz ANDA until the earlier of the expiration of a 30-month period, the expiration of the 222 and 218 patents, the entry of a settlement order or consent decree stating that the 222 and 218 patents are invalid or not infringed, a decision in the case concerning infringement or validity that is favorable to Fresenius and/or the Sandoz Parties, or such shorter or longer period as the Court may order.

In January 2014, Cadence entered into a settlement agreement and a binding term sheet for a license agreement with the Sandoz Parties. The settlement agreement includes a stipulation by the parties requesting dismissal with prejudice of the lawsuit filed by Cadence relating to the ANDA filed by Sandoz. Under the terms of the license, Cadence granted to the holder of the Sandoz ANDA and its affiliates the non-exclusive right to market a generic intravenous acetaminophen product in the United States under the Sandoz ANDA beginning December 6, 2020, or earlier under certain circumstances. Cadence also agreed that in the event that Cadence determines to launch an authorized generic version of OFIRMEV (i.e., a generic version marketed under Cadence s NDA) in the U.S. and Perrigo elects not to exercise its right of first refusal to become the distributor of the authorized generic version of the product, Cadence

will grant a similar right of first refusal to the holder of the Sandoz ANDA on substantially the same terms as those previously granted to Perrigo. In addition, the license

agreement will contain provisions regarding indemnification, confidentiality and other customary provisions for agreements of these kinds. The settlement documents are subject to submission to the Federal Trade Commission and the U.S. Department of Justice. Litigation remains ongoing against Fresenius, and the bench trial for such lawsuit is tentatively scheduled to commence on July 14, 2014.

In December 2013, Cadence received a notice from Wockhardt USA LLC (Wockhardt) stating that Wockhardt filed an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. This notice stated that the Paragraph IV patent certification was made with respect to both the 222 patent and the 218 patent. Cadence filed suit against Wockhardt Limited, Wockhardt BIO AG and Wockhardt on January 22, 2014 in the U.S. District Court of Delaware, and on January 23, 2014, in the U.S. District Court of New Jersey.

Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature and may be very expensive and time-consuming. If our pending acquisition of Cadence is completed, litigation relating to Cadence and its intellectual property may result in unfavorable results that could adversely impact our ability to prevent third parties from competing with our products. Any adverse outcome of such litigation could result in one or more generic versions of OFIRMEV being launched without our or Cadence s consent before the expiration of one or both of the patents Cadence has in-licensed from BMS and its licensor, Pharmatop, which could adversely affect our ability to successfully execute our business strategy to increase sales of OFIRMEV following the completion of the Merger and negatively impact our financial condition and results of operations. Cadence and, following the completion of the Merger, Mallinckrodt, intends to vigorously enforce Cadence s consent prior to the expiration of its patents. However, given the unpredictability inherent in litigation, we cannot predict or guarantee the outcome of these matters or any other litigation. Regardless of how these matters are ultimately resolved, these matters may be costly, time-consuming and distracting to our management, which could have a material adverse effect on our business.

# The protection of Cadence s intellectual property rights is critical to its success and any failure on its or our part to adequately secure such rights would materially affect our business following the completion of the Merger.

Cadence s commercial success depends on maintaining patent protection and trade secret protection for OFIRMEV, as well as for any other products or product candidates that Cadence may license or acquire, and successfully defending these patents and trade secrets against third-party challenges. Cadence will only be able to protect its technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

In April 2012, Exela filed suit against David J. Kappos and the U.S. Patent and Trademark Office (USPTO) in the United States District Court for the Eastern District of Virginia for declaratory judgment seeking a reversal of the USPTO s decision not to act on a petition by Exela to vacate the USPTO s April 2003 order reviving the international application for the 218 patent. The lawsuit followed the USPTO s rejection of Exela s petition to the USPTO filed in November 2011, which sought to vacate the April 23, 2003 order granting Pharmatop s petition to revive the 218 patent. The USPTO determined that Exela lacked standing to seek such relief. Exela also seeks declaratory judgment that the USPTO s rules and regulations that allow for revival of abandoned, international patent applications under the unintentional standard are invalid, and similar relief in connection with one or more counterclaims it has filed in the Delaware litigation. Cadence s motion to intervene in this lawsuit was granted in October 2012. In December 2012, the district court dismissed the case with prejudice as barred by the applicable statute of limitations. In February 2013, Exela appealed the district court s decision to the Court of Appeals for the Federal Circuit. Oral argument was held on February 3, 2014. A decision by the Court of Appeals in favor of Exela could result in the invalidation of the 218 patent.

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Additionally, in September 2012, an unidentified third party (subsequently identified as Exela) filed with the USPTO a Request for Ex Parte Reexamination of the 222 patent. In December 2012, Cadence received notice that the USPTO had granted the Request for Reexamination. The reexamination process is provided for by law and requires the USPTO to consider the scope and validity of the patent based on substantial new questions of patentability raised by a third party or the USPTO. In February 2013, Cadence and Pharmatop filed with the USPTO a patent owner s statement commenting on the reexamination request, and in April 2013, Exela filed comments in response to the patent owner s statement. In a non-final, initial office action issued by the USPTO on August 13, 2013, the USPTO rejected certain claims of the 222 patent. A response to the first office action was filed in November 2013.

In addition, in January 2014, an unidentified third party filed with the USPTO a Request for Ex Parte Reexamination of the 218 patent. All of the claims of the 222 and 218 patents remain valid and in force during the reexamination proceedings. Because Cadence and Pharmatop believe that the scope and validity of the patent claims in these patents are appropriate and that the USPTO s prior issuances of the patents were correct, Cadence, in conjunction with Pharmatop, will vigorously defend these patents. We cannot predict whether Cadence and Pharmatop (and us, if our acquisition of Cadence is completed) ultimately will succeed in maintaining the scope and validity of the claims of these patents during reexamination. If any of the patent claims in these patents ultimately are narrowed during prosecution before the USPTO, the extent of the patent coverage afforded to OFIRMEV could be impaired, which could potentially harm our business and operating results.

On November 4, 2013, Cadence submitted a citizen petition to the FDA requesting that the FDA refrain from approving any new acetaminophen product for parenteral use that does not have an identical inactive ingredient profile as OFIRMEV without nonclinical studies and adequate and well-controlled clinical trials demonstrating the product is as safe and effective as OFIRMEV. The FDA is required by statute to issue a response to Cadence s citizen petition within 150 days, or no later than April 3, 2014; however, we cannot predict when or if the FDA will issue a final response to, or otherwise take any other action with respect to, Cadence s petition.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the U.S. The patent situation outside the U.S. is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of Cadence s intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in Cadence s patents or in third-party patents.

The degree of future protection for Cadence s proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect its rights or permit Cadence to gain or keep its competitive advantage. For example:

Cadence s licensors might not have been the first to make the inventions covered by each of its pending patent applications and issued patents;

Cadence s licensors might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative technologies or duplicate any of Cadence s products, product candidates or technologies;

the issued patents covering Cadence s products or product candidates may not provide a basis for commercially viable active products, may not provide Cadence with any competitive advantages, or may be challenged by third parties;

Cadence may not develop additional proprietary technologies that are patentable; or

patents of others may have an adverse effect on Cadence s business.

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Patent applications in the U.S. are maintained in confidence for at least 18 months after their earliest effective filing date. Consequently, Cadence cannot be certain that its licensors were the first to invent or the first to file patent applications on its products or product candidates. In the event that a third party has also filed a U.S. patent application relating to its products or product candidates or a similar invention, Cadence may have to participate in interference proceedings declared by the USPTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial and it is possible that Cadence s efforts would be unsuccessful, resulting in a material adverse effect on its U.S. patent position. Furthermore, Cadence may not have identified all U.S. and foreign patents or published applications that affect its business either by blocking its ability to commercialize its drugs or by covering similar technologies that affect its drug market.

In addition, some countries, including Canada, do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect Cadence s products or product candidates. Even if patents are issued, we cannot guarantee that the claims of those patents will be valid and enforceable or provide Cadence with any significant protection against competitive products, or otherwise be commercially valuable to Cadence.

Cadence also relies on trade secrets to protect its technology, particularly where it does not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Cadence s licensors, employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose its information to competitors. Enforcing a claim that a third party illegally obtained and is using Cadence s trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, Cadence s competitors may independently develop equivalent knowledge, methods and know-how.

If Cadence s licensors or Cadence fail to obtain or maintain patent protection or trade secret protection for OFIRMEV or any other product or product candidate it may license or acquire, third parties could use its proprietary information, which could impair its ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability if our acquisition of Cadence is completed.

### **Risks Related to Our Business**

# The DEA regulates the availability of controlled substances that are API, drug products under development and marketed drug products. At times, the procurement and manufacturing quotas granted by the DEA may be insufficient to meet our commercial and R&D needs.

The U.S. DEA is the federal agency responsible for domestic enforcement of the Controlled Substances Act of 1970 (the CSA). The CSA classifies drugs and other substances based on identified potential for abuse. Schedule I controlled substances, such as heroin and LSD, have a high abuse potential and have no currently accepted medical use; thus, they cannot be lawfully marketed or sold. Schedule II or III controlled substances include molecules such as oxycodone, oxymorphone, morphine, fentanyl, hydrocodone and methylphenidate.

The manufacture, storage, distribution and sale of these controlled substances are permitted, but highly regulated. The DEA regulates the availability of API, products under development and marketed drug products that are Schedule II or III by setting annual quotas. Every year, we must apply to the DEA for manufacturing quota to manufacture API and procurement quota to manufacture finished dosage products. Given that the DEA has discretion to grant or deny our manufacturing and procurement quota requests, the quota the DEA grants may be insufficient to meet our commercial and R&D needs. To date in calendar 2013, manufacturing and procurement quotas granted by the DEA have been sufficient to meet our sales and inventory requirements on most products. During calendar 2012, the initial

hydrocodone manufacturing and procurement quota grants we received from the DEA were below the amounts requested and were therefore insufficient to meet customer demand. While we were granted additional quota, these shortfalls did result in lost sales of hydrocodone products, the amount of which was not significant. Future delay or refusal by the DEA to grant, in whole or in

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part, our quota requests could delay or result in stopping the manufacture of our marketed drug products, new product launches or the conduct of bioequivalence studies and clinical trials. Such delay or refusal also could require us to allocate marketed drug products among our customers. These factors, along with any delay or refusal by the DEA to provide customers who purchase API from us with sufficient quota, could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

### The manufacture of our products is highly exacting and complex, and our business could suffer if we, or our suppliers, encounter manufacturing or supply problems.

The manufacture of our products is highly exacting and complex, due in part to strict regulatory and manufacturing requirements. Problems may arise during manufacturing for a variety of reasons including equipment malfunction, failure to follow specific protocols and procedures, defective raw materials and environmental factors. If a batch of finished product fails to meet quality standards during a production run, then that entire batch of product may have to be discarded. These problems could lead to backorders, increased costs (including contractual damages for failure to meet supply requirements), lost revenue, damage to customer relationships, time and expense spent investigating, correcting and preventing the root causes and, depending on the root causes, similar losses with respect to other products. In fiscal 2012, we experienced disruptions in supplying products to our customers due to a number of factors, including mechanical, capacity and packaging quality control issues and the implementation of a new production planning system at our Hobart, New York manufacturing facility. These issues resulted in higher than usual backorders and obligations to pay contractual damages for failure to meet supply requirements. During fiscal 2012, our Generics business incurred approximately \$13 million of expenses for such contractual damages, a substantial portion of which was attributable to the issues experienced at this facility. We did not experience material expenses in fiscal 2013 related to manufacturing problems. In the event that manufacturing problems are not discovered before the product is released to the market, we also could incur product recall and product liability costs. If we incur a product recall or product liability costs involving one of our products, such product could receive reduced market acceptance and thus reduced product demand and could harm our reputation and our ability to market our products in the future. Significant manufacturing problems could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

# The global supply of fission-produced Mo-99 is limited. Our inability to obtain and/or to timely transport Mo-99 to our Tc-99m generator production facilities could prevent us from delivering our Ultra-Technekow DTE Tc-99m generators to our customers in the required quantities, within the required timeframe, or at all, which could result in order cancellations and decreased revenues or increased costs if we procure supply from other sources.

Mo-99 is a critical ingredient of our Tc-99m generators. Mo-99 is produced in nuclear research reactors utilizing HEU or LEU targets. These targets, either tubular or flat and of varying sizes, are fabricated from HEU or LEU and, in either case, aluminum. The targets are placed in or near the core of the nuclear reactor where fission reactions occur resulting in the production of Mo-99 and other isotopes. This process, which takes approximately six days, is known as target irradiation. There are currently eight reactors around the world producing the global supply of Mo-99. We have agreements to obtain Mo-99 from three of these reactors and we rely predominantly on two of these reactors for our Mo-99 supply. These reactors are subject to scheduled and unscheduled shutdowns which can have a significant impact on the amount of Mo-99 available for processing. Mo-99 produced at these reactors is then finished at one of five processing sites located throughout the world, including our processing facility located in the Netherlands. At the processing facility, the targets are dissolved and chemically separated. In this process, the Mo-99 is isolated as a radiochemical. Once finished, Mo-99 must be transported to generator facilities where it is loaded into our Tc-99m generators that are sold, in the U.S., principally to nuclear radiopharmacies as well as hospitals and, in Europe and other markets, principally to hospitals, where single unit doses are then prepared. Mo-99 has a 66-hour half-life and decays primarily into Tc-99m, which has a half-life of only six hours. The radiopharmacies or hospitals prepare

dosages from the Tc-99m generators for use in SPECT imaging medical procedures. Given the product s radioactive decay, if we encounter

delays in transporting Mo-99 to our generator facilities, or if the generator facilities experience delays in loading Mo-99, we may be limited in the amount of Ultra-Technekow DTE generators that we could manufacture, distribute and sell, which could have a material adverse effect on our competitive position, business, financial condition, results of operation and cash flows.

In November 2012, the High Flux Reactor ( HFR ) in the Netherlands, one of two primary reactors we utilize, experienced an unscheduled shutdown. We were able to receive increased target irradiations at the two other reactors and purchased additional Mo-99 from other sources to continue meeting customer orders; however, the additional Mo-99 we procured from alternative sources came at a higher than normal cost. The reactor resumed production in June 2013.

In October 2013, the HFR experienced another unscheduled shutdown. In addition, our own Mo-99 processing facility in the Netherlands also experienced a shutdown. The HFR resumed production in late February 2014. Our Mo-99 processing facility remains shut down. Until it resumes production, we expect to fulfill customer orders through processing of Mo-99 from alternative sources at higher costs.

Future unplanned shutdowns of nuclear reactors that we use to irradiate targets could impact the amount of available Mo-99, which could result in global shortages, continued increased raw material costs and decreased sales. While we are pursuing additional sources of Mo-99 from potential producers around the world to augment our current supply, it is not certain whether these possible additional sources of Mo-99 will produce commercial quantities of Mo-99 for our business, or that these suppliers, together with our current suppliers, will be able to deliver a sufficient quantity of Mo-99 to meet our needs. Ongoing increased raw material and manufacturing costs will limit our ability to return the Global Medical Imaging segment to historical operating margins.

# In response to the U.S. National Security Administration s Global Threat Initiative, we are in the process of converting our Mo-99 production operation in the Netherlands from HEU targets to LEU targets. There can be no assurance that we will be successful in completing this conversion.

We currently use HEU targets for the production of Mo-99. In 2004, the U.S. National Security Administration established its Global Threat Initiative to, as quickly as possible, identify, secure and remove or facilitate the disposition of vulnerable, high-risk nuclear and radiological materials around the world. Included as one of the stated initiatives is the conversion by research reactors and isotope production facilities to LEU from HEU. We are in the process of converting our Mo-99 production operation in the Netherlands to LEU targets. However, there is no assurance that we will be successful in completing the conversion. If we are successful in converting to LEU targets, we expect that the manufacturing costs will be higher than those incurred while utilizing HEU targets, which may negatively impact the profitability of our Global Medical Imaging segment.

### Our customer concentration may materially adversely affect our financial condition and results of operations.

We primarily sell our products to a limited number of wholesale drug distributors and large pharmacy chains. In turn, these wholesale drug distributors and large pharmacy chains supply products to pharmacies, hospitals, governmental agencies and physicians. Sales to two of our distributors that supply our products to many end user customers, Cardinal Health, Inc. and McKesson Corporation, each accounted for 10% or more of our total net sales in each of the past three fiscal years. Additionally, AmerisourceBergen Corporation accounted for 10% of our total net sales in fiscal 2011. If we were to lose the business of these distributors, or if these distributors were to experience difficulty in paying us on a timely basis, this could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

### Cost-containment efforts of our customers, purchasing groups, third-party payors and governmental organizations could materially adversely affect our net sales and results of operations.

In an effort to reduce cost, many existing and potential customers for our products within the U.S. have become members of group purchasing organizations (GPOs) and integrated delivery networks (IDNs). GPOs and IDNs negotiate pricing arrangements with healthcare product manufacturers and distributors and offer the negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple manufacturers with the intention of driving down pricing. Due to the highly competitive nature of the GPO and IDN contracting processes, there is no assurance that we will be able to obtain or maintain contracts with major GPOs and IDNs across our product portfolio. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our products, thereby reducing our profitability. While having a contract with a GPO or IDN for a given product can facilitate sales to members of that GPO or IDN, having a contract is no assurance that sales volume of those products will be maintained. GPOs and IDNs increasingly are awarding contracts to multiple suppliers for the same product category. Even when we are the sole contracted supplier of a GPO or IDN for a certain product, members of the GPO or IDN generally are free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause upon 60 to 90 days prior notice. Accordingly, although we have contracts with many major GPOs and IDNs, the members of such groups may choose to purchase from our competitors, which could result in a decline in our net sales and results of operations.

Distributors of our products are negotiating terms of sale more aggressively in an effort to increase their profitability. Failure to negotiate distribution arrangements having advantageous pricing and other terms of sale could cause us to lose market share to our competitors and could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. Outside the U.S., we have experienced pricing pressure due to the concentration of purchasing power in centralized governmental healthcare authorities and increased efforts by such authorities to lower healthcare costs. We frequently are required to engage in competitive bidding for the sale of our products to governmental purchasing agents. Our failure to offer acceptable prices to these customers could materially adversely affect our net sales and results of operations in these markets.

### We may be unable to successfully develop or commercialize new products or adapt to a changing technology and diagnostic treatment landscape and, as a result, our results of operations may suffer.

Our future results of operations will depend to a significant extent upon our ability to successfully develop and commercialize new products in a timely manner. There are numerous difficulties in developing and commercializing new products, including:

developing, testing and manufacturing products in compliance with regulatory and quality standards in a timely manner;

receiving requisite regulatory approvals for such products in a timely manner, or at all;

the availability, on commercially reasonable terms, of raw materials, including API and other key ingredients;

developing and commercializing a new product is time-consuming, costly and subject to numerous factors, including legal actions brought by our competitors, that may delay or prevent the development and commercialization of new products;

unanticipated costs;

payment of prescription drug user fees to the FDA to defray the costs of review and approval of marketing applications for branded and generic drugs;

experiencing delays as a result of limited resources at the FDA or other regulatory authorities;

changing review and approval policies and standards at the FDA or other regulatory authorities;

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potential delay in the commercializing of generic products by up to 30 months resulting from the listing of patents with the FDA; and

effective execution of the planned launch in a manner that is consistent with anticipated costs. As a result of these and other difficulties, products currently in development by us may or may not receive timely regulatory approvals, or approvals at all, as to one or more dosage strengths. This risk particularly exists with respect to the development of proprietary products due to the uncertainties, higher costs and length of time associated with R&D of such products and the inherent unproven market acceptance of such products. In addition, we face heightened risks in connection with our development of extended-release products because of the technical complexities and evolving regulatory and quality requirements related to such products. Moreover, the FDA regulates the facilities, processes and procedures used to manufacture and market pharmaceutical products in the U.S. Manufacturing facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with current good manufacturing practice ( cGMP ) regulations enforced by the FDA. Compliance with cGMP regulations requires the dedication of substantial resources and requires significant expenditures. The FDA periodically inspects both our facilities and procedures to ensure compliance. The FDA may cause a suspension or withdrawal of product approvals if regulatory standards are not maintained. In the event an approved manufacturing facility for a particular drug is required by the FDA to curtail or cease operations, or otherwise becomes inoperable, obtaining the required FDA authorization to manufacture at the same or a different manufacturing site could result in production delays, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

With respect to generic products for which we are the first developer to have its application accepted for filing by the FDA, and which filing includes a certification that the applicable patent(s) are invalid, unenforceable and/or not infringed (known as a Paragraph IV certification ), our ability to obtain and realize the full benefits of 180-days of market exclusivity is dependent upon a number of factors, including, for example, being the first to file, the status of any litigation that might be brought against us as a result of our filing or our not meeting regulatory, manufacturing or quality requirements or standards. If any of our products are not timely approved, or if we are unable to obtain and realize the full benefits of the 180-day market exclusivity period for our products, or if our products cannot be successfully manufactured or timely commercialized, our results of operations could be materially adversely affected. In addition, we cannot guarantee that any investment we make in developing products will be recouped, even if we are successful in commercializing those products.

Also, new products, including contrast agents, are being developed and existing products are being refined in the field of diagnostic imaging. Our own diagnostic imaging agents compete not only with other similarly administrated imaging agents, but also with imaging agents employed in different and often competing diagnostic modalities. New imaging agents in a given diagnostic modality may be developed that provide benefits superior to the then-dominant agent in that modality, resulting in commercial displacement. Similarly, changing perceptions about comparative efficacy and safety, including, among other things, with respect to comparative radiation exposure, and changing availability of supply may favor one agent over another or one modality over another.

### We may be unable to protect our intellectual property rights or we may be subject to claims that we infringe on the intellectual property rights of others.

We rely on a combination of patents, trademarks, trade secrets, market exclusivity gained from the regulatory approval process and other intellectual property to support our business strategy. However, our efforts to protect our intellectual property rights may not be sufficient. If we do not obtain sufficient protection for our intellectual property, or if we are unable to effectively enforce our intellectual property rights, our competitiveness could be impaired,

which would limit our growth and future revenue.

Our pending patent applications may not result in the issuance of patents, or the patents issued to or licensed by us in the past or in the future may be challenged or circumvented by competitors. Existing patents may be found to be invalid or insufficiently broad to preclude our competitors from using methods or making or selling products similar or identical to those covered by our patents and patent applications. Regulatory agencies may refuse to grant us the market exclusivity that we were anticipating, or may unexpectedly grant market exclusivity rights to other parties. In addition, our ability to obtain and enforce intellectual property rights is limited by the unique laws of each country. In some countries it may be particularly difficult to adequately obtain or enforce intellectual property rights, which could make it easier for competitors to capture market share in such countries by utilizing technologies and product features that are similar or identical to those developed or licensed by us. Competitors also may harm our sales by designing products that mirror the capabilities of our products or technology without infringing our patents. Competitors may diminish the value of our trade secrets by reverse engineering or by independent invention. Additionally, current or former employees may improperly disclose such trade secrets to competitors or other third parties. We may not become aware of any such improper disclosure, and, in the event we do become aware, we may not have an adequate remedy available to us.

We operate in an industry characterized by extensive patent litigation, and we may from time to time be a party to such litigation. In *Tyco Healthcare Group LP, et al. v. Mutual Pharmaceutical Company, Inc.*, we filed a patent infringement suit in the U.S. District Court for the District of New Jersey against Mutual Pharmaceutical Co., Inc., et al. (collectively, Mutual) on March 20, 2007 pursuant to procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984, after Mutual submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking to sell a generic version of our 7.5 mg Restoril sleep aid product. Mutual also filed antitrust and unfair competition counterclaims. The patents at issue have since expired or been found invalid. On January 18, 2013, the trial court issued an opinion and order granting our motion for summary judgment regarding Mutual s antitrust and unfair competition counterclaims. On May 1, 2013, Mutual appealed this decision to the U.S. Court of Appeals for the Federal Circuit and oral arguments were heard February 6, 2014.

The pursuit of or defense against patent infringement, such as the case discussed above, is costly and time-consuming and we may not know the outcomes of such litigation for protracted periods of time. We may be unsuccessful in our efforts to enforce our patent or other intellectual property rights. In addition, patent litigation can result in significant damage awards, including the possibility of treble damages and injunctions. Additionally, we could be forced to stop manufacturing and selling certain products, or we may need to enter into license agreements that require us to make significant royalty or up-front payments in order to continue selling the affected products. Given the nature of our industry, we are likely to face additional claims of patent infringement in the future. A successful claim of patent or other intellectual property infringement against us could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

### We face significant competition and may not be able to compete effectively.

The industries in which we operate are highly competitive. Competition takes many forms, such as price reductions on products that are comparable to our own, development, acquisition or in-licensing of new products that may be more cost-effective than or have performance superior to our products, and the introduction of generic versions when our proprietary products lose their patent protection or market exclusivity. For further discussion on the competitive nature of our business, as well as intellectual property rights and market exclusivity, refer to the section entitled

Business. Our current or future products could be rendered obsolete or uneconomical as a result of this competition. Our failure to compete effectively could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

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### Any acquisitions of technologies, products and businesses may be difficult to integrate, could materially adversely affect our relationships with key customers and/or could result in significant impairment charges.

We regularly review potential acquisitions of technologies, products and businesses complementary to our business. Acquisitions typically entail many risks and could result in difficulties in integrating operations, personnel, technologies and products. If we are not able to successfully integrate our acquisitions, we may not obtain the advantages and synergies that the acquisitions were intended to create, which may have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. Moreover, the due diligence that we conduct in conjunction with an acquisition may not sufficiently discover risks and contingent liabilities associated with the acquisition target and, consequently, we may consummate an acquisition for which the risks and contingent liabilities are greater than were projected. In addition, in connection with acquisitions, we could experience disruption in our business, technology and information systems, and our customer or employee base, including diversion of management s attention from our continuing operations. There is also a risk that key employees of companies that we acquire or key employees necessary to successfully commercialize technologies and products that we acquire may seek employment elsewhere, including with our competitors. Furthermore, there may be overlap between our products or customers and the companies which we acquire that may create conflicts in relationships or other commitments detrimental to the integrated businesses. Additionally, the time between our expenditures to acquire new products, technologies or businesses and the subsequent generation of revenues from those acquired products, technologies or businesses (or the timing of revenue recognition related to licensing agreements and/or strategic collaborations) could cause fluctuations in our financial performance from period. Finally, if we are unable to successfully integrate products, technologies, businesses or personnel that we acquire, we could incur significant impairment charges or other adverse financial consequences.

### We may incur product liability losses and other litigation liability.

We are or may be involved in various legal proceedings and certain government inquiries and investigations, including, but not limited to, patent infringement, product liability, antitrust matters, breach of contract, Medicare and Medicaid reimbursements claims, or compliance with laws relating to marketing and sales or controlled substance distribution practices, including those relating to the establishment of suspicious order monitoring (SOM) programs. Such proceedings, inquiries and investigations may involve claims for, or the possibility of fines and penalties involving substantial amounts of money or other relief, including but not limited to civil or criminal fines and penalties and exclusion from participation in various government healthcare-related programs. If any of these legal proceedings, inquiries or investigations were to result in an adverse outcome, the impact could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

With respect to product liability and clinical trial risks, in the ordinary course of business we are subject to liability claims and lawsuits, including potential class actions, alleging that our marketed products or products in development have caused, or could cause, serious adverse events or other injury. Any such claim brought against us, with or without merit, could be costly to defend and could result in an increase in our insurance premiums. We retain liability for the first \$2.5 million per claim and purchase, through a combination of primary and umbrella/excess liability policies, \$150 million of coverage beyond the retained liabilities. We believe this coverage level is adequate to meet our current business exposure. However, some claims brought against us might not be covered by our insurance policies. Moreover, where the claim is covered by our insurance, if our insurance coverage is inadequate, we would have to pay the amount of any settlement or judgment that is in excess of our policy limits. We may not be able to obtain insurance on terms acceptable to us or at all since insurance varies in cost and can be difficult to obtain. Our failure to maintain adequate insurance coverage or successfully defend against product liability claims could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

### The implementation of healthcare reform in the U.S. may materially adversely affect us.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the Healthcare Reform Act ) was enacted into law in the U.S. The Healthcare Reform Act contains a number of provisions that affect coverage and reimbursement of drug products and the medical imaging procedures in which our drug products are used. For example, the Healthcare Reform Act includes a provision that imposes a \$28 billion fee on the branded pharmaceutical industry over nine years, starting in 2011, and a \$2.8 billion annual fee on the branded pharmaceutical industry thereafter. To the extent that the market share of our Brands business grows, the portion of this fee that we will be obligated to pay will increase.

There can be no assurance that the Healthcare Reform Act as currently enacted, and when fully implemented, will not materially adversely affect our competitive position, business, financial condition, results of operations and cash flows, nor can we predict with certainty how federal or state legislative or administrative changes relating to healthcare will affect our business.

# Sales of our products are affected by the reimbursement practices of a small number of large public and private insurers. In addition, reimbursement criteria and the use of tender systems outside the U.S. could reduce prices for our products or reduce our market opportunities.

Sales of our products depend, in part, on the extent to which the costs of our products are reimbursed by governmental health administration authorities, private health coverage insurers and other third-party payors. Our potential customers ability to obtain appropriate reimbursement for products and services from these third-party payors affects the selection of products they purchase and the prices they are willing to pay. In addition, demand for new products may be limited unless we obtain reimbursement approval from governmental and private third-party payors prior to introduction. Reimbursement criteria, which vary by country, are becoming increasingly stringent and require management expertise and significant attention to obtain and maintain qualification for reimbursement.

In addition, a number of markets in which we operate have implemented or may implement tender systems in an effort to lower prices. Under such tender systems, manufacturers submit bids which establish prices for products. The company that wins the tender receives preferential reimbursement for a period of time. Accordingly, the tender system often results in companies underbidding one another by proposing low pricing in order to win the tender. Certain other countries may consider implementation of a tender system. Even if a tender system is ultimately not implemented, the anticipation of such could result in price reductions. Failing to win tenders, or the implementation of similar systems in other markets leading to price declines, could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

### Our reporting and payment obligations under the Medicare and Medicaid rebate programs, and other governmental purchasing and rebate programs, are complex. Any determination of failure to comply with these obligations or those relating to healthcare fraud and abuse laws could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The regulations regarding reporting and payment obligations with respect to Medicare and Medicaid reimbursement programs, and rebates and other governmental programs, are complex. Because our processes for these calculations and the judgments used in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material adjustments to amounts previously paid.

Any governmental agencies that have commenced, or may commence, an investigation of Mallinckrodt relating to the sales, marketing, pricing, quality or manufacturing of pharmaceutical products could seek to

impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal healthcare programs including Medicare and Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments, and even in the absence of any such ambiguity, a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. For example, from time to time states attorneys general have brought cases against us that allege generally that we and numerous other pharmaceuticals companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid, resulting in overpayment by state Medicaid programs for those drugs, and generally seek monetary damages and attorneys fees. For example, we are named as a defendant in *State of Utah v. Actavis US, Inc., et al.*, filed May 8, 2008, which is pending in the Third Judicial Circuit of Salt Lake County, Utah. While we intend to contest this case and explore other options as appropriate, any such penalties or sanctions that we might receive in this or other actions could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

### Changes in laws and regulations may materially adversely affect us.

The development, manufacture, marketing, sale, promotion, and distribution of our products are subject to comprehensive government regulation. Changes in laws and regulations could affect us in various ways. For example, both the federal and state governments have given increased attention to the public health issue of opioid abuse, overdose and diversion. At the federal level, the White House Office of National Drug Control Policy continues to coordinate efforts between the FDA, DEA and other agencies to address this problem. In January 2013, the FDA released draft guidance on incorporating abuse-deterrent characteristics into extended-release opioids. When the FDA finds that a new formulation has abuse-deterrent characteristics, the agency has the authority to require that generics also have abuse-deterrent characteristics. One of our ANDAs that is currently under review in the U.S. refers to a NDA that did not have abuse-deterrent characteristics. From a compliance standpoint, the DEA continues to increase its efforts to hold manufacturers, distributors and pharmacies accountable through various enforcement actions as well as the implementation of compliance practices for controlled substances, including SOM activities for Schedule II opioids. In addition, many state legislatures continue to consider various bills intended to reduce opioid abuse, overdose and diversion, for example by establishing prescription drug monitoring programs, mandating prescriber education and prohibiting the substitution of generic versions of opioids that lack abuse-deterrent characteristics for branded products that have them. Future legislation and regulation in the markets that we serve could affect access to healthcare products and services, increase rebates, reduce prices or the rate of price increases for healthcare products and services, change healthcare delivery systems, create new fees and obligations for the pharmaceutical industry, or require additional reporting and disclosure. These and other changes in laws and regulations could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

In October 2013, the FDA announced its recommendation that the DEA reschedule hydrocodone combination products (such as Vicodin<sup>®</sup> (registered trademark of AbbVie, Inc.) and our developmental product MNK-155) from Schedule III to Schedule II, thereby increasing regulatory controls on these drug products. The FDA issued its formal recommendation to the DHHS, who in turn issued a similar recommendation to the DEA in December 2013. In February 2014, the DEA issued its proposal to reschedule hydrocodone combination products from Schedule III to Schedule II. The DEA proposal is open for comment through April 28, 2014. At this time, it is too early to determine the degree of impact the hydrocodone rescheduling, if adopted, will have on our business.

### Global economic conditions could harm us.

Over the course of the last few years, global market and economic conditions have been unprecedented and challenging, with tighter credit conditions and recession in most major economies. Continued concerns about the

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systemic impact of potential long-term and wide-spread recession (including concerns that certain European

countries may default on payments due on their national debt), energy costs, geopolitical issues and the availability and cost of credit have contributed to increased market volatility and diminished growth expectations for developed and developing economies.

As a result of these market conditions, the cost and availability of credit may be adversely affected. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide credit to businesses and consumers. These factors have resulted in a decrease in spending by businesses and consumers alike. Continued turbulence in the U.S. and international markets and economies and prolonged declines in consumer spending may materially adversely affect our liquidity and financial condition as well as our share price.

### Our global operations expose us to risks and challenges associated with conducting business internationally.

We operate globally with offices or activities in Europe, Africa, Asia, South America, Australia and North America. We face several risks inherent in conducting business internationally, including compliance with international and U.S. laws and regulations that apply to our international operations. These laws and regulations include data privacy requirements, labor relations laws, tax laws, anti-competition regulations, import and trade restrictions, export requirements, U.S. laws such as the Foreign Corrupt Practices Act of 1977 and local laws which also prohibit corrupt payments to governmental officials or certain payments or remunerations to customers. Given the high level of complexity of these laws, there is a risk that some provisions may be violated, for example inadvertently or through fraudulent or negligent behavior of individual employees, our failure to comply with certain formal documentation requirements or otherwise. Violations of these laws and regulations could result in fines or criminal sanctions against us, our officers or our employees, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, our business and our results of operations. Our success depends, in part, on our ability to anticipate and prevent or mitigate these risks and manage difficulties as they arise.

In addition to the foregoing, engaging in international business inherently involves a number of other difficulties and risks, including:

longer payment cycles in countries like Spain and Italy and difficulties in enforcing agreements and collecting receivables through certain non-U.S. legal systems;

political and economic instability, including, most notably, the risks and uncertainty associated with the current concerns regarding the stability of the Eurozone and the related possibility of sovereign defaults in countries such as Spain and Italy, and the possibility that such a default or the exit of one or more member countries from the Eurozone or from the European Union ( E.U. ) entirely may lead to difficulties for other members of the E.U.;

potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and trade barriers; and

failure to successfully implement our new non-U.S. operating structure, and difficulties and costs of staffing and managing non-U.S. operations.

These or other factors or any combination of them may have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

### Currency exchange rate fluctuations could materially adversely affect our business and results of operations.

We do business and generate sales in numerous countries outside the U.S. As such, currency exchange rate fluctuations may affect the costs that we incur in such international operations. Some of our operating expenses

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are incurred in non-U.S. dollar currencies. The appreciation of non-U.S. dollar currencies relative to the U.S. dollar in those countries where we have operations could increase our costs and could harm our results of operations and financial condition. We also have significant intercompany financing arrangements that may result in gains and losses in our results of operations. In an effort to mitigate the impact of currency exchange rate effects we may hedge certain of these intercompany transactions; however, our hedging strategies may not fully offset gains and losses recognized in our results of operations. In addition, we report our operating results in U.S. dollars, so the appreciation of the U.S. dollar relative to such other currencies could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

### Our operations expose us to the risk of material health, safety and environmental liabilities, litigation and violations.

We are subject to numerous federal, state, local and non-U.S. environmental protection and health and safety laws and regulations governing, among other things:

the generation, storage, use and transportation of hazardous materials;

emissions or discharges of substances into the environment;

investigation and remediation of hazardous substances or materials at various sites;

chemical constituents in products and end-of-life disposal, mandatory recycling and take-back programs; and

the health and safety of our employees.

We may not have been, or we may not at all times be, in full compliance with environmental and health and safety laws and regulations. In the event a regulatory authority concludes that we are not in full compliance with these laws, we could be fined, criminally charged or otherwise sanctioned. Environmental laws are becoming more stringent, including outside the U.S., resulting in increased costs and compliance burdens.

Certain environmental laws assess liability on current or previous owners of real property and current or previous owners or operators of facilities for the costs of investigation, removal or remediation of hazardous substances or materials at such properties or at properties at which parties have disposed of hazardous substances. Liability for investigative, removal and remedial costs under certain federal and state laws is retroactive, strict (*i.e.*, can be imposed regardless of fault) and joint and several. In addition to cleanup actions brought by governmental authorities, private parties could bring personal injury or other claims due to the presence of, or exposure to, hazardous substances. Certain radiological licenses at certain manufacturing sites owned by us require the establishment of decommissioning programs which will require remediation in accordance with regulatory requirements upon cessation of operations at such sites. We have received notification from the EPA and similar state environmental agencies that conditions at a number of sites where the disposal of hazardous substances requires investigation, cleanup and other possible remedial action. These agencies may require that we reimburse the government for its costs incurred at these sites or otherwise pay for the costs of investigation and cleanup of these sites, including by providing compensation for natural resource damage claims arising from such sites.

In the ordinary course of our business planning process, we take into account our known environmental matters as we plan for our future capital and operating expenditures requirements. The ultimate cost of site cleanup and timing of future cash outflows is difficult to predict, given the uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations, and alternative cleanup methods. We concluded that, as of December 27, 2013, it was probable that we would incur remedial costs in the range of \$44.5 million to \$80.3 million. We also concluded that, as of December 27, 2013, the best estimate within this range was \$44.5 million. For further information on our environmental obligations, refer to Business Legal Proceedings and Note 18 of the notes to our annual consolidated and combined financial statements included

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elsewhere in this prospectus. Based upon information known to date, we believe our current capital and operating plans are adequate for costs associated with the investigation, cleanup and potential remedial action for our known environmental matters.

While we have planned for future capital and operating expenditures to comply with environmental laws, our costs of complying with current or future environmental protection and health and safety laws and regulations, or our liabilities arising from past or future releases of, or exposures to, hazardous substances may exceed our estimates or could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. We may also be subject to additional environmental claims for personal injury or cost recovery actions for remediation of facilities in the future based on our past, present or future business activities.

### If we are unable to retain our key personnel, we may be unable to maintain or expand our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors will remain highly dependent, in large part, upon our ability to attract and retain qualified scientific, technical, regulatory and commercial personnel. The loss of key scientific, technical, regulatory and commercial personnel, technical, regulatory and commercial personnel, could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. There is intense competition for qualified personnel in the areas of our activities, and we may not be able to continue to attract and retain the qualified personnel necessary for the development of our business.

### Our business depends on the continued effectiveness and availability of our information technology infrastructure, and failures of this infrastructure could harm our operations.

To remain competitive in our industry, we must employ information technologies to support manufacturing processes, quality processes, distribution, R&D and regulatory applications that capture, manage and analyze, in compliance with applicable regulatory requirements, the large streams of data generated in our clinical trials. We rely extensively on technology to allow concurrent work sharing around the world. As with all information technology, our systems are vulnerable to potential damage or interruptions from fires, blackouts, telecommunications failures and other unexpected events, as well as physical and electronic break-ins, sabotage, piracy or intentional acts of vandalism. Given the extensive reliance of our business on technology, any substantial disruption or resulting loss of data that is not avoided or corrected by our backup measures could harm our business, operations and financial condition.

### We may not achieve some or all of the expected benefits of our restructuring activities and our restructuring activities may adversely affect our business.

From time to time, we initiate restructuring programs as we continue to realign our cost structure due to the changing nature of our business and look for opportunities to achieve operating efficiencies that will reduce costs. We may not be able to obtain the cost savings and benefits that were initially anticipated when we launched our restructuring programs. Additionally, as a result of our restructuring activities we may experience a loss of continuity, loss of accumulated knowledge and/or inefficiency during transitional periods. Reorganizations and restructurings can require a significant amount of management and other employees time and focus, which may divert attention from operating and growing our business. If we fail to achieve some or all of the expected benefits of our restructuring activities, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

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### **Risks Related to the Separation**

We have not operated as an independent company for a significant period of time, and our historical financial information is not necessarily representative of the results that we would have achieved had we been an independent, publicly-traded company for the entirety of the periods presented, and may not be an accurate indicator of our future results of operations.

Historical information about Mallinckrodt for periods prior to the separation reflects the results of the Pharmaceuticals business of Covidien, as operated by and integrated with Covidien, and is derived from the consolidated financial statements and accounting records of Covidien. Accordingly, this historical financial information does not necessarily reflect the financial condition, results of operations or cash flows that we would have achieved as an independent, publicly-traded company during the entirety of the periods presented or those that we will achieve in the future for various factors, including those described below.

Our business had historically been operated by Covidien as part of its broader corporate organization, rather than as an independent company, particularly in relation to our non-U.S. locations. Covidien or one of its affiliates performed various corporate functions for us, such as accounting, information technology and finance. Covidien will continue to provide some of these functions to us for a period of time pursuant to a transition services agreement. Our historical financial results for periods prior to the separation include allocations of corporate expenses from Covidien for such functions and are likely to be less than the expenses we will incur operating as an independent, publicly-traded company.

We expect to incur additional expenses as a result of being an independent, publicly-traded company including, among other things, directors and officers liability insurance, director fees, reporting fees with the SEC, New York Stock Exchange listing fees, transfer agent fees, increased auditing and legal fees. These expenses may be significant and may negatively impact our results of operations as compared to periods prior to the separation.

Our financial results for periods prior to the separation include costs incurred to separate Mallinckrodt from Covidien, which primarily related to legal, accounting, tax and other professional fees. We continue to incur separation related costs as a result of our transition services agreement with Covidien, as well as other transitional costs, such as costs to implement our own information and accounting systems. Our future separation related costs may fluctuate based on the nature and timing of our separation activities.

We will need to make significant investments to replicate or outsource from other providers certain facilities, systems, infrastructure and personnel that were formerly available to us through Covidien. The initiatives to develop our independent operational and administrative infrastructure will be costly to implement, and we may not be able to operate our business efficiently or at comparable costs, which may cause our profitability to decline.

Prior to the separation, our working capital and capital for our general corporate purposes had been provided as part of the corporate-wide cash management policies of Covidien. In the future, we may need to obtain additional financing from lenders, through public offerings or private placements of debt or equity securities, strategic relationships or other arrangements.

The cost of debt or equity capital for our business may be significantly different than that of Covidien.

Prior to the separation, we were able to use Covidien s purchasing power in procuring various goods and services and had shared economies of scope and scale in vendor relationships. As a standalone company, we may be unable to obtain goods and services at the prices and terms obtained prior to the separation, which could decrease our overall profitability.

Other significant changes may occur in our cost structure, management, financing and business operations as a result of operating as a company separate from Covidien. Additional information about the past financial performance of our business and the basis of presentation of the historical combined financial statements is included elsewhere in this prospectus.

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### As we build our information technology infrastructure and transition our data to our own systems, we could incur substantial additional costs and experience temporary business interruptions.

We continue to install and implement information technology infrastructure to support our critical business functions, particularly in relation to areas outside the U.S., including systems relating to accounting and reporting, manufacturing process control, customer service, inventory control and distribution. We may incur temporary interruptions in business operations if we cannot transition effectively from Covidien s existing transactional and operational systems and data centers and the transition services that support these functions as we replace these systems. We may not be successful in effectively and efficiently implementing our new systems and transitioning our data, and we may incur substantially higher costs for implementation than currently anticipated. Our failure to avoid operational interruptions as we implement the new systems and replace Covidien s information technology services, or our failure to implement the new systems and replace Covidien s information technology services, or our failure to implement the new systems and replace Covidien s information technology services, or our failure to implement the new systems and replace Covidien s information technology services, or our failure to implement the new systems and replace Covidien s information technology services, or our failure to implement the new systems and could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

### If we are unable to satisfy our reporting requirements or our internal control over financial reporting is not effective, our business, financial condition or results of operations could be materially adversely affected.

Prior to the separation, our financial results were included within the consolidated results of Covidien, and our reporting of internal control systems were appropriate for those of subsidiaries of a public company. Prior to the effectiveness of our registration statement on Form 10, we were not directly subject to reporting and other requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act ) and Section 404 of the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act ).

As an independent, publicly-traded company, we are now subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act, as well as other reporting requirements. The Exchange Act requires that we file annual, quarterly and current reports about our business and financial condition. The Sarbanes-Oxley Act requires our management to report on its assessment of the effectiveness of our internal control over financial reporting, and our independent auditors will be required to issue an opinion on their audit of our internal control over financial reporting. Our management report on internal controls and our auditors report are not contained in this prospectus due to a transition period established under SEC rules for newly public companies. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require demands on our management and administrative and operational resources, including accounting and information technology resources. To comply with these requirements we are upgrading our systems, including computer hardware infrastructure, implementing additional financial and management controls, reporting systems and procedures and have hired additional accounting, finance and information technology staff. If we are unable to upgrade our financial and management controls, reporting systems, information technology and procedures in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies could be impaired. Any failure to meet our reporting requirements or achieve and maintain effective internal controls could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

### We may have received more favorable or less favorable terms from unaffiliated third parties than the terms we received in our agreements with Covidien.

We entered into agreements with Covidien in connection with the separation, including a separation and distribution agreement, a transition services agreement, a tax matters agreement and an employee matters agreement. Since such agreements were negotiated in the context of the separation, the terms of such agreements may be more favorable or

less favorable than the terms that would have resulted from arm s-length negotiations between unaffiliated third parties.

### Covidien may fail to perform under various transaction agreements that were executed as part of the separation, or we may fail to have necessary systems and services in place when certain of the transaction agreements expire.

In connection with the separation, we entered into various agreements with Covidien, including a separation and distribution agreement, a tax matters agreement, an employee matters agreement and a transition services agreement. For further information on these agreements, refer to Exhibits 2.1, 10.1, 10.2 and 10.3, respectively, of the registration statement of which this prospectus forms a part. Certain of these agreements provide for the performance of services by each company for the benefit of the other for a period of time after the separation. We will rely on Covidien to satisfy its performance and payment obligations under these agreements. If Covidien is unable to satisfy its obligations under these agreements, including its indemnification obligations, we could incur operational difficulties or losses. If we do not have in place our own systems and services, or if we do not have agreements with other providers of these services when the transaction or long-term agreements terminate, we may not be able to operate our business effectively and our profitability may decline. We continue the process of creating our own, or engaging third parties to provide, systems and services to replace many of the systems and services Covidien provided to us prior to the separation, and is continuing to provide us pursuant to these agreements. These systems and services may be more expensive or less efficient than the systems and services Covidien is providing during the transition period.

### Potential indemnification liabilities to Covidien pursuant to the separation and distribution agreement could materially adversely affect us.

The separation and distribution agreement with Covidien provided for, among other things, the principal corporate transactions required to effect the separation, certain conditions to the distribution and provisions governing the relationship between us and Covidien following the separation. The separation and distribution agreement is included as Exhibit 2.1 of the registration statement of which this prospectus forms a part. Among other things, the separation and distribution agreement provides for indemnification obligations principally designed to place financial responsibility for the obligations and liabilities of our business with us and financial responsibility for the obligations and liabilities of Covidien s remaining business with Covidien, among other indemnifies. If we are required to indemnify Covidien under the circumstances set forth in the separation and distribution agreement, we may be subject to substantial liabilities. These potential indemnification obligations could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

### We may not achieve some or all of the expected benefits of the separation, and the separation may materially adversely affect our business.

We may not be able to achieve the full strategic and financial benefits expected to result from the separation, or such benefits may be delayed or not occur at all. The separation was expected to provide the following benefits, among others: (i) our ability to focus on our own strategic and operational plans and capital structure; (ii) an appropriate capital structure for Mallinckrodt; (iii) a distinct investment identity allowing investors to evaluate the merits, performance and future prospects of us separately from Covidien; and (iv) more effective share-based compensation and currency for acquisitions.

We may not achieve these and other anticipated benefits for a variety of reasons, including, among others: (a) the separation required significant amounts of management s time and effort, which may have diverted management s attention from operating and growing our business; (b) as an independent, publicly-traded company, we may be more susceptible to market fluctuations and other adverse events than if it were still a part of Covidien; (c) our business is less diversified than Covidien s business prior to the separation; and (d) the continuing actions required to separate Covidien s and our respective businesses could disrupt our operations. If we fail to achieve some or all of the benefits expected to result from the separation, or if such benefits are delayed, it could have a material adverse effect on our

competitive position, business, financial condition, results of operations and cash flows.

### **Risks Related to Tax Matters**

### If the distribution fails to qualify as a tax-free transaction for U.S. federal income tax purposes, then Mallinckrodt and Mallinckrodt s shareholders could be subject to significant tax liability or tax indemnity obligations.

Covidien received a U.S. Internal Revenue Service (IRS) ruling substantially to the effect that, for U.S. federal income tax purposes, (i) certain transactions effected in connection with the separation qualified as transactions under Sections 355 and 368(a) of the U.S. Internal Revenue Code (the Code), and (ii) the distribution of Mallinckrodt shares qualified as a transaction under Sections 355 and 368(a)(1)(D) of the Code. In addition to obtaining the IRS ruling, Covidien received a tax opinion from Skadden, Arps, Slate, Meagher & Flom LLP, which relied on the effectiveness of the IRS ruling, substantially to the effect that, for U.S. federal income tax purposes, the distribution and certain transactions entered into in connection with the distribution qualified as transactions under Sections 355 and 368(a) of the Code.

The IRS ruling and tax opinion rely on certain facts and assumptions, certain representations from Covidien and us regarding the past and future conduct of our respective businesses and other matters, and certain undertakings made by Covidien and us. Notwithstanding the IRS ruling and tax opinion, the IRS could determine on audit that the distribution should be treated as a taxable transaction if it determines that any of these facts, assumptions, representations or undertakings is not correct or has been violated, or that the distribution should be taxable for other reasons, including as a result of a significant change in stock or asset ownership after the distribution, or if the IRS were to disagree with the conclusions of the tax opinion that are not covered by the IRS ruling. In addition, Covidien or we could incur significant U.S. federal income tax liabilities or tax indemnification obligations, whether under applicable law or the tax matters agreement (the tax matters agreement ) dated June 28, 2013 that we entered into with Covidien, if it is ultimately determined that certain related transactions undertaken in anticipation of the distribution are taxable.

### We could have significant tax liabilities under the tax matters agreement with Covidien for periods during which our subsidiaries and operations were those of Covidien and of Tyco International Ltd.

Our tax returns are subject to examination by various tax authorities, including the IRS. The IRS is examining our U.S. federal income tax returns for periods during which certain of our subsidiaries and operations were those of Covidien. In addition, the IRS continues to examine the U.S. federal income tax returns of Tyco International Ltd. (Tyco International ) for periods during which certain of our subsidiaries and operations were those of Tyco International. Our potential liability under the tax matters agreement with Covidien for any taxes related to periods prior to the separation (after taking into account certain tax benefits realized by us), including those which are subject to the provisions of the tax sharing agreement by and among Covidien, Tyco International and TE Connectivity Ltd. (the Tyco Tax Sharing Agreement ), is anticipated to be approximately \$175 million, which excludes associated tax benefits from such payments, and will be subject to an overall limitation of \$200 million, net of any benefits. For further information on the tax matters agreement, see Our Relationship with Covidien Following the Distribution Tax Matters Agreement.

The resolution of the matters arising during periods in which certain of our subsidiaries and operations were subsidiaries and operations of Covidien will be subject to the provisions of the tax matters agreement. Under this agreement, Covidien will have the right to administer, control and settle, in its sole and absolute discretion, all tax audits that do not relate solely to non-U.S. taxes for periods prior to the separation that are not covered by the Tyco Tax Sharing Agreement. The outcome of any such examination, and any associated litigation which might arise, is uncertain and could result in a significant increase in our liability for taxes arising during these periods, subject to the overall \$200 million limitation described above. The timing and outcome of such examination or litigation is highly

uncertain and could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. Under the tax matters agreement, Covidien will agree to provide to us information it receives related to examinations of tax matters for which we may be liable but we will not otherwise be permitted to control or participate in the settlement or defense of such examinations.

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The resolution of the matters arising during periods in which certain of our subsidiaries and operations were subsidiaries and operations of Tyco International will be subject to the provisions of the tax matters agreement and the Tyco Tax Sharing Agreement. Under the Tyco Tax Sharing Agreement, Covidien, Tyco International and TE Connectivity Ltd. are responsible for 42%, 27% and 31%, respectively, of U.S. income tax liabilities prior to the 2007 separation of Covidien, Tyco International and TE Connectivity Ltd. We are not a party to the Tyco Tax Sharing Agreement. Under the tax matters agreement we will, however, be liable for certain taxes relating to our subsidiaries and operations arising during periods governed by the Tyco Tax Sharing Agreement. Although we will be liable to Covidien for certain taxes arising during periods governed by the Tyco Tax Sharing Agreement, we will not be liable to Tyco International or TE Connectivity Ltd. under the Tyco Tax Sharing Agreement, nor will we share in the receivable that Covidien has from Tyco International or TE Connectivity Ltd. In addition, Covidien will retain all reimbursements for taxes that are borne by us pursuant to the tax matters agreement, including reimbursements for taxes that are borne by us pursuant to the tax matters agreement.

Under the Tyco Tax Sharing Agreement, Tyco International has the right to administer, control and settle all U.S. income tax audits for periods prior to the separation from Tyco International. In connection with such examinations, tax authorities, including the IRS, have proposed tax adjustments. Tyco International has appealed certain of the proposed tax adjustments and all but one of the matters associated with the proposed tax adjustments has been resolved. With respect to the remaining unresolved matter, Tyco International is contesting the adjustments through litigation. The outcome of any such litigation is uncertain and could result in a significant increase in our liability for taxes arising during these periods, subject to the overall \$200 million limitation described above. While we believe that the amounts recorded as income taxes payable related to these adjustments are adequate, the timing and outcome of such litigation is highly uncertain and could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. Under the tax matters agreement, Covidien has agreed to provide to us information it receives from Tyco International related to examinations of tax matters for which we may be liable that are governed by the Tyco Tax Sharing Agreement.

### Examination and audits by tax authorities, including the IRS, could result in additional tax payments.

We provide reserves for potential payments of tax to various tax authorities related to uncertain tax positions. It is Covidien s intention to vigorously defend our prior tax returns. However, the calculation of our tax liabilities involves the application of complex tax regulations to our global operations in many jurisdictions. Therefore, any dispute with a tax authority may result in a payment that is materially different from our current estimate of the tax liabilities associated with these returns. If payment of these amounts ultimately proves to be less than the recorded amounts, the reversal of the reserves generally would result in tax benefits being recognized in the period when we determine the reserves are no longer necessary. If our estimate of tax liabilities proves to be less than the amount for which we are ultimately liable, we would incur additional charges to expense and such charges could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

### We may not be able to maintain a competitive worldwide effective corporate tax rate.

We cannot give any assurance as to what our effective tax rate will be in the future, because of, among other things, uncertainty regarding the tax policies of the jurisdictions where we operate. Our actual effective tax rate may vary from our expectation and that variance may be material. Additionally, the tax laws of Ireland and other jurisdictions could change in the future, and such changes could cause a material change in our effective tax rate.

### Risks Related to Mallinckrodt plc s and MIFSA s Jurisdictions of Incorporation

Legislative action in the U.S. could materially adversely affect us.

Legislative action may be taken by the U.S. Congress which, if ultimately enacted, could limit the availability of tax benefits or deductions that we currently claim, override tax treaties upon which we rely, or

otherwise affect the taxes that the U.S. imposes on our worldwide operations. Such changes could materially adversely affect our effective tax rate and/or require us to take further action, at potentially significant expense, to seek to preserve our effective tax rate. In addition, if proposals were enacted that had the effect of limiting Mallinckrodt plc s ability as an Irish company or MIFSA s ability as a Luxembourg company to take advantage of tax treaties with the U.S., we could incur additional tax expense and/or otherwise incur business detriment.

### The laws of Luxembourg and Ireland differ from the laws in effect in the United States and may afford less protection to holders of our securities.

It may not be possible to enforce court judgments obtained in the United States against MIFSA in Luxembourg or Mallinckrodt plc in Ireland, based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland or Luxembourg would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of the U.S. federal or state securities laws. We have been advised that the United States currently does not have a treaty with either Ireland or Luxembourg providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland or Luxembourg.

A final and conclusive judgment obtained against MIFSA would nonetheless be enforceable by the Luxembourg courts subject to the applicable enforcement procedure provided under the Luxembourg New Civil Procedure Code. Such foreign judgment would be enforceable, *provided* that: (i) it is enforceable in the country of origin; (ii) the court of origin must have had jurisdiction both according to its own laws and to the Luxembourg conflict of jurisdictions rules; (iii) the foreign proceedings must have been regular in light of the laws of the country of origin; (iv) the rights of defense must not have been violated; (v) the foreign court must have applied the law which is designated by the Luxembourg conflict of law rules, or, at least, the judgment must not contravene the principles underlying these rules; (vi) the considerations of the foreign judgment as well as the judgment as such must not contravene Luxembourg international public policy; and (vii) the foreign judgment must not have been rendered as a result of or in connection with an evasion of Luxembourg law (*fraude à la loi*).

A judgment obtained against Mallinckrodt plc will be enforced by the courts of Ireland if the following general requirements are met: (i) U.S. courts must have had jurisdiction in relation to the particular defendant according to Irish conflict of law rules (the submission to jurisdiction by the defendant would satisfy this rule) and (ii) the judgment must be final and conclusive and the decree must be final and unalterable in the court which pronounces it. A judgment can be final and conclusive even if it is subject to appeal or even if an appeal is pending. Where however the effect of lodging an appeal under the applicable law is to stay execution of the judgment, it is possible that in the meantime the judgment may not be actionable in Ireland. It remains to be determined whether final judgment given in default of appearance is final and conclusive. However, Irish courts may refuse to enforce a judgment of the U.S. courts which meets the above requirements for one of the following reasons: (i) if the judgment is not for a definite sum of money; (ii) if the judgment was obtained by fraud; (iii) the enforcement of the judgment in Ireland would be contrary to natural or constitutional justice; (iv) the judgment is contrary to Irish public policy or involves certain U.S. laws which will not be enforced in Ireland; or (v) jurisdiction cannot be obtained by the Irish courts over the judgment debtors in the enforcement proceedings by personal service Ireland or outside Ireland under Order 11 of the Ireland Superior Courts Rules.

As a Luxembourg company, MIFSA is governed by the law of August 10, 1915, on commercial companies, as amended, and its articles of association (the 1915 Law ). The 1915 Law differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including differences relating to interested director

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transactions, shareholder lawsuits and shareholder indemnification. Under Luxembourg law, any director having an interest in a transaction submitted for approval to the board of directors (*conseil d administration*) conflicting with that of the company shall be obliged to advise the board thereof and to cause a record of his or her statement to be included in the minutes of the meeting. The director may not take part in these deliberations.

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At the next following general meeting of shareholders, before any other resolution is put to vote, a special report shall be made on any transactions in which any of the directors may have had an interest conflicting with that of the company.

The duties of directors (*administrateurs*) of a Luxembourg company are also generally owed to the company only. Except under certain limited circumstances, shareholders of a Luxembourg company do not generally have a personal right of action against the directors. Under Luxembourg law, a company may indemnify its directors for personal liability related to the exercise of their functions of director. Such indemnity typically does not apply in cases of fraud and criminal acts.

Due to the nature of Luxembourg s insolvency laws, the ability of the holders of the notes to protect their interests may be more limited than would be the case under U.S. bankruptcy laws. In the event of a winding up of MIFSA, the notes will be paid after payment of all secured debts, the cost of liquidation and certain debts of MIFSA that are entitled to priority under Luxembourg law. Such preferential debts include the following:

money owed to Luxembourg tax authorities, for example, in respect of income tax deducted at the source;

value-added tax and certain other taxes and duties owed to Luxembourg Customs and Excise;

social security contributions; and

remuneration owed to employees.

If the bankruptcy administrator can show that preference has been given to any person by defrauding rights of creditors generally, regardless of when the transaction giving fraudulent preference to a party occurred, or if certain abnormal transactions have been effected during a relevant suspect period of six months plus 10 days prior to the date of bankruptcy, a court has the power, among other things, to void the preferential or abnormal transaction. This provision of Luxembourg insolvency law may affect transactions entered into or payments made by MIFSA during the period before liquidation or administration.

As an Irish company, Mallinckrodt plc is governed by the Irish Companies Act, which differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of Mallinckrodt plc securities may have more difficulty protecting their interests than would holders of securities of a corporation incorporated in a jurisdiction of the United States.

Any insolvency proceedings applicable to Mallinckrodt plc will be likely to be governed by Irish insolvency laws. Due to the nature of Ireland s insolvency laws, the ability of the holders of the notes to protect their interests may be more limited than would be the case under U.S. bankruptcy laws.

If an Irish company is unable, or likely to be unable, to pay its debts, an examiner may be appointed to facilitate the survival of the company and the whole or any part of its business. If an examiner is appointed, a protection period will be imposed so that the examiner can formulate and implement his proposals for a compromise or scheme of arrangement. During the protection period, any enforcement action by a creditor of the Irish company is prohibited. In addition, the Irish company would be prohibited from paying any debts existing at the time of the presentation of the petition to appoint an examiner.

In an insolvency of Mallinckrodt plc, the claims of certain preferential creditors (including the Irish Revenue Commissioners for certain unpaid taxes) will rank in priority to claims of unsecured creditors. Also under Irish insolvency laws, if a company goes into liquidation, a liquidator may apply to the court to have

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certain transactions unwound if they are deemed fraudulent preferences or have the effect of perpetrating a fraud on the company, its creditors or its shareholders.

If Mallinckrodt plc becomes subject to an insolvency proceeding and Mallinckrodt plc has obligations to creditors that are treated under Irish law as creditors that are senior relative to the holders of the notes, the holders of the notes may suffer losses as a result of their subordinated status during such insolvency proceeding.

#### Irish law imposes restrictions on certain aspects of capital management.

Irish law allows Mallinckrodt plc s shareholders to pre-authorize shares to be issued by its board of directors without further shareholder approval for up to a maximum of five years. The authorization in place at the time of the distribution (*i.e.*, when Mallinckrodt plc s guarantee of the notes became effective) will therefore lapse approximately five years after the distribution unless renewed by shareholders and we cannot guarantee that such renewal will always be approved. Additionally, subject to specified exceptions, including the opt-out included in Mallinckrodt plc s articles of association upon consummation of the distribution, Irish law grants statutory pre-emptive rights to existing shareholders to subscribe for new issuances of shares for cash. This opt-out also expires approximately five years after the distribution unless renewed by further shareholder approval and we cannot guarantee that such renewal of the opt-out from pre-emptive rights will always be approved. We cannot assure you that these Irish legal restrictions will not interfere with our capital management.

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## **USE OF PROCEEDS**

We will not receive any proceeds from the issuance of the exchange notes in the exchange offer. The exchange offer is intended to satisfy MIFSA s obligations under the registration rights agreement that MIFSA entered into in connection with the private offering of the outstanding notes. As consideration for issuing the exchange notes as contemplated in this prospectus, we will receive in exchange a like principal amount of outstanding notes, the terms of which are substantially identical in all material respects to the exchange notes, except that the exchange notes will not contain terms with respect to transfer restrictions or additional interest upon a failure to fulfill certain of our obligations under the registration rights agreement. The outstanding notes that are surrendered in exchange for the exchange notes will be retired and cannot be reissued. As a result, the issuance of the exchange notes will not result in any change in our capitalization.

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## CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 27, 2013. Completion of the exchange offer will not result in any change to our capitalization. The historical information below is not necessarily indicative of our future capitalization. This table should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated and combined financial statements and accompanying notes included elsewhere in this prospectus.

(Dollars in Millions)	ember 27, 2013
Cash and Cash Equivalents	\$ 287.8
Debt:	
Current maturities of long-term debt:	
Capital lease obligation	1.4
Loan payable	
Total current debt	1.4
Long-term debt:	
Unsecured senior revolving credit facility	
Outstanding 2018 notes	299.9
9.50% debentures due May 2022	10.4
8.00% debentures due March 2023	8.0
Outstanding 2023 notes	598.2
Capital lease obligation	1.5
Total long-term debt	918.0
Total debt	919.4
Equity:	
Total equity	1,309.3
Total capitalization	\$ 2,228.7

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## **RATIO OF EARNINGS TO FIXED CHARGES**

The following table contains our ratio of earnings to fixed charges for the periods indicated. For purposes of computing the ratio of earnings to fixed charges, earnings consist of income from continuing operations before taxes plus interest expense after capitalized interest and a reasonable estimate of interest within rental expense. Fixed charges consist of interest expense before capitalized interest and a reasonable estimate of interest within rental expense. Fixed charges. Exhibit 12.1, filed as part of the registration statement of which this prospectus is a part, reflects the calculation of the ratios.

This table should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated and combined financial statements and notes to our consolidated and combined financial statements included elsewhere in this prospectus.

	Three Months Ended				Fiscal			
D	ecember 27, 2048er	nber 28, 2012	2013	2012	2011	2010	2009	
Ratio of earnings to fixed charges	6.1	25.6	5.9	45.5	47.8	40.9	99.5	

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#### SELECTED FINANCIAL DATA

The following table sets forth selected financial data as of and for the three months ended December 27, 2013 and December 28, 2012 and the fiscal years ended September 27, 2013, September 28, 2012, September 30, 2011, September 24, 2010 and September 25, 2009. This selected financial data reflects the consolidated position of Mallinckrodt plc and its consolidated subsidiaries as an independent, publicly-traded company for periods on or after its legal separation from Covidien plc on June 28, 2013. Selected financial data for periods prior to June 28, 2013 reflect the combined historical business and operations of Covidien s Pharmaceuticals business as it was historically managed as part of Covidien.

The condensed consolidated and combined income statement data for the three months ended December 27, 2013 and December 28, 2012 and the condensed consolidated balance sheet data at December 27, 2013 have been derived from our unaudited condensed consolidated and combined financial statements included elsewhere in this prospectus. The consolidated and combined statement of income data for fiscal 2013, the combined statement of income data for fiscal 2012 and 2011, the consolidated balance sheet data as of September 27, 2013 and the combined balance sheet data as of September 28, 2012 were derived from our consolidated and combined financial statements and accompanying notes included elsewhere in this prospectus. The combined statement of income data for fiscal 2010 and the combined balance sheet data as of September 30, 2011 were derived from our audited combined financial statements that are not included in this prospectus. The combined statement of income data for fiscal 2009 and the combined balance sheet data as of December 28, 2012, September 24, 2010 and September 25, 2009 were derived from our unaudited combined financial statements that are not included in this prospectus. This selected financial information should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated and combined financial statements and accompanying notes included elsewhere in this prospectus. Our historical results for periods prior to June 28, 2013 are not necessarily indicative of the results of operations or financial condition that would have been obtained had we operated as an independent, publicly-traded company for the entirety of the periods presented, nor are they necessarily indicative of our future performance as an independent, publicly-traded company.

(in millions, except per share data) Three Months Ended December Øzcember 28,					Fiscal Year <sup>(1)</sup>							
	2013		2012	2013	20	012	201	1		2010	2	2009
Consolidated and Combined												
Statement of Income Data:												
Net sales <sup>(2)</sup>	\$ 540.2	\$	504.0	\$2,204.5	\$2,0	056.2	\$2,02	21.8	\$2	2,047.6	\$2	,429.5
Gross profit	255.6		233.5	1,024.9	(	964.8	9	14.9		932.4	1	,296.3
Research and development												
expenses <sup>(3)</sup>	39.0		38.4	165.7		144.1	14	41.5		119.1		155.2
Operating income <sup>(4)(5)</sup>	73.1		36.8	144.8	1	235.2	24	40.7		240.4		508.5
Income from continuing operations												
before income taxes	63.0		36.9	126.4		236.1	24	43.2		243.2		512.0
Income from continuing operations	46.4		19.8	57.8		141.3	1:	57.0		145.9		315.5
Share Data: <sup>(6)</sup>												
Basic income from continuing												
operations per share	\$ 0.80	\$	0.34	\$ 1.00	\$	2.45	\$ 2	2.72	\$	2.53	\$	5.47
Diluted income from continuing												
operations per share	0.79		0.34	1.00		2.45	-	2.72		2.53		5.47

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Cash dividends per ordinary share

	December 2	December 2	September 28	æptember 2	eptember 3	eptember 28	leptember 25,
	2013	2012	2013	2012	2011	2010	2009
Consolidated and							
<b>Combined Balance Sheet</b>							
Data:							
Total assets	\$ 3,569.4	\$ 3,083.2	\$ 3,556.6	\$ 2,898.9	\$ 2,832.2	\$ 2,892.6	\$ 3,167.4
Long-term debt	918.0	2.8	918.3	8.9	10.4	11.6	13.6
Shareholders equity	1,309.3	2,113.7	1,255.6	1,891.9	1,788.7	1,835.9	2,016.4

(1) Fiscal 2011 included 53 weeks. All other fiscal years presented include 52 weeks.

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- (2) Fiscal 2009 includes \$354.5 million of sales of oxycodone hydrocodone extended-release tablets, which were sold under a license agreement that began in the fourth quarter of fiscal 2008 and ended in the second quarter of fiscal 2009.
- (3) Fiscal 2013 includes a \$5.0 million charge related to milestone payments related to the acceptance of our Xartemis XR NDA for filing with the FDA. Fiscal 2009 includes a \$35.3 million charge related to upfront fees and milestone payments related to a product acquisition and licensing agreements.
- (4) Fiscal 2013 and 2012 include costs related to the build-out of our corporate infrastructure of \$70.6 million and \$10.7 million, respectively. The three months ended December 27, 2013 and December 28, 2012 include separation related costs of \$2.2 million and \$12.0 million, respectively. Fiscal 2013, 2012 and 2011 include separation related costs of \$74.2 million, \$25.5 million and \$2.9 million, respectively. The three months ended December 27, 2013 and December 27, 2013 and December 28, 2012 include restructuring and related charges, net of \$8.0 million and \$0.2 million, respectively. Fiscal 2013, 2012, 2011, 2010 and 2009 include restructuring charges, net, of \$33.2 million, \$11.2 million, \$8.4 million, \$11.5 million and \$26.7 million, respectively. Fiscal 2010 and 2009 include product liability charges of \$31.3 million and \$27.8 million, respectively. Fiscal 2009 also includes a \$71.2 million charge for the estimated additional cost to remediate environmental matters at a site located in Orrington, Maine, the liability for which was retained by Covidien pursuant to the separation and distribution agreement.
- (5) Fiscal 2013, 2012, 2011, 2010 and 2009 include expense allocations from Covidien of \$39.6 million, \$49.2 million, \$56.3 million, \$60.8 million and \$60.6 million, respectively, which relate to finance, legal, information technology, human resources, communications, employee benefits and incentives, insurance and share-based compensation. The three months ended December 28, 2012 include expense allocations from Covidien of \$11.9 million. Effective with the legal separation from Covidien on June 28, 2013, we have assumed responsibility for all of these functions and related costs and anticipate our costs as an independent, publicly-traded company will be higher than those allocated to us from Covidien.
- (6) The computation of basic and diluted earnings per share assumes that the number of shares outstanding for periods prior to June 28, 2013 was equal to the number of ordinary shares of Mallinckrodt outstanding on June 28, 2013, immediately following the distribution of one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien.

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# MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated and combined financial statements and the accompanying notes included elsewhere in this prospectus. The following discussion may contain forward-looking statements that reflect our plans, estimates and beliefs and involve risks, uncertainties and assumptions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed in Risk Factors and Cautionary Statement Concerning Forward-Looking Statements.

#### Overview

We are a global company that develops, manufactures, markets and distributes both branded and generic specialty pharmaceuticals, API and diagnostic imaging agents. Our products are found in almost every hospital, standalone diagnostic imaging center or pharmacy in the U.S. and we have a commercial presence in approximately 70 countries. We believe our extensive commercial reach and formulation expertise, coupled with our ability to navigate the highly regulated and technical nature of our business, have created compelling competitive advantages that we anticipate will sustain future revenue growth.

We conduct our business in the following two segments:

*Specialty Pharmaceuticals* produces and markets branded and generic pharmaceuticals and API, comprised of medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients; and

*Global Medical Imaging* develops, manufactures and markets CMDS and radiopharmaceuticals (nuclear medicine).

For further information on our business and products, refer to Business Our Businesses and Product Strategies.

#### **Significant Events**

#### Separation from Covidien

Mallinckrodt plc was incorporated in Ireland on January 9, 2013 for the purpose of holding the Pharmaceuticals business of Covidien plc. On June 28, 2013, Covidien shareholders of record received one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien held as of the record date, June 19, 2013, and the Pharmaceuticals business of Covidien was transferred to Mallinckrodt plc, thereby completing its legal separation from Covidien. On July 1, 2013, we began regular way trading on the New York Stock Exchange under the ticker symbol MNK.

Our consolidated and combined financial statements reflect the consolidated financial position of Mallinckrodt plc and its subsidiaries as an independent publicly-traded company for periods subsequent to June 28, 2013, and as a combined reporting entity of Covidien, including operations relating to Covidien s Pharmaceuticals business, for periods prior to June 28, 2013. Our results for periods prior to June 28, 2013, including the nine months ended June 28, 2013 that is included with our fiscal 2013 results and the three months ended December 28, 2012, may not be indicative of our future performance and do not necessarily reflect the results of operations, financial position and cash

flows that would have been had we operated as an independent, publicly-traded company for the entirety of the periods presented, including as a result of changes in our capitalization in connection with the separation. The combined financial statements for periods prior to June 28, 2013 include expense allocations related to finance, legal, information technology, human resources, communications, employee benefits and incentives, insurance and share-based compensation. The amounts allocated were \$39.6 million, \$49.2 million and \$56.3 million in fiscal 2013, 2012 and 2011, respectively, and \$11.9 million for the three months ended December 28, 2012. Management considers the bases on which the

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expenses have been allocated to reasonably reflect the utilization of services provided to, or the benefit received by, us during the periods presented; however, the allocations may not reflect the expense we would have incurred as an independent, publicly-traded company. These allocations have not recurred following the completion of the separation on June 28, 2013, as we have been performing these functions using our own resources or purchased services, certain of which are being provided by Covidien during a transitional period pursuant to a transition services agreement dated June 28, 2013, between us and Covidien, particularly in relation to areas outside the U.S. The terms and prices on which such services are rendered may not be as favorable as those allocated to us by Covidien. We also may incur additional costs associated with being an independent, publicly-traded company. These additional anticipated costs are not reflected in our historical combined financial statements for periods prior to June 28, 2013.

#### Acquisitions

In October 2012, we acquired CNS Therapeutics, a specialty pharmaceutical company focused on developing and commercializing intrathecal products for site-specific administration to the central nervous system to treat neurological disorders and intractable chronic pain, for total consideration of \$95.0 million. The total consideration was comprised of an upfront cash payment of \$88.1 million (net of cash acquired) and the fair value of contingent consideration of \$6.9 million. This contingent consideration, which could potentially total a maximum of \$9.0 million, is primarily based on whether the FDA approves another concentration of Gablofen on or before December 31, 2016. Gablofen injections are indicated for use in the management of severe spasticity of cerebal or spinal origin in patients age four years and above. The acquisition of CNS Therapeutics expanded our branded pharmaceuticals portfolio and supports our strategy of leveraging our therapeutic expertise and core capabilities in manufacturing, regulatory and commercialization to serve patients. The consolidated and combined income statement for fiscal 2013 included \$29.2 million of net sales of intrathecal products added to our portfolio with this acquisition.

In August 2012, we paid \$13.2 million under an agreement to acquire all of the rights to Roxicodone<sup>®</sup> from Xanodyne Pharmaceuticals, Inc., which was capitalized as an intangible asset. Roxicodone is an immediate-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain where the use of an opioid analgesic is appropriate. Roxicodone is the Reference Listed Drug for one of our generic products and is important to our product pipeline. Net sales of Roxicodone during fiscal 2013 were \$8.4 million. There are no ongoing royalty payments under this agreement.

## Divestitures

During fiscal 2011, we sold the rights to market TussiCaps, which are hydrocodone bitartrate and chlorpheniramine maleate extended-release capsules for use as a cough suppressant, for an upfront cash payment of \$11.5 million. As a result of this transaction, we recorded a \$11.1 million gain. The purchaser also may be obligated to make contingent payments to us of up to \$11.5 million from December 31, 2011 through September 30, 2015, payable in equal quarterly installments until such time as a new competitive generic product is introduced into the market. In addition, we would receive a \$1.0 million contingent payment if certain sales targets are achieved over the same time period. We received contingent payments of \$2.9 million during both fiscal 2013 and 2012.

## **Royalty and Milestone Payments**

We are required to pay royalties and milestone payments for various product acquisitions and license agreements we have entered into with third parties. For EXALGO<sup>®</sup> (hydromorphone HCl) extended-release tablets (Exalgo), a pain management drug we acquired the rights to distribute and market in fiscal 2009, we are obligated to make additional payments based on the successful completion of specified development and regulatory milestones. Additionally, we are required to pay royalties on sales of the product. During fiscal 2013, 2012 and 2011, we paid royalties of \$24.0

million, \$16.1 million and \$5.5 million, respectively. No milestone payments were made in any of the periods presented.

Also in fiscal 2009, we entered into a licensing agreement to utilize Depomed Inc. s ( Depomed ) Acuforngastric retentive drug delivery technology for the exclusive development of four products. This agreement may obligate us to make development milestone payments, and we are required to pay royalties on sales of products developed under this agreement. During fiscal 2013, we made a \$5.0 million milestone payment upon the acceptance for filing by the FDA of our Xartemis XR NDA. During fiscal 2012, an insignificant amount of milestone payments were expensed as incurred since regulatory approval had not been received. No milestone payments were made in fiscal 2011. No royalty payments have been made under this agreement.

We also entered into a license agreement which granted us rights to market and distribute Pennsaid and MNK-395, an investigational product candidate that is a formulation of diclofenac sodium topical solution which we anticipate will be indicated for the treatment of pain associated with osteoarthritis of the knee. We are responsible for all future development activities and expenses under this agreement, are required to pay royalties on sales of the products and may also be required to make additional payments based upon the successful completion of specified regulatory and sales milestones. No milestone payments were made during fiscal 2013, 2012 or 2011. During fiscal 2013 and 2012, we paid royalties of \$3.9 million and \$7.5 million. The amount of royalties paid in fiscal 2011 was insignificant.

## Nuclear Imaging

In November 2012, the HFR in the Netherlands, one of two primary reactors we utilize to irradiate targets as part of our Mo-99 processing operation experienced an unscheduled shutdown. Mo-99 is a key raw material in our Ultra-Technekow DTE technetium generators that are sold by our Global Medical Imaging segment. We were able to receive increased target irradiations at two other reactors and purchased additional Mo-99 from other sources to continue meeting customer orders; however, the additional Mo-99 we procured from alternative sources came at a higher than normal cost. The reactor resumed production in June 2013.

In October 2013, the HFR experienced another unscheduled shutdown. In addition, our own Mo-99 processing facility in Petten, the Netherlands also experienced a shutdown. The HFR resumed production in late February. Our Mo-99 processing facility remains shut down. Until it resumes production, we expect to fulfill customer orders through processing of Mo-99 from alternative sources at higher costs. Ongoing increased raw material and manufacturing costs will limit our ability to return the Global Medical Imaging segment to historical operating margins.

## **Business Factors Influencing the Results of Operations**

## New Products

On December 28, 2012, we received approval from the FDA to manufacture Methylphenidate HCl extended-release tablets USP (CII) (Methylphenidate ER), a generic version of the branded Concerta, a registered trademark of Alza Corporation, for the treatment of attention deficit hyperactivity disorder in 27 mg, 36 mg and 54 mg tablets. We held a 180-day exclusivity period for each of the 27 mg, 36 mg and 54 mg strengths, which began upon the commercial launch of each tablet. We launched the 27 mg tablet upon FDA approval during the first quarter of fiscal 2013 and launched the 36 mg and 54 mg tablets during the second quarter of fiscal 2013. In February 2013, we submitted a supplement to our approved ANDA for an 18 mg tablet, which the FDA has accepted and granted priority review. In January 2014, we received a Complete Response Letter from the FDA approval to manufacture all strengths of Methylphenidate ER and has entered the marketplace. As our exclusivity has expired, other competitors may also enter the market for Methylphenidate ER. Despite increased competition for Methylphenidate ER, we continue to see steady demand trends.

In August 2012, the FDA approved a 32 mg tablet of Exalgo, which further expanded the patient population that Exalgo can effectively treat with a single daily dose. The 8 mg, 12 mg and 16 mg tablets of Exalgo were approved by the FDA in March 2010 for the treatment of chronic pain in opioid-tolerant patients requiring

continuous around-the-clock opioid analgesia for an extended amount of time; and have shown significant prescription growth since launch in April 2010. Exalgo was granted marketing exclusivity in the U.S. as a prescription medicine through March 2013 and is protected by two Orange Book-listed patents for a method of treating moderate to severe pain. Beginning in November 2013 for the 8 mg, 12 mg and 16 mg tablets and May 2014 for the 32 mg tablet, a third party has the right, pursuant to agreements with us, to sell a generic version of Exalgo; however, their entrance into the market is dependent upon receiving FDA marketing approval. We expect sales of Exalgo to decrease in fiscal 2014 (compared with \$126.1 million in fiscal 2013) when the third party enters the market pursuant to these agreements. Additionally, our patents for the 8 mg, 12 mg and 16 mg tablets expire in July 2014.

Net sales of Methylphenidate ER and Exalgo were \$92.5 million and \$38.6 million during the three months ended December 27, 2013 and December 28, 2012, respectively. Net sales of Methylphenidate ER and Exalgo were \$274.4 million, \$91.9 million and \$41.2 million in fiscal 2013, 2012, and 2011, respectively.

## **Restructuring Initiatives**

We continue to look for opportunities to improve our cost structure and achieve operating excellence and efficiencies. Our initiatives prior to the separation have primarily been part of Covidien s 2011 restructuring program, which also applied to its Pharmaceutical business. We launched an initiative that closed a manufacturing facility in Chesterfield, United Kingdom (U.K.). The manufacturing facility produced API products and we transferred these processes to another manufacturing site, creating operating and logistic efficiencies. In addition, we announced a comprehensive initiative to renovate, upgrade and modernize key manufacturing operations at our Saint Louis, Missouri manufacturing facility. We began to realize benefits from these initiatives in fiscal 2012.

Following the separation, we continue to realign our cost structure due to the changing nature of our business and look for opportunities to achieve operating efficiencies. As such, in August 2013 our board of directors approved a restructuring program in the amount of \$100 million to \$125 million that is expected to occur over a three year period. We expect to recover the charges of each restructuring action taken within two years.

During the three months ended December 27, 2013 and December 28, 2012, we incurred restructuring and related charges, net, of \$8.1 million and \$1.0 million, respectively, which included accelerated depreciation costs of \$0.1 million and \$0.8 million, respectively. The restructuring charges incurred during the three months ended December 27, 2013 primarily related to severance and employee benefit costs in our Global Medical Imaging segment.

During fiscal 2013, 2012 and 2011, we incurred restructuring and related charges, net, of \$35.8 million, \$19.2 million and \$10.0 million, respectively, which included accelerated depreciation costs of \$2.6 million, \$8.0 million and \$1.6 million, respectively. The restructuring charges incurred during all of these periods primarily related to severance and employee benefit costs across both of our segments.

## **Research and Development Investment**

We expect to continue to invest in R&D activities, as well as enter into license agreements to supplement our internal R&D initiatives. We intend to focus our R&D investments in the specialty pharmaceuticals area, specifically investments to support our Brands business, where we believe there is the greatest opportunity for growth and profitability. We currently expect our R&D investments to be in the range of 6% to 8% of annualized net sales.

*Specialty Pharmaceuticals.* We devote significant R&D resources for our branded products. A number of our branded products are protected by patents and have enjoyed market exclusivity. Our R&D strategy focuses on branded product development in the area of pain, other central nervous system areas, such as spasticity, and

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adjacent areas. We are presently developing a number of branded products, some of which utilize novel drug-delivery systems, through a combination of internal and collaborative programs. As of December 27, 2013, we had two NDAs under review in the U.S. In July 2013, the FDA accepted our MNK-795 NDA and granted it priority review. The FDA has granted conditional approval of the brand name Xartemis XR for the MNK-795 NDA. In November 2013, in response to additional data we submitted, the FDA extended their review of the Xartemis XR NDA by three months. We anticipate, if approved, Xartemis XR will be launched during the second quarter of fiscal 2014. Our NDA for Pennsaid 2%, originally filed as MNK-395, was approved by the FDA in January 2014. We expect to launch this product in the second quarter of fiscal 2014. MNK-155 has completed Phase III clinical trials and our NDA is expected to be filed with the FDA during the second half of fiscal 2014.

We are presently developing a number of specialty generic products through a combination of internal and collaborative programs. From a product development perspective, we are focused on controlled substances with difficult-to-replicate pharmacokinetic profiles. In addition, we are focused on process improvements to increase yields and reduce costs. As of December 27, 2013, we had five ANDAs on file with the FDA. This includes a supplement, filed in February 2013, to our approved ANDA for the 18 mg tablet of Methylphenidate ER. The FDA has accepted this supplement and granted it priority review. In January 2014, we received a Complete Response Letter from the FDA requesting additional information, and we are working to address this request. If accepted, we will have all four tablet strengths available on the market, as we currently offer the 27 mg, 36 mg and 54 mg strengths.

*Global Medical Imaging*. Our R&D efforts in our Global Medical Imaging segment are focused on driving efficiency throughout CMDS. In our Nuclear Imaging business, we are expanding our portfolio of radioisotopes and better utilizing existing capacity.

## **Results of Operations**

#### Three Months Ended December 27, 2013 Compared with Three Months Ended December 28, 2012

#### Net Sales

Net sales by geographic area were as follows (dollars in millions):

	Three Mo		
	December 27, 2013	December 28, 2012	Percentage Change
U.S.	\$ 383.0	\$ 336.1	14.0%
Europe, Middle East and Africa	94.2	93.6	0.6
Other	63.0	74.3	(15.2)
Net sales	\$ 540.2	\$ 504.0	7.2

Net sales in the three months ended December 27, 2013 increased \$36.2 million, or 7.2%, to \$540.2 million, compared with \$504.0 million for the three months ended December 28, 2012. This increase was primarily driven by increased sales within our Specialty Pharmaceuticals segment resulting from the launch timing of Methylphenidate ER in December 2012, strategic pricing initiatives and increased sales of Exalgo. These increases were partially offset by decreased sales in our CMDS businesses. For further information on changes in our net sales, refer to Business Segment Results.

#### **Operating Income**

*Gross profit.* Gross profit for the three months ended December 27, 2013 increased \$22.1 million, or 9.5%, to \$255.6 million, compared with \$233.5 million for the three months ended December 28, 2012. The increase in gross profit primarily resulted from higher net sales in the current year period, benefits from strategic pricing

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initiatives and a favorable product mix from increased sales of our higher margin pharmaceutical products. These factors were partially offset by increased manufacturing and raw material costs in the Global Medical Imaging segment, including the unscheduled shutdowns of the HFR that supplies us with Mo-99 and our Mo-99 processing facility. Gross profit margin was 47.3% for the three months ended December 27, 2013, compared with 46.3% for the three months ended December 28, 2012.

*Selling, general and administrative expenses.* Selling, general and administrative expenses for the three months ended December 27, 2013 were \$146.2 million, compared with \$146.8 million for the three months ended December 28, 2012, a decrease of \$0.6 million, or 0.4%. The decrease resulted from benefits from restructuring activities, cost containment efforts and certain prior year costs that did not recur in the three months ended December 27, 2013, partially offset by higher internal and third-party expenses associated with being an independent, publicly-traded company. In the three months ended December 28, 2012, selling, general and administrative expenses included higher legal settlement costs and allocations from Covidien of \$11.9 million for general corporate expenses. These allocations are generally consistent with functions we have developed in our corporate build-out and ceased following the completion of the separation on June 28, 2013. Selling, general and administrative expenses were 27.1% of net sales for the three months ended December 27, 2013 and 29.1% of net sales for the three months ended December 28, 2014 included minimal launch expenses related to Xartemis XR and Pennsaid 2%. Beginning in the second quarter of fiscal 2014, we expect expenses in our Brands business to increase in anticipation of our launch of these products.

*Research and development expenses.* R&D expenses increased \$0.6 million, or 1.6%, to \$39.0 million for the three months ended December 27, 2013, compared with \$38.4 million for the three months ended December 28, 2012. As products, such as Xartemis XR, Pennsaid 2% and MNK-155, move toward or through the FDA review process, we have devoted additional resources to other potential products in our R&D pipeline. As a percentage of our net sales, R&D expenses were 7.2% and 7.6% for the three months ended December 27, 2013 and December 28, 2012, respectively.

*Separation costs.* During the three months ended December 27, 2013 and December 28, 2012, we incurred separation costs of \$2.2 million and \$12.0 million, respectively, primarily related to legal, accounting, tax and other professional fees. Separation costs were higher in the prior year period as we approached and completed the separation on June 28, 2013. We have continued to incur costs related to the separation as a result of our transition services agreement with Covidien, our costs to implement information and accounting systems, share-based compensation related to the conversion of Covidien awards to Mallinckrodt awards, and other transitional costs; however, these costs are not expected to recur at historical levels.

*Restructuring and related charges, net.* During the three months ended December 27, 2013, we recorded \$8.1 million of restructuring and related charges, net, of which \$0.1 million related to accelerated depreciation and was included in cost of sales. The remaining \$8.0 million primarily related to severance and employee benefits costs incurred in our Global Medical Imaging segment. During the three months ended December 28, 2012, we recorded restructuring and related charges, net of \$1.0 million, of which \$0.8 million related to accelerated depreciation and was included in cost of sales.

*Gains on divestiture and license*. During the three months ended December 27, 2013 and December 28, 2012, we recorded gains on divestiture and license of \$12.9 million and \$0.7 million, respectively. The \$12.9 million gain recorded during the three months ended December 27, 2013 primarily resulted from the license of intellectual property to a third-party related to extended release oxymorphone.

## Non-Operating Items

*Interest expense and interest income.* During the three months ended December 27, 2013, net interest expense was \$9.5 million. Net interest expense is primarily attributable to our \$900.0 million issuance of senior unsecured notes in April 2013. Interest expense during the three months ended December 27, 2013 includes \$0.6 million non-cash interest expense.

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*Other (expense) income, net.* During the three months ended December 27, 2013, we recorded other expense, net of \$0.6 million and during the three months December 28, 2012, we recorded other income, net of \$0.2 million, both of which represent miscellaneous items, including gains and losses on intercompany financing foreign currency transactions and related hedging instruments.

*Provision for income taxes.* Income tax expense was \$16.6 million and \$17.1 million on income from continuing operations before income taxes of \$63.0 million and \$36.9 million for the three months ended December 27, 2013 and December 28, 2012, respectively. Our effective tax rate was 26.3% compared with 46.3% for the three months ended December 27, 2013 and December 28, 2012, respectively. The effective tax rates were impacted by the deductibility of separation costs, due to the tax free status of the separation. During the three months ended December 27, 2013, we received a \$0.7 million tax benefit on \$2.2 million of separation costs compared with a \$0.3 million tax benefit on \$12.0 million of separation costs for the three months ended December 28, 2012. Furthermore, our effective tax rate for the three months ended December 28, 2012 reflected the business as historically managed by Covidien rather than as an independent, publicly-traded company.

*Loss from discontinued operations, net of income taxes.* We recorded \$0.8 million and \$0.6 million losses on discontinued operations, net of income taxes, during the three months ended December 27, 2013 and December 28, 2012, respectively. These amounts relate to indemnification obligations to the purchaser of our Specialty Chemicals business (formerly known as Mallinckrodt Baker), which was sold during fiscal 2010.

#### Fiscal Year Ended September 27, 2013 Compared with Fiscal Year Ended September 28, 2012

#### Net Sales

Net sales by geographic area are as follows (dollars in millions):

	Fiscal		
	2013	2012	Percentage Change
U.S.	\$1,518.7	\$1,350.2	12.5%
Europe, Middle East and Africa	404.3	411.0	(1.6)
Other	281.5	295.0	(4.6)
Net sales	\$ 2,204.5	\$2,056.2	7.2

Net sales in fiscal 2013 increased \$148.3 million, or 7.2%, to \$2,204.5 million, compared with \$2,056.2 million in fiscal 2012. This increase was primarily driven by increased sales within our Specialty Pharmaceuticals segment resulting from the launch of Methylphenidate ER, increased sales of Exalgo and the addition of Gablofen to our product portfolio in early fiscal 2013. These increases were partially offset by decreased sales in both our CMDS and Nuclear Imaging businesses. For further information on changes in our net sales, refer to Business Segment Results.

## **Operating Income**

*Gross profit.* Gross profit for fiscal 2013 increased \$60.1 million, or 6.2%, to \$1,024.9 million, compared with \$964.8 million in fiscal 2012. The increase in gross profit primarily resulted from higher net sales in the current year period, in addition to a favorable product mix from increased sales of our higher margin pharmaceutical products. These

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factors were offset by increased manufacturing and raw material costs, primarily attributable to the unscheduled shutdown of the HFR that supplies us with Mo-99. Gross profit margin was 46.5% during fiscal 2013, compared with 46.9% during fiscal 2012.

*Selling, general and administrative expenses.* Selling, general and administrative expenses for fiscal 2013 were \$609.9 million, compared with \$551.7 million for fiscal 2012, an increase of \$58.2 million, or 10.5%. The increase primarily resulted from \$70.6 million of costs in the current year period related to the build-out of our

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corporate infrastructure, compared with \$10.7 million in the prior year period. Selling, general and administrative expenses were 27.7% of net sales for fiscal 2013 and 26.8% of net sales for fiscal 2012. Selling, general and administrative expenses include allocations from Covidien of \$39.6 million and \$49.2 million in fiscal 2013 and 2012, respectively, for general corporate expenses. These expenses are generally consistent with functions we have developed in our corporate build-out and ceased following the completion of the separation on June 28, 2013. Fiscal 2013 included minimal launch expenses related to Xartemis XR and Pennsaid 2%. Beginning in the first half of fiscal 2014, we expect expenses in our Brands business to increase in anticipation of our launch of these products.

*Research and development expenses*. R&D expenses increased \$21.6 million, or 15.0%, to \$165.7 million in fiscal 2013, compared with \$144.1 million in fiscal 2012. The increase in R&D expenses is primarily attributable to increased development activities related to our MNK-155, Pennsaid 2% and intrathecal products. The increase in R&D also reflects a \$5.0 million milestone payment related to acceptance of the Xartemis XR NDA for priority review by the FDA. As a percentage of our net sales, R&D expenses were 7.5% and 7.0% in fiscal 2013 and 2012, respectively.

*Separation costs.* During fiscal 2013 and 2012, we incurred separation costs of \$74.2 million and \$25.5 million, respectively, primarily related to legal, accounting, tax and other professional fees. Separation costs were higher in the current year period as we approached and completed the separation on June 28, 2013. We expect to continue to incur costs related to the separation as a result of our transition services agreement with Covidien, our costs to implement information and accounting systems, share-based compensation related to the conversion of Covidien awards to Mallinckrodt awards, and other transitional costs; however, these costs are not expected to recur at similar levels in future periods.

*Restructuring and related charges, net.* During fiscal 2013, we recorded \$35.8 million of restructuring and related charges, net, of which \$2.6 million related to accelerated depreciation and was included in cost of sales. The remaining \$33.2 million primarily related to severance and employee benefits costs incurred across both our segments. During fiscal 2012, we recorded restructuring and related charges, net of \$19.2 million, of which \$8.0 million related to accelerated depreciation and was included in cost of sales. The remaining \$11.2 million primarily related to severance and employee benefits costs incurred across both our segments.

*Gain on divestitures*. During both fiscal 2013 and 2012, we recorded gains of \$2.9 million related to the sale of the rights to market TussiCaps extended-release capsules in fiscal 2011.

## Non-Operating Items

*Interest expense and interest income*. During fiscal 2013, net interest expense was \$19.2 million. Net interest expense is primarily attributable to our \$900 million issuance of senior unsecured notes in April 2013. Interest expense during fiscal 2013 includes \$1.1 million non-cash interest expense.

*Other income, net.* During fiscal 2013 and 2012, we recorded other income, net of \$0.8 million and \$1.0 million, respectively, which represents miscellaneous items, including gains and losses on intercompany financing foreign currency transactions and related hedging instruments.

*Provision for income taxes*. Income tax expense was \$68.6 million and \$94.8 million on income from continuing operations before income taxes of \$126.4 million and \$236.1 million for fiscal 2013 and 2012, respectively. Our effective tax rate was 54.3% compared with 40.2% for fiscal 2013 and 2012, respectively. Our effective tax rate for fiscal 2013 was impacted by only receiving a \$4.2 million tax benefit on \$74.2 million of separation costs due to the tax-free status of the separation, \$13.3 million of expense associated with uncertain tax positions, and an \$11.6 million

benefit associated with intercompany debt transferred to the Company at the separation. Our effective tax rate for fiscal 2012 was impacted by only receiving \$1.8 million of tax benefit on \$25.5 million of separation costs due to the tax-free status of the separation and recognizing \$2.3 million of expense associated with uncertain tax positions.

*Income (loss) from discontinued operations, net of income taxes.* We recorded a \$1.0 million gain and \$6.7 million loss on discontinued operations, net of income taxes, during fiscal 2013 and 2012, respectively. These amounts relate to indemnification obligations to the purchaser of our Specialty Chemicals business (formerly known as Mallinckrodt Baker), which was sold during fiscal 2010.

## Fiscal Year Ended September 28, 2012 Compared with Fiscal Year Ended September 30, 2011

#### Net Sales

Net sales by geographic area are as follows (dollars in millions):

	Fiscal		
	2012	2011	Percentage Change
U.S.	\$1,350.2	\$1,293.8	4.4%
Europe, Middle East and Africa	411.0	419.7	(2.1)
Other	295.0	308.3	(4.3)
Net sales	\$ 2,056.2	\$ 2,021.8	1.7

Net sales in fiscal 2012 increased \$34.4 million, or 1.7%, to \$2,056.2 million, compared with \$2,021.8 million in fiscal 2011. This increase was primarily driven by a \$50.7 million increase in sales of Exalgo within our Specialty Pharmaceuticals segment, partially offset by a \$22.7 million decrease in sales of our Optiray contrast product within our Global Medical Imaging segment. For further information on changes in our net sales, refer to Business Segment Results.

## **Operating Income**

*Gross profit.* Gross profit for fiscal 2012 increased \$49.9 million, or 5.5%, to \$964.8 million, compared with \$914.9 million in fiscal 2011. The increase in gross profit was primarily a result of overall higher net sales. Gross margin was 46.9% in fiscal 2012, compared with 45.3% in fiscal 2011. The increase in gross margin was primarily attributable to a more favorable product mix resulting from increased sales of our higher margin branded pharmaceutical products.

*Selling, general and administrative expenses.* Selling, general and administrative expenses for fiscal 2012 were \$551.7 million, compared with \$532.5 million for fiscal 2011, an increase of \$19.2 million, or 3.6%. The increase in selling, general and administrative expenses primarily resulted from higher legal and benefit costs. Selling, general and administrative expenses were 26.8% of net sales for fiscal 2012, compared with 26.3% of net sales for fiscal 2011.

*Research and development expenses*. R&D expenses increased \$2.6 million, or 1.8%, to \$144.1 million in fiscal 2012, compared with \$141.5 million in fiscal 2011. The increase in R&D expenses is primarily attributable to increased development activities related to our Xartemis XR and MNK-155 products, as well as higher salary and benefit costs. As a percentage of our net sales, R&D expenses were 7.0% in both fiscal 2012 and 2011.

*Separation costs.* During fiscal 2012 and 2011, we incurred separation costs of \$25.5 million and \$2.9 million, respectively, primarily related to tax, accounting and other professional fees.

*Restructuring and related charges, net.* During fiscal 2012, we recorded \$19.2 million of restructuring and related charges, net, of which \$8.0 million related to accelerated depreciation and was included in cost of sales. The accelerated depreciation resulted from the decision to shut down our plant in Chesterfield, U.K. The remaining \$11.2 million primarily related to severance and employee benefits costs due to a reduction in work force. During fiscal 2011, we recorded restructuring and related charges, net of \$10.0 million, of which \$1.6 million related to accelerated depreciation and was included in cost of sales. The remaining \$8.4 million primarily related to severance and employee benefit costs incurred within our Specialty Pharmaceuticals segment.

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*Gain on divestitures*. During fiscal 2011, we recorded a \$11.1 million gain related to the sale of the rights to market TussiCaps extended-release capsules. We recorded an additional \$2.9 million gain related to this sale during fiscal 2012.

#### Non-Operating Items

*Interest expense and interest income*. During fiscal 2012 and 2011, interest expense, net of interest income, was \$0.1 million and \$0.4 million, respectively.

*Other income, net.* During fiscal 2012 and 2011, we recorded other income, net, of \$1.0 million and \$2.9 million, respectively, which primarily represented royalty payments from a subsidiary of Covidien for use of certain of our trademarks and technology.

*Provision for income taxes.* Income tax expense was \$94.8 million and \$86.2 million on income from continuing operations before income taxes of \$236.1 million and \$243.2 million for fiscal 2012 and 2011, respectively. Our effective tax rate was 40.2% and 35.4% for fiscal 2012 and 2011, respectively. The increase in effective tax rate for fiscal 2012 resulted primarily from a decrease in earnings in lower-tax jurisdictions. The expiration of the U.S. R&D tax credit as of December 31, 2011 and the retroactive reenactment of the 2010 R&D tax credit during fiscal 2011 also contributed to the increase in the effective tax rate in fiscal 2012, as compared with fiscal 2011. Had the U.S. R&D tax credit been fully enacted during fiscal 2012, our effective tax rate would have been approximately 0.7% lower. In addition, in fiscal 2011, we reached a settlement with certain non-U.S. taxing authorities that favorably benefited our fiscal 2011 effective tax rate.

*Loss from discontinued operations, net of income taxes.* We recorded \$6.7 million and \$6.3 million losses on discontinued operations, net of income taxes, during fiscal 2012 and 2011, respectively. These losses related to indemnification obligations to the purchaser of our Specialty Chemicals business (formerly known as Mallinckrodt Baker), which was sold during fiscal 2010.

#### **Business Segment Results**

The businesses included within our Specialty Pharmaceuticals and our Global Medical Imaging segments are described below:

#### Specialty Pharmaceuticals

Brands include branded pharmaceuticals for pain and spasticity.

*Generics and API* produces generic pharmaceutical products (including those to treat attention deficit hyperactivity disorder and addiction), medicinal opioids, synthetic controlled substances and acetaminophen. *Global Medical Imaging* 

*Contrast Media and Delivery Systems* develops, manufactures and markets contrast media for diagnostic imaging applications, and power injectors to allow delivery of contrast media.

*Nuclear Imaging* manufactures and markets radioactive isotopes and associated pharmaceuticals used for the diagnosis and treatment of disease.

Management measures and evaluates our operating segments based on segment net sales and operating income. Management excludes corporate expenses, amortization of intangibles, restructuring and related charges, net and separation costs from segment operating income. In addition, management evaluates the operating results of the segments excluding revenues and expenses associated with sales of products to our former parent company, Covidien. Although these amounts are excluded from segment operating income, as applicable, they are included in reported consolidated and combined operating income and accordingly, are included in our discussion of our consolidated and combined results of operations.

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### Three Months Ended December 27, 2013 Compared with Three Months Ended December 28, 2012

#### Net Sales

Net sales by segment are shown in the following table (dollars in millions):

	Three Months Ended						
	December 27,	December 28,		Percentage			
	2013		2012	Change			
Specialty Pharmaceuticals	\$ 309.5	\$	260.2	18.9%			
Global Medical Imaging	218.6		229.7	(4.8)			
Net sales of operating segments	528.1		489.9	7.8			
Other <sup>(1)</sup>	12.1		14.1	(14.2)			
Net sales	\$ 540.2	\$	504.0	7.2			

## (1) Represents products that were sold to Covidien.

*Specialty Pharmaceuticals.* Net sales for the three months ended December 27, 2013 increased \$49.3 million, or 18.9%, to \$309.5 million, compared with \$260.2 million for the three months ended December 28, 2012. The increase in net sales was primarily driven by a \$47.0 million increase in sales from Methylphenidate ER, which was launched in December 2012, and a \$20.7 million increase in other controlled substances resulting from certain strategic pricing initiatives. These increases were partially offset by a \$25.7 million decrease in Oxycodone (API) and oxycodone-containing tablets, primarily due to a \$19.4 million payment to a customer as a consequence of implementing strategic pricing initiatives on this product, as well as decreases in other product categories.

Net sales for Specialty Pharmaceuticals by geography were as follows (dollars in millions):

	Three Mo			
	December 27, 2013	Decem	,	Percentage Change
U.S.	\$ 281.9	\$	233.6	20.7%
Europe, Middle East and Africa	24.8		22.5	10.2
Other	2.8		4.1	(31.7)
Net sales	\$ 309.5	\$	260.2	18.9

Net sales for Specialty Pharmaceuticals by key products were as follows (dollars in millions):

### **Three Months Ended**

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	December 27, 2013	mber 28, 2012	Percentage Change
Oxycodone (API) and oxycodone-containing tablets	\$ 11.6	\$ 37.3	(68.9)%
Hydrocodone (API) and hydrocodone-containing tablets	30.1	31.6	(4.7)
Methylphenidate ER	56.3	9.3	505.4
Other controlled substances	120.2	99.5	20.8
Other	31.7	35.9	(11.7)
Specialty Generics and API	249.9	213.6	17.0
Exalgo	36.2	29.3	23.5
Other	23.4	17.3	35.3
Brands	59.6	46.6	27.9
Specialty Pharmaceuticals	\$ 309.5	\$ 260.2	18.9

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*Global Medical Imaging*. Net sales for the three months ended December 27, 2013 decreased \$11.1 million, or 4.8%, to \$218.6 million compared with \$229.7 million for the three months ended December 28, 2012. The decrease was primarily driven by a \$9.8 million decline in net sales of CMDS products, which were negatively impacted by the effects of commoditization in mature markets, which we expect to continue in the future, and certain restructuring actions in Asia.

Net sales for Global Medical Imaging by geography were as follows (dollars in millions):

	Three Mo		
	December 27, 2013	ember 28, 2012	Percentage Change
U.S.	\$ 101.1	\$ 101.8	(0.7)%
Europe, Middle East and Africa	69.4	71.1	(2.4)
Other	48.1	56.8	(15.3)
Net sales	\$218.6	\$ 229.7	(4.8)

Net sales for Global Medical Imaging by key products were as follows (dollars in millions):

	Three Months Ended			
	December 27,		mber 28,	Percentage
	2013		2012	Change
Optiray	\$ 72.1	\$	79.4	(9.2)%
Other	39.5		42.0	(6.0)
Contrast Media and Delivery Systems	111.6		121.4	(8.1)
Nuclear Imaging	107.0		108.3	(1.2)
Global Medical Imaging	\$218.6	\$	229.7	(4.8)

## **Operating Income**

Operating income by segment and as a percentage of segment net sales for the three months ended December 27, 2013 and December 28, 2012 is shown in the following table (dollars in millions):

	,	<b>Three Months Ended</b>			
	December 27, 2013		December 28, 2012		
Specialty Pharmaceuticals	\$113.0	36.5%	\$ 35.0	13.5%	
Global Medical Imaging	4.4	2.0	49.1	21.4	
Segment operating income	117.4	22.2	84.1	17.2	

(25.2)	(25.4)
(8.8)	(8.9)
(8.1)	(1.0)
(2.2)	(12.0)
\$ 73.1	\$ 36.8
	(8.8) (8.1) (2.2)

(1) Includes restructuring-related accelerated depreciation of \$0.1 million and \$0.8 million for the three months ended December 27, 2013 and December 28, 2012, respectively.

*Specialty Pharmaceuticals*. Operating income for the three months ended December 27, 2013 increased \$78.0 million to \$113.0 million, compared with \$35.0 million for the three months ended December 28, 2012. Our operating margin increased to 36.5% for the three months ended December 27, 2013, compared with 13.5% for the three months ended December 28, 2012. The increase in operating income and margin was primarily due

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to increased net sales of higher margin products, such as Methylphenidate ER, strategic pricing actions and the \$11.7 million gain on the license of intellectual property to a third-party. In addition, the three months ended December 28, 2012 included certain legal settlement costs that did not recur in the current year quarter.

*Global Medical Imaging.* Operating income for the three months ended December 27, 2013 decreased \$44.7 million to \$4.4 million, compared with \$49.1 million for the three months ended December 28, 2012. Our operating margin decreased to 2.0% for the three months ended December 27, 2013, compared with 21.4% for the three months ended December 28, 2012. The decrease in operating income was attributable to lower net sales, increased nuclear manufacturing and raw material costs and higher regulatory compliance costs. Our increased nuclear manufacturing and raw material costs were most significantly impacted by the unscheduled shutdowns of the HFR that supplies us with Mo-99 and our Mo-99 processing facility, which decreased operating income by \$15.3 million compared to the prior year quarter. Ongoing increased materials and manufacturing costs and lower net sales will limit our ability to return the Global Medical Imaging segment to historical operating margins on a long-term basis.

*Corporate and allocated expenses.* Corporate and allocated expenses were \$25.2 million and \$25.4 million for the three months ended December 27, 2013 and December 28, 2012, respectively. The decrease primarily resulted from cost containment efforts and certain prior year costs that did not recur in the three months ended December 27, 2013. We were allocated general corporate expenses of \$11.9 million during the three months ended December 28, 2012 for certain functions provided by Covidien. These allocations ceased in periods following the completion of the separation on June 28, 2013. These decreases were partially offset by higher internal and third-party expenses associated with being an independent, publicly-traded company.

## Fiscal Year Ended September 27, 2013 Compared with Fiscal Year Ended September 28, 2012

#### Net Sales

Net sales by segment are shown in the following table (dollars in millions):

	Fisc		
	2013	2012	Percentage Change
Specialty Pharmaceuticals	\$ 1,217.6	\$1,005.2	21.1%
Global Medical Imaging	935.7	996.8	(6.1)
Net sales of operating segments	2,153.3	2,002.0	7.6
Other <sup>(1)</sup>	51.2	54.2	(5.5)
Net sales	\$ 2,204.5	\$ 2,056.2	7.2

#### (1) Represents products that were sold to Covidien.

*Specialty Pharmaceuticals*. Net sales for fiscal 2013 increased \$212.4 million, or 21.1%, to \$1,217.6 million, compared with \$1,005.2 million for fiscal 2012. The increase in net sales was primarily driven by \$148.3 million of sales from the launch of Methylphenidate ER during fiscal 2013, a \$34.2 million increase in net sales of Exalgo, which was aided by the launch of the 32mg dosage in August 2012, and \$29.2 million in net sales of intrathecal products.

Net sales for Specialty Pharmaceuticals by geography are as follows (dollars in millions):

	Fisca	<b>Fiscal Year</b>		
	2013	2012	Percentage Change	
U.S.	\$ 1,097.9	\$ 880.6	24.7%	
Europe, Middle East and Africa	104.1	108.7	(4.2)	
Other	15.6	15.9	(1.9)	
Net sales	\$ 1,217.6	\$ 1,005.2	21.1	

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Net sales for Specialty Pharmaceuticals by key products are as follows (dollars in millions):

	Fiscal Year		
	Percentage		
	2013	2012	Change
Acetaminophen (API) products	\$ 216.2	\$ 217.7	(0.7)%
Oxycodone (API) and oxycodone-containing tablets	139.0	144.1	(3.5)
Hydrocodone (API) and hydrocodone-containing tablets	140.0	130.5	7.3
Other controlled substances	112.0	111.7	0.3
Methylphenidate ER	148.3		
Other	255.7	244.8	4.5
Generics and API	1,011.2	848.8	19.1
Exalgo	126.1	91.9	37.2
Intrathecal products	29.2		
Other	51.1	64.5	(20.8)
Brands	206.4	156.4	32.0
Specialty Pharmaceuticals	\$1,217.6	\$1,005.2	21.1

*Global Medical Imaging*. Net sales for fiscal 2013 decreased \$61.1 million, or 6.1%, to \$935.7 million compared with \$996.8 million for fiscal 2012. Net sales of CMDS products decreased \$43.9 million, and were negatively impacted by the effects of commoditization in mature markets, which we expect to continue into the future, and a renegotiated customer contract in the U.S. market. Net sales of nuclear products decreased \$17.2 million, primarily due to additional sales opportunities during fiscal 2012 that resulted from challenges a competitor faced in supplying the market.

Net sales for Global Medical Imaging by geography are as follows (dollars in millions):

	Fisc	<b>Fiscal Year</b>		
	2013	2012	Percentage Change	
U.S.	\$418.2	\$466.8	(10.4)%	
Europe, Middle East and Africa	300.2	302.3	(0.7)	
Other	217.3	227.7	(4.6)	
Net sales	\$ 935.7	\$ 996.8	(6.1)	

Net sales for Global Medical Imaging by key products are as follows (dollars in millions):

		Percentage
2013	2012	Change
\$318.5	\$352.2	(9.6)%
44.8	48.0	(6.7)
134.8	141.8	(4.9)
498.1	542.0	(8.1)
188.8	202.5	(6.8)
82.8	78.7	5.2
166.0	173.6	(4.4)
437.6	454.8	(3.8)
\$935.7	\$ 996.8	(6.1)
	\$318.5 44.8 134.8 498.1 188.8 82.8 166.0 437.6	\$ 318.5       \$ 352.2         44.8       48.0         134.8       141.8         498.1       542.0         188.8       202.5         82.8       78.7         166.0       173.6         437.6       454.8

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## **Operating Income**

Operating income by segment and as a percentage of segment net sales for fiscal 2013 and 2012 is shown in the following table (dollars in millions):

	Fiscal Year			
	2013		2012	
Specialty Pharmaceuticals	\$ 311.7	25.6%	\$162.8	16.2%
Global Medical Imaging	112.3	12.0	214.3	21.5
Segment operating income	424.0	19.7	377.1	18.8
Unallocated amounts:				
Corporate and allocated expenses	(133.8)		(69.9)	
Intangible asset amortization	(35.4)		(27.3)	
Restructuring and related charges, net <sup>(1)</sup>	(35.8)		(19.2)	
Separation costs	(74.2)		(25.5)	
Total operating income	\$ 144.8		\$235.2	

(1) Includes restructuring-related accelerated depreciation of \$2.6 million and \$8.0 million for fiscal 2013 and 2012, respectively.

*Specialty Pharmaceuticals*. Operating income for fiscal 2013 increased \$148.9 million to \$311.7 million, compared with \$162.8 million for fiscal 2012. Our operating margin increased to 25.6% for fiscal 2013, compared with 16.2% for fiscal 2012. The increase in operating income and margin was primarily due to increased sales of higher margin products, such as Methylphenidate ER and Exalgo, and favorable pricing.

*Global Medical Imaging*. Operating income for fiscal 2013 decreased \$102.0 million to \$112.3 million, compared with \$214.3 million for fiscal 2012. Our operating margin decreased to 12.0% for fiscal 2013, compared with 21.5% for fiscal 2012. The decrease in operating income was attributable to lower net sales, discussed previously, increased manufacturing and raw material costs and the effects of a renegotiated customer contract in the U.S., partially offset by a decrease in selling, general and administrative expenses. Our operating margin was most significantly impacted by higher raw material costs from the unscheduled shutdown of the HFR that supplies us with Mo-99. Ongoing increased materials and manufacturing costs will limit our ability to return the Global Medical Imaging segment to historical operating margins on a long-term basis.

*Corporate and allocated expenses.* Corporate and allocated expenses were \$133.8 million and \$69.9 million for fiscal 2013 and 2012, respectively. The increase primarily resulted from \$70.6 million of costs related to the build-out of our corporate infrastructure during the current year period compared with \$10.7 million during the prior year period. In addition to corporate infrastructure build-out costs, we were allocated general corporate expenses of \$39.6 million and \$49.2 million during fiscal 2013 and 2012, respectively, for certain functions provided by Covidien. These allocations ceased in periods following the completion of the separation on June 28, 2013.

Fiscal Year Ended September 28, 2012 Compared with Fiscal Year Ended September 30, 2011

# Net Sales

Net sales by segment are shown in the following table (dollars in millions):

	Fiscal Year				
			Percentage		
	2012	2011	Change		
Specialty Pharmaceuticals	\$ 1,005.2	\$ 909.4	10.5%		
Global Medical Imaging	996.8	1,060.0	(6.0)		
Net sales of operating segments	2,002.0	1,969.4	1.7		
Other <sup>(1)</sup>	54.2	52.4	3.4		
Net sales	\$ 2,056.2	\$ 2,021.8	1.7		

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## (1) Represents products that were sold to Covidien.

*Specialty Pharmaceuticals*. Net sales for fiscal 2012 increased \$95.8 million, or 10.5%, to \$1,005.2 million, compared with \$909.4 million for fiscal 2011. The increase in net sales was primarily driven by increased sales of our Exalgo and Pennsaid branded products. This increase was partially offset by the impact of the extra selling week in fiscal 2011 and a decrease in net sales of oxycodone immediate-release tablets.

Net sales for Specialty Pharmaceuticals by geography are as follows (dollars in millions):

	Fisca		
	2012	2011	Percentage Change
U.S.	\$ 880.6	\$784.8	12.2%
Europe, Middle East and Africa	108.7	93.4	16.4
Other	15.9	31.2	(49.0)
Net sales	\$ 1,005.2	\$ 909.4	10.5

Net sales for Specialty Pharmaceuticals by key products are as follows (dollars in millions):

	Fiscal		
	2012	2011	Percentage Change
Acetaminophen (API) products	\$ 217.7	\$222.2	(2.0)%
Oxycodone (API) and oxycodone-containing			
tablets	144.1	154.1	(6.5)
Hydrocodone (API) and hydrocodone-containing			
tablets	130.5	116.9	11.6
Other controlled substances	111.7	107.9	3.5
Other	244.8	223.6	9.5
Generics and API	848.8	824.7	2.9
Exalgo	91.9	41.2	123.1
Other	64.5	43.5	48.3
Brands	156.4	84.7	84.7
Specialty Pharmaceuticals	\$1,005.2	\$909.4	10.5

*Global Medical Imaging*. Net sales for fiscal 2012 decreased \$63.2 million, or 6.0%, to \$996.8 million compared with \$1,060.0 million for fiscal 2011. This decrease was largely due to decreased net sales of CMDS, primarily resulting from lower net sales of Optiray due to the renegotiation of a customer contract in the U.S. market and discontinuance of a product, combined with unfavorable currency exchange rate fluctuations and other market-related challenges. In

addition, fiscal 2012 net sales growth was negatively impacted by the extra selling week in fiscal 2011.

Net sales for Global Medical Imaging by geography are as follows (dollars in millions):

	Fisc		
	2012	2011	Percentage Change
U.S.	\$466.8	\$ 505.8	(7.7)%
Europe, Middle East and Africa	302.3	326.3	(7.4)
Other	227.7	227.9	(0.1)
Net sales	\$ 996.8	\$ 1,060.0	(6.0)

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Net sales for Global Medical Imaging by key products are as follows (dollars in millions):

Fisca		
		Percentage
2012	2011	Change
\$352.2	\$ 374.9	(6.1)%
48.0	50.3	(4.6)
141.8	170.3	(16.7)
542.0	595.5	(9.0)
202.5	200.3	1.1
78.7	76.9	2.3
173.6	187.3	(7.3)
454.8	464.5	(2.1)
\$ 996.8	\$ 1,060.0	(6.0)
	<b>2012</b> \$ 352.2 48.0 141.8 542.0 202.5 78.7 173.6 454.8	\$ 352.2       \$ 374.9         48.0       50.3         141.8       170.3         542.0       595.5         202.5       200.3         78.7       76.9         173.6       187.3         454.8       464.5

#### **Operating Income**

Operating income by segment and as a percentage of segment net sales for fiscal 2012 and 2011 is shown in the following table (dollars in millions):

	<b>Fiscal Year</b>			
	2013	3	2012	2
Specialty Pharmaceuticals	\$162.8	16.2%	\$121.5	13.4%
Global Medical Imaging	214.3	21.5	232.4	21.9
Segment operating income	377.1	18.8	353.9	18.0
Unallocated amounts:				
Corporate and allocated expenses	(69.9)		(73.3)	
Intangible asset amortization	(27.3)		(27.0)	
Restructuring and related charges, net <sup>(1)</sup>	(19.2)		(10.0)	
Separation costs	(25.5)		(2.9)	
Total operating income	\$235.2		\$ 240.7	

(1) Includes restructuring-related accelerated depreciation of \$8.0 million and \$1.6 million for fiscal 2012 and 2011, respectively.

*Specialty Pharmaceuticals.* Operating income for fiscal 2012 increased \$41.3 million to \$162.8 million, compared with \$121.5 million for fiscal 2011. Our operating margin increased to 16.2% for fiscal 2012, compared with 13.4% for fiscal 2011. The increase in operating income and margin was primarily due to favorable product mix resulting

from increased net sales of our higher margin branded products.

*Global Medical Imaging*. Operating income for fiscal 2012 decreased \$18.1 million to \$214.3 million, compared with \$232.4 million for fiscal 2011. Our operating margin decreased to 21.5% for fiscal 2012, compared with 21.9% for fiscal 2011. The decrease in operating income and margin was primarily due to lower pricing and volume from renegotiated contracts with certain customer groups, which resulted in a switch to a dual source contract from a single source contract.

*Corporate and allocated expenses.* Corporate and allocated expenses were \$69.9 million and \$73.3 million for fiscal 2012 and 2011, respectively. These amounts include allocations of \$49.2 million and \$56.3 million during fiscal 2012 and 2011, respectively, for certain functions provided by Covidien. Excluding the \$7.1 million decrease in the amount of allocated expenses, the remaining \$3.7 million increase in corporate expenses in fiscal 2012, compared with fiscal 2011, primarily resulted from \$10.7 million of costs incurred to build-out our corporate infrastructure, partially offset by lower environmental and asbestos-related costs.

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### Liquidity and Capital Resources

Significant factors driving our liquidity position include cash flows generated from operating activities, financing transactions, capital expenditures and cash paid in connection with acquisitions and license agreements. Historically, we have typically generated, and expect to continue to generate, positive cash flow from operations. Through June 28, 2013, as part of Covidien, our cash was swept regularly by Covidien at its discretion. Covidien also funded our operating and investing activities as needed prior to the separation. The cash and cash equivalents held by Covidien at the corporate level were not specifically identifiable or otherwise allocable to us and, as such, were not reflected on the combined balance sheets for dates prior to June 28, 2013. Cash flows related to financing activities prior to the separation reflect changes in Covidien s investments in us. Transfers of cash to and from Covidien were reflected as a component of parent company investment within parent company equity on our combined balance sheets through June 28, 2013. Our cash flows for periods prior to June 28, 2013, may not be indicative of our future performance and do not necessarily represent the cash flows that would have been generated had we operated as an independent, publicly-traded company for the entirety of the periods presented.

Effective June 28, 2013, we are no longer participating in cash management and funding arrangements with Covidien and our ability to fund our capital needs is impacted by our ongoing ability to generate cash from operations and access to capital markets. We believe that our future cash from operations, borrowing capacity under our revolving credit facility and access to capital markets will provide adequate resources to fund our working capital needs, capital expenditures and strategic investments.

In fiscal 2014, we expect our total capital expenditures to be in the range of \$140 million to \$160 million. While we intend to fund these capital expenditures with cash generated from operations, we also have \$250 million of borrowing capacity under a revolving credit facility. At September 27, 2013, we had capital expenditure commitments of \$6.9 million.

A summary of our cash flows from operating, investing and financing activities is provided in the following table (dollars in millions):

	Three Months Ended December 27, December 28,			Fiscal Year		
	2013		2012	2013	2012	2011
Net cash provided by (used in):						
Operating activities	\$ 22.1	\$	(59.0)	\$ 135.9	\$ 255.8	\$ 370.2
Investing activities	(12.6)		(130.2)	(234.7)	(152.2)	(112.6)
Financing activities	4.2		189.2	373.0	(103.6)	(257.6)
Effect of currency exchange rate changes on						
cash and cash equivalents	(1.4)			1.3		
Net increase in cash and cash equivalents	\$ 12.3			\$ 275.5	\$	\$

### **Operating** Activities

Net cash provided by operating activities of \$22.1 million for the three months ended December 27, 2013 was primarily attributable to income from continuing operations, as adjusted for non-cash items, partially offset by a \$73.9 million outflow from net investment in working capital. The working capital outflow was primarily driven by a \$66.4

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million decrease in accrued and other liabilities and a \$33.2 million increase in inventory, partially offset by a \$21.3 million increase in accounts payable and \$4.4 million net increases in other working capital accounts. The decrease in accrued and other liabilities resulted largely from the annual payout of cash bonuses for performance in the prior fiscal year and our semi-annual interest payment in October 2013. Inventory increased, driven in part by anticipation of calendar year DEA quota renewals, which also increased our accounts payable.

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Net cash used in operating activities of \$59.0 million for the three months ended December 28, 2012 was primarily attributable to a \$116.5 million outflow from net investments in working capital, partially offset by income from continuing operations, as adjusted for depreciation and amortization. The working capital outflow was primarily driven by an \$83.4 million decrease in accrued and other liabilities and a \$41.7 million increase in inventory, partially offset by a \$12.1 million increase in income taxes payable which was recorded in parent company investment. The decrease in accrued and other liabilities resulted largely from a \$37.5 million voluntary contribution to our pension plans and the annual payout of cash bonuses for performance in the prior fiscal year.

Net cash provided by operating activities of \$135.9 million for fiscal 2013 was primarily attributable to income from continuing operations, as adjusted for non-cash items, partially offset by a \$79.0 million outflow from net investment in working capital. The working capital outflow was primarily driven by a \$181.2 million increase in accounts receivable and a \$16.0 million outflow in other working capital accounts, partially offset by a \$60.7 million increase in increase in income taxes payable, which was substantially settled through parent company investment, a \$27.7 million decrease in inventory and a \$22.6 million increase in accrued and other liabilities. The increase in accounts receivable was primarily attributable to the fact that \$95.6 million of accounts receivable in certain jurisdictions outside the U.S. were retained by Covidien through parent company investment, which is included within the financing section of the consolidated and combined statement of cash flows.

Net cash provided by operating activities of \$255.8 million for fiscal 2012 was primarily attributable to income from continuing operations, as adjusted for depreciation and amortization, partially offset by a \$25.4 million outflow from net investments in working capital. The working capital outflow was primarily driven by a \$62.8 million increase in inventory and a \$38.7 million decrease in accrued and other liabilities, partially offset by a \$79.4 million increase in income taxes payable, the latter of which was recorded in parent company investment. A build-up of inventory in advance of a planned plant closure contributed to the increase in inventory, while environmental payments contributed to the decrease in accrued and other liabilities.

Net cash provided by operating activities of \$370.2 million in fiscal 2011 was primarily attributable to income from continuing operations, as adjusted for depreciation and amortization, deferred income taxes and an increase in working capital of \$58.1 million. The increase in working capital was primarily driven by a \$36.0 million increase in income taxes payable, which was recorded in parent company investment.

### **Investing** Activities

Net cash used in investing activities decreased \$117.6 million to \$12.6 million for the three months ended December 27, 2013, compared with \$130.2 million for the three months ended December 28, 2012. This increase primarily resulted from an \$88.1 million payment made during the three months ended December 28, 2012 to acquire CNS Therapeutics, Inc. and a \$21.1 million decrease in capital expenditures.

Net cash used in investing activities increased \$82.5 million to \$234.7 million for fiscal 2013, compared with \$152.2 million for fiscal 2012. This increase primarily resulted from an \$88.1 million payment made during fiscal 2013 to acquire CNS Therapeutics and a \$3.7 million increase in capital expenditures. These increases were partially offset by a \$13.2 million payment in fiscal 2012 to acquire rights to Roxicodone.

Net cash used in investing activities increased \$39.6 million to \$152.2 million in fiscal 2012, compared with \$112.6 million in fiscal 2011. This increase primarily resulted from a \$23.8 million increase in capital expenditures and a \$13.2 million payment made in fiscal 2012 to acquire rights to Roxicodone.

### **Financing** Activities

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Net cash provided by financing activities was \$4.2 million for the three months ended December 27, 2013, compared with \$189.2 million for the three months ended December 28, 2012. The \$185.0 million decrease largely resulted from net transfers from Covidien of \$187.6 million made during the prior year period, which reflected the funding of the CNS Therapeutics, lnc. acquisition and higher capital expenditures.

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Net cash provided by financing activities was \$373.0 million for fiscal 2013, compared with net cash used in financing activities of \$103.6 million for fiscal 2012. The \$476.6 million increase in cash provided by financing activities resulted from the receipt of \$886.1 million of cash proceeds from the issuance of debt, net of debt financing costs, partially offset by a \$411.9 million increase in net transfers to Covidien. This increase was attributable to remitting the net proceeds from the issuance of debt partially offset by the initial cash capitalization, funding of higher capital expenditures and funding of the CNS Therapeutics acquisition.

Net cash used in financing activities decreased \$154.0 million to \$103.6 million in fiscal 2012, compared with \$257.6 million in fiscal 2011. This resulted from a decrease in net transfers to Covidien. Net transfers to Covidien were lower in fiscal 2012 due to a decrease in operating cash flow and an increase in capital expenditures.

### Inflation

Inflationary pressures have had an adverse effect on us through higher raw material and fuel costs, primarily in our Global Medical Imaging segment as noted previously. We have entered into commodity swap contracts in the past to mitigate the impact of rising prices and may do so in the future. If these contracts are not effective or we are not able to achieve price increases on our products, we may continue to be impacted by these increased costs.

# Foreign Currency

Certain net sales and costs of our international operations are denominated in the local currency of the respective countries. As such, profits from these subsidiaries may be impacted by fluctuations in the value of these local currencies relative to the U.S. dollar. We also have significant intercompany financing arrangements that may result in gains and losses in our results of operations. In an effort to mitigate the impact of currency exchange rate effects we may hedge certain operational and intercompany transactions; however, our hedging strategies may not fully offset gains and losses recognized in our results of operations.

### Concentration of Credit and Other Risks

Financial instruments that potentially subject us to concentrations of credit risk primarily consist of accounts receivable. We generally do not require collateral from customers. A portion of our accounts receivable outside the U.S. includes sales to government-owned or supported healthcare systems in several countries, which are subject to payment delays. Payment is dependent upon the financial stability and creditworthiness of those countries national economies. Deteriorating credit and economic conditions in parts of Western Europe, particularly in Spain and Italy, may continue to increase the average length of time it takes us to collect our accounts receivables in certain regions within these countries.

We routinely evaluate all government receivables for potential collection risks associated with the availability of government funding and reimbursement practices. We have not incurred any significant losses on government receivables; however, if the financial condition of customers or the countries healthcare systems continue to deteriorate such that their ability to make payments is uncertain, additional allowances may be required in future periods.

For further information on these and other concentration risks, refer to Note 20 of the notes to our annual consolidated and combined financial statements included elsewhere in this prospectus.

# Debt and Capitalization

At December 27, 2013, total debt was \$919.4 million compared with total debt at September 27, 2013 of \$919.8 million.

In March 2013, MIFSA entered into a \$250 million five-year senior unsecured revolving credit facility that matures in June 2018. Borrowings under the credit facility will initially bear interest at LIBOR plus 2.375% per annum (subject to adjustment pursuant to a ratings-based pricing grid). The credit facility contains a \$150 million letter of credit sublimit. The credit facility is subject to an initial annual facility fee of 0.375%, which is also subject to adjustment pursuant to a ratings-based pricing grid, and the fee applied to outstanding letters of credit is based on the interest rate applied to borrowings. The credit facility agreement contains customary affirmative and negative covenants, including a financial maintenance covenant that limits our ratio of debt to earnings before interest, income taxes, depreciation and amortization, as adjusted for certain items, and another financial maintenance covenant that requires our ratio of earnings before interest, income taxes, depreciation and amortization, as adjusted for certain items, the ability of non-guarantor subsidiaries to incur additional indebtedness and our ability to merge or consolidate with any other person or sell or convey certain of our assets to any one person. MIFSA was not permitted to draw upon the credit facility until certain conditions were met, including completion of the separation and Mallinckrodt plc s guaranty of MIFSA s obligations under the credit facility. These conditions were satisfied as of June 28, 2013; however, there were no borrowings or letters of credit facility.

In April 2013, MIFSA issued the outstanding notes. For more information, see Description of the Notes. The net proceeds to MIFSA from the issuance and sale of the outstanding notes was \$889.3 million, the majority of which was retained by Covidien per the terms of the separation and distribution agreement entered into with Covidien on June 28, 2013.

### Debt Covenants

As of December 27, 2013, we were, and expect to remain, in compliance with the provisions and covenants associated with our credit agreement, the notes and our other debt agreements.

### Capitalization

The cash capitalization at June 28, 2013 was subject to adjustment to compensate either Mallinckrodt or Covidien, as applicable, to the extent that the aggregate of our cash, indebtedness and specified working capital accounts as of the distribution date, as well as capital expenditures made with respect to our business during fiscal 2013 through the distribution date, deviated from a target. The adjustment payment would only be payable if the amount of the adjustment payment exceeded \$20 million (in which case the entire amount would be paid). Upon final calculation, no adjustment payment was required by either us or Covidien.

### Dividends

We currently do not anticipate paying any cash dividends for the foreseeable future, as we intend to retain any earnings to finance R&D, acquisitions and the operation and expansion of our business. The recommendation, declaration and payment of any dividends in the future by us will be subject to the sole discretion of our board of directors and will depend upon many factors, including our financial condition, earnings, capital requirements of our operating subsidiaries, covenants associated with certain of our debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by our board of directors. Moreover, if we determine to pay any dividends in the future, there can be no assurance that we will continue to pay such dividends.

## **Commitments and Contingencies**

### **Contractual Obligations**

The following table summarizes our contractual obligations as of September 27, 2013 (in millions):

		Payments Due By Period					
	Total	Less tl	han 1 year	1-3 years	3-5 years	More t	han 5 years
Long-term debt obligations <sup>(1)</sup>	\$1,270.8	\$	40.7	\$ 81.2	\$ 381.2	\$	767.7
Capital lease obligations <sup>(1)</sup>	3.4		1.5	1.9			
Operating lease obligations	66.7		19.3	23.7	13.5		10.2
Purchase obligations <sup>(2)</sup>	120.9		74.9	46.0			
Total contractual obligations	\$1,461.8	\$	136.4	\$ 152.8	\$ 394.7	\$	777.9

- (1) Interest on debt and capital lease obligations are projected for future periods using interest rates in effect as of September 27, 2013. Certain of these projected interest payments may differ in the future based on changes in market interest rates.
- (2) Purchase obligations consist of commitments for purchases of goods and services made in the normal course of business to meet operational and capital requirements.

The preceding table does not include other liabilities of \$472.4 million, primarily consisting of obligations under our pension and postretirement benefit plans, unrecognized tax benefits for uncertain tax positions and related accrued interest and penalties, environmental liabilities and asset retirement obligations, because the timing of their future cash outflow is uncertain. The most significant of these liabilities are discussed below.

Income taxes payable is included within other income tax liabilities on the consolidated and combined balances sheets and, as of September 27, 2013, was \$153.1 million. Payment of these liabilities is uncertain and, even if payments are determined to be necessary, they are subject to the timing of rulings by the IRS of tax positions we take. For further information on income tax related matters, refer to Note 7 of the notes to our annual consolidated and combined financial statements included elsewhere in this prospectus.

As of September 27, 2013, we had net unfunded pension and postretirement benefit obligations of \$45.7 million and \$53.2 million, respectively. While the timing and amounts of long-term funding requirements for pension and postretirement obligations are uncertain, we do not anticipate making material contributions to our pension and postretirement benefit plans during fiscal 2014.

We are involved in various stages of investigation and cleanup related to environmental remediation matters at a number of sites. These projects relate to a variety of activities, including decontamination and decommissioning of radioactive materials and removal of solvents, metals and other hazardous substances from soil and groundwater. The ultimate cost of cleanup and timing of future cash outlays is difficult to predict given uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations and alternative cleanup methods. As of September 27, 2013, we believe that it is probable that we will incur investigation and remedial costs of approximately \$46.4 million, of which \$6.9 million is included in accrued and other current liabilities on our consolidated balance sheet at September 27, 2013. Note 18 of the notes to our annual consolidated and combined

financial statements included elsewhere in this prospectus provides additional information regarding environmental matters, including asset retirement obligations.

# Legal Proceedings

We are subject to various legal proceedings and claims, including patent infringement claims, product liability matters, environmental matters, employment disputes, contractual disputes and other commercial disputes, including those described in Business Legal Proceedings. We believe that these legal proceedings and claims likely will be resolved over an extended period of time. Although it is not feasible to predict the outcome of these matters, management believes that their ultimate resolution will not have a material adverse effect on our financial condition, results of operations and cash flows.

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### Guarantees

In disposing of assets or businesses, we have historically provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to the assets, environmental risks involved in the sale of real estate, liability to investigate and remediate environmental contamination at waste disposal sites and manufacturing facilities, and unidentified tax liabilities related to periods prior to disposition. We assess the probability of potential liabilities related to such representations, warranties and indemnities and adjust potential liabilities as a result of changes in facts and circumstances. We believe, given the information currently available, that their ultimate resolution will not have a material adverse effect on our financial condition, results of operations and cash flows.

In connection with the sale of the Specialty Chemicals business (formerly known as Mallinckrodt Baker) in fiscal 2010, we agreed to indemnify the purchaser with respect to various matters, including certain environmental, health, safety, tax and other matters. The indemnification obligations relating to certain environmental, health and safety matters have a term of 17 years from the sale, while some of the other indemnification obligations have an indefinite term. The amount of the liability relating to all of these indemnification obligations included in other liabilities on our unaudited condensed consolidated balance sheet as of December 27, 2013 was \$16.8 million, of which \$13.9 million related to environmental, health and safety matters. The value of the environmental, health and safety indemnify was measured based on the probability-weighted present value of the costs expected to be incurred to address environmental, health and safety claims made under the indemnity. The aggregate fair value of these indemnification obligations did not differ significantly from their aggregate carrying value at December 27, 2013. As of December 27, 2013, the maximum future payments we could be required to make under these indemnification obligations was \$71.4 million. We were required to pay \$30.0 million into an escrow account as collateral to the purchaser, of which \$19.4 million remained in other assets on our unaudited condensed consolidated balance sheet at December 27, 2013.

We have recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 18 of the notes to our annual consolidated and combined financial statements included elsewhere in this prospectus. In addition, we are liable for product performance; however, in the opinion of management, such obligations will not have a material adverse effect on our financial condition, results of operations and cash flows.

### **Off-Balance Sheet Arrangements**

We are required to provide the NRC financial assurance demonstrating our ability to fund the decommissioning of our Maryland Heights, Missouri radiopharmaceuticals production facility upon closure, though we do not intend to close this facility. We have provided this financial assurance in the form of a \$58.0 million surety bond.

In addition, as of December 27, 2013, we had a \$21.1 million letter of credit to guarantee decommissioning costs associated with our Saint Louis, Missouri plant. As of December 27, 2013, we had various other letters of credit and guarantee and surety bonds totaling \$32.7 million.

As of December 27, 2013, we have exchanged title to \$27.4 million of our plant assets in return for an equal amount of Industrial Revenue Bonds (IRB) issued by Saint Louis County. We also simultaneously leased such assets back from Saint Louis County under a capital lease expiring December 2025, the terms of which provide us with the right of offset against the IRBs. The lease also provides an option for us to repurchase the assets at the end of the lease for nominal consideration. These transactions collectively result in a property tax abatement ten years from the date the property is placed in service. Due to right of offset, the capital lease obligation and IRB asset are recorded net in the

unaudited condensed consolidated balance sheets. The Company expects that the right of offset will be applied to payments required under these arrangements.

In addition, the separation and distribution agreement provides for cross-indemnities principally designed to place financial responsibility of the obligations and liabilities of our business with us and financial responsibility for the obligations and liabilities of Covidien s remaining business with Covidien, among other indemnities.

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#### **Critical Accounting Policies and Estimates**

The consolidated and combined financial statements have been prepared in U.S. dollars and in accordance with accounting principles generally accepted in the U.S. (GAAP). The preparation of the consolidated and combined financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses. The following accounting policies are based on, among other things, judgments and assumptions made by management that include inherent risks and uncertainties. Management s estimates are based on the relevant information available at the end of each period.

### **Revenue Recognition**

We recognize revenue for product sales when title and risk of loss have transferred from us to the buyer, which may be upon shipment or upon delivery to the customer site, based on contract terms or legal requirements in non-U.S. jurisdictions. We sell products direct to retail pharmacies and end user customers and through distributors who resell the products to retail pharmacies, institutions and end user customers. We establish contracts with wholesalers, chain stores, government agencies, institutions ervice agreements (DSAs) fees, fees for services and administration fees. Direct rebates and fees are paid based on direct customer s purchases from us, including DSA fees paid to wholesalers under our DSAs. Indirect rebates and fees are paid based on products purchased from a wholesaler under a contract with us. We enter into agreements with some indirect customers to establish contract pricing for certain products. These indirect customers then independently select a wholesaler from which to purchase the products at these contracted prices. Alternatively, we may enter into agreements with wholesalers at a contract price to offer our products to other indirect customers. Under either arrangement, we provide credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler s invoice price. Such credit is called a chargeback.

When we recognize net sales, we simultaneously record an adjustment to revenue for estimated chargebacks, rebates, product returns and other sales deductions. These provisions are estimated based upon historical experience, estimated future trends, estimated customer inventory levels, current contracted sales terms with customers, level of utilization of our products and other competitive factors. We adjust reserves for rebates and chargebacks, product returns and other sales deductions to reflect differences between estimated and actual experience. Such adjustments impact the amount of sales we recognize in the period of adjustment.

Sales return reserves for new products are estimated and primarily based on our historical sales return experience with similar products, such as those within the same product line or those within the same or similar therapeutic category. In limited circumstances, where the new product is not an extension of an existing product line or where we have no historical experience with products in a similar therapeutic category (such that we cannot reliably estimate expected returns), we would defer recognition of revenue until the right of return no longer exists or until we have developed sufficient historical experience to estimate sales returns. When establishing sales return reserves for new products, we also consider estimated levels of inventory in the distribution channel and projected demand. The following table reflects activity in our sales reserve accounts (dollars in millions):

	Rebates and Chargebacks	Product Returns	Other Sales Deductions	Total
Balance at September 24, 2010	\$ 205.3	\$ 32.5	\$ 11.9	\$ 249.7

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Provisions		1,218.8	40.5		47.1	1,306.4	
Payments or credits		(1,200.1)	(39.1)		(45.7)	(1,284.9)	
Balance at September 30, 2011		224.0	33.9		13.3	271.2	
Provisions		1,085.9	30.0		41.9	1,157.8	
Payments or credits		(1,077.7)	(29.2)		(42.3)	(1,149.2)	
Balance at September 28, 2012		232.2	34.7		12.9	279.8	
Provisions		1,219.8	37.1		60.0	1,316.9	
Payments or credits		(1,194.9)	(21.7)		(57.2)	(1,273.8)	
Balance at September 27, 2013	\$	257.1	\$ 50.1	\$	15.7	\$ 322.9	

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#### Inventory

Inventories are recorded at the lower of cost or market value, primarily using the first-in, first-out convention. We reduce the carrying value of inventories for those items that are potentially excess, obsolete or slow-moving based on changes in customer demand, technology developments or other economic factors. If market conditions and actual demands are less favorable than projected, additional inventory write-downs may be required.

### Goodwill and Other Intangible Assets

In performing goodwill assessments, management relies on a number of factors including operating results, business plans, economic projections, anticipated future cash flows, and transactions and market place data. There are inherent uncertainties related to these factors and judgment in applying them to the analysis of goodwill impairment. Since judgment is involved in performing goodwill valuation analyses, there is risk that the carrying value of our goodwill may be overstated or understated. We calculate our goodwill valuations using an income approach based on the present value of future cash flows of each reporting unit. This approach incorporates many assumptions including future growth rates, discount factors and income tax rates. Changes in economic and operating conditions impacting these assumptions could result in goodwill impairment in future periods.

We test goodwill during the fourth quarter of each year for impairment, or more frequently if certain indicators are present or changes in circumstances suggest that impairment may exist. We utilize a two-step approach. The first step requires a comparison of the carrying value of the reporting units to the fair value of these units. We estimate the fair value of our reporting units through internal analyses and valuation, using an income approach based on the present value of future cash flows. If the carrying value of a reporting unit exceeds its fair value, we will perform the second step of the goodwill impairment to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of a reporting unit s goodwill with its carrying value. To determine the implied fair value of goodwill, we allocate the fair value of a reporting unit to all of the assets and liabilities of that unit, including intangible assets, as if the reporting unit had been acquired in a business combination. Any excess of the value of a reporting unit over the amounts assigned to its assets and liabilities represents the implied fair value of goodwill. The results of our annual goodwill impairment test for fiscal 2013 showed that the fair value of each of our reporting units exceeded their respective carrying values.

Intangible assets include completed technology, licenses, trademarks and in-process research and development. We record intangible assets at cost and amortize finite-lived intangible assets using the straight-line method over five to thirty years. When a triggering event occurs, we evaluate potential impairment of finite-lived intangible assets by first comparing undiscounted cash flows associated with the asset to its carrying value. If the carrying value is greater than the undiscounted cash flows, the amount of potential impairment is measured by comparing the fair value of the assets with their carrying value. The fair value of the intangible asset is estimated using an income approach. If the fair value is less than the carrying value of the intangible asset, the amount recognized for impairment is equal to the difference between the carrying value of the assets and the present value of future cash flows. In the fourth quarter of each year, we test the indefinite-lived intangible assets for impairment by comparing the fair value of the assets, estimated using an income approach, with their carrying value and record an impairment when the carrying value exceeds the fair value. We assess the remaining useful life and the recoverability of finite-lived intangible assets whenever events or circumstances indicate that the carrying value of an asset may not be recoverable.

### Contingencies

We are involved, both as a plaintiff and a defendant, in various legal proceedings that arise in the ordinary course of business, including, without limitation, patent infringement, product liability and environmental matters, as further

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discussed in Business Legal Proceedings. Accruals recorded for various contingencies,

including legal proceedings, self-insurance and other claims, are based on judgment, the probability of losses and, where applicable, the consideration of opinions of internal and/or external legal counsel, internal and/or external technical consultants and actuarially determined estimates. When a range is established but a best estimate cannot be made, we record the minimum loss contingency amount. These estimates are often initially developed substantially earlier than the ultimate loss is known, and the estimates are reevaluated each accounting period as additional information becomes available. When we are initially unable to develop a best estimate of loss, we record the minimum amount of loss, which could be zero. As information becomes known, additional loss provision is recorded when either a best estimate can be made or the minimum loss amount is increased. When events result in an expectation of a more favorable outcome than previously expected, our best estimate is changed to a lower amount. We record receivables from third-party insurers up to the amount of the related liability when we have determined that existing insurance policies will provide reimbursement. In making this determination, we consider applicable deductibles, policy limits and the historical payment experience of the insurance carriers. Receivables are not netted against the related liabilities for financial statement presentation.

### Pension and Postretirement Benefits

Our pension expense and obligations are developed from actuarial valuations. Two critical assumptions in determining pension expense and obligations are the discount rate and expected long-term return on plan assets. We evaluate these assumptions at least annually. Other assumptions reflect demographic factors such as retirement, mortality and turnover and are evaluated periodically and updated to reflect our actual experience. Actual results may differ from actuarial assumptions. The discount rate is used to calculate the present value of the expected future cash flows for benefit obligations under our pension plans. For our U.S. plans, we use a broad population of Moody s AA-rated corporate bonds to determine the discount rate assumption. All bonds are non-callable, denominated in U.S. dollars and have a minimum amount outstanding of \$250 million. This population of bonds was used to generate a yield curve and associated spot rate curve, to discount the projected benefit payments for the U.S. plans, the discount rate is generally determined by reviewing country- and region-specific government and corporate bond interest rates. As of September 27, 2013, a decrease in the discount rate increases the present value of pension benefit obligations and increases pension expense. A 50 basis point decrease in the discount rate would increase our present value of pension obligations by approximately \$29.8 million.

We consider the current and expected asset allocations of our pension plans, as well as historical and expected long-term rates of return on those types of plan assets, in determining the expected long-term return on plan assets. In determining the expected return on pension plan assets, we consider the relative weighting of plan assets by class and individual asset class performance expectations as provided by external advisors in reaching our conclusions on appropriate assumptions. Our overall investment objective is to obtain a long-term return on plan assets that is consistent with the level of investment risk that is considered appropriate. Investment risks and returns are reviewed regularly against benchmarks to ensure objectives are being met. As of September 27, 2013, a 50 basis point decrease in the expected long-term return on plan assets would increase our annual pension expense by approximately \$2.2 million.

### Share-Based Compensation

Share-based compensation cost is measured at the grant or modification date based on the value of the award and is recognized as expense over the vesting period for awards expected to vest. Determining the fair value of share-based awards at the grant date requires judgment, including estimating the expected term, expected stock price volatility, risk-free interest rate and expected dividends. Additionally, judgment is required in estimating the amount of share-based awards that are expected to be forfeited before vesting. The original estimate of the grant date fair value is

not subsequently revised unless the awards are modified, but the estimate of expected forfeitures is revised throughout the vesting period and the cumulative share-based compensation cost recognized is adjusted accordingly. For more information about our share-based awards, refer to Note 14 of the notes to our annual consolidated and combined financial statements included elsewhere in this prospectus.

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#### Income Taxes

In determining income for financial statement purposes, we must make certain estimates and judgments. These estimates and judgments affect the calculation of certain tax liabilities and the determination of the recoverability of certain of the deferred tax assets, which arise from temporary differences between the tax and financial statement recognition of revenue and expense.

Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. In evaluating our ability to recover our deferred tax assets, we consider all available positive and negative evidence including our past operating results, the existence of cumulative losses in the most recent years and our forecast of future taxable income. In estimating future taxable income, we develop assumptions including the amount of future state, federal and international pre-tax operating income, the reversal of temporary differences, and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates we use to manage the underlying businesses.

We determine whether it is more likely than not that a tax position will be sustained upon examination. The tax benefit of any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the uncertainty. To the extent a full benefit is not realized on the uncertain tax position, an income tax liability is established. We adjust these liabilities as a result of changing facts and circumstances; however, due to the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the tax liabilities. A significant portion of our potential tax liabilities are recorded in non-current income taxes payable, which is included in other liabilities on our consolidated and combined balance sheets, as payment is not expected within one year.

The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations in a multitude of jurisdictions across our global operations. Changes in tax laws and rates could affect recorded deferred tax assets and liabilities in the future. Management is not aware of any such changes, however, which would have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We believe that we will generate sufficient future taxable income in the appropriate jurisdictions to realize the tax benefits related to the net deferred tax assets on our consolidated and combined balance sheets. However, any reduction in future taxable income, including any future restructuring activities, may require that we record an additional valuation allowance against our deferred tax assets. An increase in the valuation allowance would result in additional income tax expense in such period and could have a significant impact on our future earnings. Our income tax expense recorded in the future may also be reduced to the extent of decreases in our valuation allowances.

#### **Recently Issued Accounting Standards**

Refer to Note 3 of the notes to our annual consolidated and combined financial statements included elsewhere in this prospectus for a discussion regarding recently issued accounting standards and their estimated impact on our financial condition, results of operations and cash flows.

#### Quantitative and Qualitative Disclosures About Market Risk

Our operations include activities in the U.S. and countries outside of the U.S. These operations expose us to a variety of market risks, including the effects of changes in interest rates and currency exchange rates. We monitor and manage

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these financial exposures as an integral part of our overall risk management program. We do not utilize derivative instruments for trading or speculative purposes.

### Interest Rate Risk

As of December 27, 2013, our outstanding debt consisted primarily of our fixed-rate 3.50% and 4.75% senior unsecured notes due in April 2018 and April 2023, respectively, with a combined principal amount of \$900 million. The carrying value of these notes was \$898.1 million as of December 27, 2013. As these notes are fixed-rate debt, they do not subject us to interest rate risk.

In addition, we maintain a \$250 million five-year senior unsecured revolving credit facility with a variable interest rate equal to LIBOR plus a margin subject to adjustment pursuant to a ratings-based pricing grid. As a result, we will be exposed to fluctuations in interest rates to the extent of our borrowings under this facility. As of December 27, 2013, there were no outstanding borrowings under this credit facility.

### Currency Risk

Certain net sales and costs of our international operations are denominated in the local currency of the respective countries. As such, profits from these subsidiaries may be impacted by fluctuations in the value of these local currencies relative to the U.S. dollar. We also have significant intercompany financing arrangements that may result in gains and losses in our results of operations. In an effort to mitigate the impact of currency exchange rate effects we may hedge certain operational and intercompany transactions; however, our hedging strategies may not fully offset gains and losses recognized in our results of operations.

The unaudited condensed consolidated statement of income and the audited consolidated statement of income are significantly exposed to currency risk from intercompany financing arrangements, which primarily consist of intercompany debt and intercompany cash pooling, where the denominated currency of the transaction differs from the functional currency of one or more of our subsidiaries. We performed a sensitivity analysis for these arrangements as of December 27, 2013 that measures the potential unfavorable impact to income from continuing operations before income taxes from a hypothetical 10% adverse movement in foreign exchange rates relative to the U.S. dollar, with all other variables held constant. The aggregate potential unfavorable impact from a hypothetical 10% adverse change in foreign exchange rates was \$30.5 million as of December 27, 2013. This hypothetical loss does not reflect any hypothetical benefits that would be derived from hedging activities, including cash holdings in similar foreign currencies, that we have historically utilized to mitigate our exposure to movements in foreign exchange rates.

The financial results of our non-U.S. operations are translated into U.S. dollars, further exposing us to currency exchange rate fluctuations. We have performed a sensitivity analysis as of December 27, 2013 that measures the change in the net financial position arising from a hypothetical 10% adverse movement in the exchange rates of the Euro, the British Pound and the Canadian Dollar, our most widely used foreign currencies, relative to the U.S. dollar, with all other variables held constant. The aggregate potential change in net financial position from a hypothetical 10% adverse change in the above currencies was \$39.2 million as of December 27, 2013. The change in the net financial position associated with the translation of these currencies is generally recorded as an unrealized gain or loss on foreign currency translation within accumulated other comprehensive income in shareholders equity of our consolidated and combined balance sheets.

## BUSINESS

### Overview

We are a global company that develops, manufactures, markets and distributes both branded and generic specialty pharmaceuticals, API and diagnostic imaging agents. Our products are found in almost every hospital, standalone diagnostic imaging center or pharmacy in the U.S. and we have a commercial presence in approximately 70 countries. We believe our extensive commercial reach and formulation expertise, coupled with our ability to navigate the highly regulated and technical nature of our business, have created compelling competitive advantages that we anticipate will sustain future revenue growth.

We conduct our business in the following two segments:

*Specialty Pharmaceuticals* produces and markets branded and generic pharmaceuticals and API, comprised of medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients; and

*Global Medical Imaging* develops, manufactures and markets CMDS and radiopharmaceuticals (nuclear medicine).

For further information on our products and segments, refer to Our Businesses and Product Strategies.

### **History and Development**

Our Specialty Pharmaceuticals segment can trace its development from the founding of G. Mallinckrodt & Co. in 1867 (predecessor of today s API business). We expanded from the controlled substance API business into controlled substance generics in the mid-1990s to become the 12th largest U.S. generic pharmaceuticals business in 2012, as measured by prescription volume. We started our Brands product portfolio in 2001 and, by 2010, we had more than doubled our branded pharmaceuticals sales force and shifted our focus to pain management. We have since developed the business and are now providing physicians and patients with a comprehensive suite of pain management products, including our Exalgo Extended-Release tablets. Most recently, in October 2012, we acquired CNS Therapeutics, a specialty pharmaceutical company focused on developing and commercializing intrathecal products for site-specific administration to the central nervous system to treat neurological disorders and intractable chronic pain.

Our Global Medical Imaging segment traces its start from a series of innovations by Mallinckrodt and its predecessors, including the introduction of barium in 1916 and of iodeikon as the first contrast agent for gall bladder imaging in 1920. Since then, we have expanded our CMDS business, including products for computed tomography (CT) imaging and magnetic resonance imaging (MRI). We entered the nuclear imaging business in 1966 with our Ultra-Technekow DTE technetium generators, and have subsequently expanded this product line with cold kits and other radioisotopes. In 2008, we launched a generic version of Cardiolite<sup>®</sup> Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, a leading branded cardiac imaging agent and registered trademark of Lantheus Medical Imaging, Inc., which allowed us to fundamentally change the competitive dynamics for technetium generators.

In 2010, we divested our nuclear radiopharmacies in the U.S., which allowed us to focus on our Mo-99 supply. Also, in 2010, we divested our Specialty Chemicals business (formerly known as Mallinckrodt Baker) to better focus our businesses on our pharmaceutical products.

Mallinckrodt plc was incorporated in Ireland on January 9, 2013 for the purpose of holding the Pharmaceuticals business of Covidien. On June 28, 2013, Covidien shareholders of record received one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien held as of the record date, June 19, 2013, and the Pharmaceuticals business of Covidien was transferred to Mallinckrodt plc, thereby completing our legal separation from Covidien. On July 1, 2013, we began regular way trading on the New York Stock Exchange under the ticker symbol MNK.

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Our principal executive offices are located at Damastown, Mulhuddart, Dublin 15, Ireland. Our telephone number at this location is +353 (1) 880-8180. Our U.S. headquarters is located at 675 James S. McDonnell Boulevard, Hazelwood, Missouri 63042. Our telephone number at this location is (314) 654-2000.

#### **Our Competitive Strengths**

We believe we have the following strengths:

*Expertise in the acquisition and importation of highly regulated raw materials, and strong regulatory relationships.* We have expertise in the acquisition and importation of highly regulated raw materials, such as opioids, other controlled substances and radioisotopes. For example, in calendar 2012, we believe we received almost 40% of the DEA s total annual quota for controlled substances that we manufacture. In calendar 2012, our Generics business had an approximate 30% market share of DEA Schedules II and III opioid, oral solid doses, based on IMS Health data. The acquisition of certain raw materials and the processing of them into finished products requires a close collaboration with a wide variety of regulatory authorities including the DEA, FDA, NRC, European Medicines Agency and Irish Medicines Board, among many others. We have a long history of working closely with regulatory agencies to ensure ongoing, reliable access to these highly regulated materials.

*Specialized chemistry, development and formulation expertise which supports a product pipeline.* We have specialized chemistry expertise in the formulation of new drug combinations and reformulation of existing drugs into a wide range of products, such as tablets, capsules, oral liquids, injectable and intrathecal products. In late 2009, we completed a significant upgrade to our formulation pilot plant in Webster Groves, Missouri. This expansion greatly enhanced our pharmaceutical formulation capability, which has resulted in a significant increase in both branded and generic formulations that have been approved by the FDA, or that are in various stages of pre-clinical development, clinical development or regulatory review.

A broad portfolio of generic products and controlled substance API for pain and a pipeline of branded pharmaceutical pain products. Our Generics and API businesses have a strong position in the controlled substance generics market. We believe our Generics and API businesses offer the broadest product line of opioid and other controlled substances available (primarily DEA Schedules II and III), and we focus in a number of therapeutic areas with high barriers to entry, limited competition and long product life-cycles. Our strong market position is a result of the following:

Formulation and manufacturing expertise in controlled substances and complex generics;

Our commitment to investment in our R&D infrastructure and capabilities has resulted in a pipeline of generic and branded controlled substances, many of which are long-acting or hard to formulate products, which are under development or pending approval by the FDA. For example, in the fourth quarter of fiscal 2013, the FDA accepted for filing and granted priority review to our NDA for the drug filed as MNK-795, which the FDA has granted conditional approval for the brand name Xartemis XR. Pennsaid 2%, originally filed as MNK-395, was approved by the FDA in January 2014 and launched

in February 2014. In addition, on December 28, 2012, we became the first company to receive approval from the FDA to manufacture and market in the U.S. a generic version of Concerta, a branded pharmaceutical for the treatment of ADHD;

Our strong position in controlled substance API and vertical integration from opioid raw materials to finished dosage forms; and

U.S. importation restrictions of controlled substance API and finished products.

*Solid market position in diagnostic imaging agents.* We believe that we are one of the top three participants globally in nuclear radiopharmaceutical products. We are one of only two manufacturers of Tc-99m generators (marketed under the brand name Ultra-Technekow DTE) in North America, one of only three in Europe and the only one on either continent that has its own Mo-99 processing facility,

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which provides cost and raw material supply advantages. In CMDS, we offer a fully integrated line of contrast media, pre-filled syringes and proprietary power injectors. Our leading contrast media product, Optiray, has been on the market for over 25 years and is differentiated in part by being offered in pre-filled syringes that fit our proprietary power injectors, which enhances clinician safety and reduces risks in medication management.

*Distinctive high-quality manufacturing and distribution skills with vertical integration where there are competitive advantages.* Our manufacturing and supply chain capabilities enable highly efficient controlled substance tableting, packaging and distribution. Our investments include one of the world s largest DEA Schedule C-II vault storage capacities for raw materials, intermediates and finished dosages. In our Global Medical Imaging segment, we have the capability to process Mo-99 for use in our Ultra-Technekow DTE generators and to manufacture cyclotron-derived isotopes such as thallium-201, indium-111, gallium-67, germanium-68 and iodine-123. In addition, we produce the large-volume terminally sterilized pre-filled plastic syringes that fit into our power injectors. Where appropriate, we have also pursued selective vertical integration initiatives to ensure our manufacturing and supply chain benefit from cost and productivity efficiencies, such as using several of our API products to provide the raw materials for some of our generic products.

*Global commercial reach.* Our Global Medical Imaging segment operates throughout the world and its direct and indirect marketing and selling capabilities are tailored to business and geographic needs. We have unique capabilities in complex markets that are not easy to enter, navigate or operate in, and there are very few companies that have the experience and expertise in manufacturing, regulatory and distribution to effectively manage controlled substances on a global scale. Our Global Medical Imaging segment has a commercial presence in approximately 70 countries that has positioned us for growth in select markets.

Strong management team with extensive industry experience. We benefit from having a management team with extensive experience in small, medium and large life sciences firms. Mark Trudeau, our President and Chief Executive Officer, has more than 29 years of experience in the pharmaceuticals industry. Prior to joining Covidien s Pharmaceuticals business in January 2012, Mr. Trudeau served as Chief Executive Officer of Bayer Healthcare LLC USA, the U.S. healthcare business of Bayer AG, and as President of Bayer HealthCare Pharmaceuticals U.S. Region. Mr. Trudeau also served on the Board of the Pharmaceutical Researchers and Manufacturers of America, the National Pharmaceutical Council and as a Trustee of the HealthCare Institute of New Jersey. Matthew Harbaugh, our Senior Vice President and Chief Financial Officer, joined Covidien s Pharmaceuticals business in 2007 and has over 20 years of financial experience, mostly in the life sciences field. Additional members of the senior management team include Peter Edwards, our Senior Vice President and General Counsel; Hugh O Neill, our Senior Vice President and President of U.S. Specialty Pharmaceuticals; Steve Merrick, our Senior Vice President and President, Commercial Operations, International; Gary Phillips, our Senior Vice President and Chief Strategy Officer; Mario Saltarelli, our Senior Vice President and Chief Science Officer; Ian Watkins, our Senior Vice President and Chief Human Resources Officer; Meredith Fischer, our Senior Vice President, Communications and Public Affairs; and Sandra Hatten, our Senior Vice President, Quality and Regulatory Compliance; all of whom have industry experience.

While we have set forth our competitive strengths above, our business involves numerous risks and uncertainties which may prevent us from executing our strategies. These risks include, among others, risks relating to: DEA regulation of the availability of controlled substances that are API, drug products under development and marketed

drug products; the highly exacting and complex nature of our manufacturing processes; the limited global supply of fission-produced Mo-99 for use in our Ultra-Technekow DTE generators; our customer concentration; cost-containment efforts of our customers, purchasing groups, third-party payors and governmental organizations; developing or commercializing new products or adapting to a changing technology and diagnostic treatment landscape; protecting our intellectual property rights or being subject to claims that we infringe on the intellectual property rights of others; and significant competition. For a more complete description of the risks associated with our business, see Risk Factors.

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#### **Our Businesses and Product Strategies**

We manage our business in two reportable segments: Specialty Pharmaceuticals and Global Medical Imaging. Management measures and evaluates our operating segments based on segment net sales and operating income. Information regarding the product portfolios and business strategies of these segments is included in the following discussion. Financial information regarding each of our reportable segments, as well as other geographical information, is included in Management s Discussion and Analysis of Financial Condition and Results of Operations and in Note 21 of the notes to our annual consolidated and combined financial statements included elsewhere in this prospectus.

#### Specialty Pharmaceuticals

Our Specialty Pharmaceuticals segment has two major components (1) Brands, which we believe will continue to be a growth area for our business, and (2) Generics and API, which we expect will continue to grow and generate significant cash.

Our Brands business markets branded pain drugs, including Exalgo, to physicians. In addition, we have an organic pipeline of branded pain products that are either in clinical trials or awaiting approval from the FDA. We also provide generic drugs, including a variety of product formulations containing hydrocodone, oxycodone, methylphenidate and several other controlled substances. We have a pipeline of controlled substance generic products either in development or awaiting approval from the FDA. Our API business provides bulk API products, including opioids and acetaminophen, to a wide variety of pharmaceutical companies, many of which are direct competitors of our Brands and Generics businesses. In addition, we use our API for internal manufacturing of our finished dosage products. In fiscal 2013, our Specialty Pharmaceuticals segment accounted for 56.5% of net sales from our operating segments. We expect this segment will represent a larger percentage of our net sales over the long term.

We are committed to responsible prescribing, dispensing, use and storage of opioid analgesics to avoid misuse, abuse, addiction, diversion and overdose. In 2010, we started the Collaborating & Acting Responsibly to Ensure Safety Alliance ( the C.A.R.E.S. Alliance ), which offers free non-branded tools and materials to patients, pharmacists and physicians to foster the safe use of opioid pain medications. The C.A.R.E.S. Alliance sponsors drug take back programs among other initiatives. In addition to educational efforts, we work closely with our major distributors to monitor suspicious controlled substance orders and take active steps to limit potential diversion.

#### Brands

We started our Brands product portfolio in 2001 with the acquisition of a suite of products, including RESTORIL (temazepan) capsules, which is indicated for the short-term treatment of insomnia, and TOFRANIL-PM (imipramine pamoate) capsules, which is indicated for the relief of symptoms of depression, from Novartis International AG. In 2010, we shifted our focus to pain management and launched several dosage strengths of our then newly acquired pain product, Exalgo. We subsequently gained approval for a 32 mg dosage strength of Exalgo in August 2012. In addition, our NDA for Pennsaid 2%, originally filed as MNK-395, was approved by the FDA in January 2014 and launched in February 2014. As of December 27, 2013, our development pipeline contains two extended-release formulations of controlled substance analgesics, Xartemis XR and MNK-155. In the fourth quarter of fiscal 2013, our filing of Xartemis XR was accepted by the FDA and granted priority review. In November 2013, in response to additional data we submitted, the FDA extended their review of the Xartemis XR NDA by three months. MNK-155 has completed Phase III clinical trials and our NDA is expected to be filed with the FDA during the second half of fiscal 2014. These two development products are combination products formulated with potentially abuse-deterrent characteristics to address unmet needs in the acute pain market. Our long-term strategy is to advance these pipeline products and bring

them to market to expand the size and profitability of our Brands business. Moreover, we plan to enhance our branded commercial infrastructure by building upon our controlled

substance core and entering into attractive adjacencies in our U.S. markets while focusing on priority markets internationally, through product launches, co-promotions, line extensions and selective acquisitions, such as our acquisition of CNS Therapeutics in October 2012.

We promote our branded products directly to physicians (including pain specialists, anesthesiologists and orthopedic surgeons) with our own direct sales force of over 200 sales representatives. To support the product launch of Xartemis XR, we have entered into an agreement to increase our Brands sales force by 150 to 200 contracted sales representatives. We also use our Brands sales force to promote other Brands products. Our products are purchased by wholesalers and retail pharmacy chains, among others, and are eventually dispensed by prescription to patients. We also market our branded products directly to managed care organizations to gain access to drug formularies and allow patients access to these medications.

The following is a description of select products in our Brands product portfolio:

*Exalgo*, which was acquired in June 2009, is the only long-acting, once-daily form of hydromorphone in the U.S. market. In August 2012, the FDA approved a 32 mg tablet of Exalgo, which further expanded the patient population that Exalgo can effectively treat with a single daily dose. The 8 mg, 12 mg and 16 mg dosages of Exalgo were approved by the FDA in March 2010 for the treatment of chronic pain in opioid-tolerant patients requiring continuous around-the-clock opioid analgesia for an extended amount of time, and have shown significant prescription growth since launch in April 2010. Exalgo was granted marketing exclusivity in the U.S. as a prescription medicine through March 2013 and is protected by two Orange Book-listed patents for a method of treating moderate to severe pain. Beginning in November 2013 for the 8 mg, 12 mg and 16 mg dosages and May 2014 for the 32 mg dosage, a third party will have the right, pursuant to agreements with us, to sell a generic version of Exalgo, contingent upon their obtaining marketing approval from the FDA. We expect sales of Exalgo to decrease in fiscal 2014 (compared with \$126.1 million in fiscal 2013) when the third party enters the market pursuant to these agreements. Additionally, our patents for the 8 mg, 12 mg and 16 mg dosages expire in July 2014.

*Gablofen*, which was acquired in October 2012 with the acquisition of CNS Therapeutics, is indicated for use in management of severe spasticity of cerebral or spinal origin in patients age four years and above. Gablofen is offered in three concentrations in vials and, after FDA approval in January 2013, in pre-filled syringes. Pre-filled syringes were created to reduce preparation steps, helping to simplify the pump refill process for patients receiving ITB Therapy<sup>SM</sup> (Intrathecal Baclofen Therapy). Gablofen is delivered to the patient via intrathecal administration (an injection into the sheath around the spinal cord). Along with the acquisition of CNS Therapeutics came a developmental pipeline of an additional presentation and concentration of Gablofen, as well as several investigational pain products for intrathecal administration.

#### Generics and API

We market our API products to other pharmaceutical companies around the world, many of which are competitors of our Brands and Generics businesses. Additionally, we use our API for internal manufacturing of our finished dosage products. We are among the largest manufacturers of bulk acetaminophen in the world and the only producer of acetaminophen outside of Asia. We manufacture controlled substances under DEA quota restrictions and in calendar 2012 we believe we received approximately 40% of the total DEA quota provided to the U.S. market for the controlled substances we manufacture. We believe that our strong market position in the API business and allocation of opioid raw materials from the DEA is a competitive advantage for our API business and, in turn, for our Generics

and Brands businesses. The strategy for our API business is based on manufacturing large volumes of high-quality product and customized product offerings, responsive technical services and timely delivery to our customers.

We believe our Generics and API businesses represent the broadest available product line of opioid and other controlled substances (primarily DEA Schedules II and III). Our Generics and API businesses have a strong

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position in the controlled substance generics market with products, including hydrocodone, hydrocodone-containing tablets, oxycodone and oxycodone-containing tablets, all of which are significant products in the overall pain products industry, as well as methylphenidate and other controlled substance products. Historically, our primary competition has been other U.S. participants due to importation restrictions on controlled substance API and finished products. Our commitment to investment in our R&D infrastructure and capabilities has resulted in a pipeline of generic controlled substances, many of which are long-acting or hard to formulate products, which are under development or pending approval by the FDA. For example, we were the first company to receive FDA approval to manufacture and market a generic version of Concerta, a branded pharmaceutical for the treatment of ADHD.

We market our generic products principally to drug wholesalers, large- and medium-size retail pharmacy chains, food store chains with pharmacies, pharmaceutical benefit managers that have mail order pharmacies and hospital buying groups.

The following is a list of significant products and product families in our Generics and API product portfolio:

acetaminophen (API) products (represent 10%, 11% and 11% of our total net sales in fiscal 2013, 2012 and 2011, respectively);

hydrocodone (API) and hydrocodone-containing tablets;

oxycodone (API) and oxycodone-containing tablets; and

### Methylphenidate ER, our generic form of Concerta. *Global Medical Imaging*

Our Global Medical Imaging segment develops, manufactures and markets products in two areas: CMDS, used in CT and MRI imaging, and Nuclear Imaging, which provides radiopharmaceuticals used in single photon emission computed tomography (SPECT) imaging for myocardial perfusion cardiac imaging and bone scans. In fiscal 2013, our Global Medical Imaging segment accounted for 43.5% of net sales from our operating segments. We believe our Global Medical Imaging segment provides a platform for growth in select markets outside the U.S. and provides cash flow that we will use to fund growth in our Specialty Pharmaceuticals segment. Therefore, we are focused on driving operating efficiencies in the Global Imaging segment to maximize operating margins and cash flow.

### Contrast Media and Delivery Systems

Our contrast media include the brands Optiray for CT and Optimark for MRI, which are packaged in pre-filled syringes, vials and bottles. Our delivery systems include power injectors to allow delivery of contrast media into the patient, coordination of the timing of the injection with the CT or MRI scanner and delivery of the contrast media at a specific rate and volume. Our CMDS product strategy is based on differentiating our Optiray and Optimark brands with pre-filled syringes as opposed to vials or bulk containers that must be transferred to a syringe for injection. Pre-filled syringes offer a safer alternative to self-filled doses and offer risk reduction benefits that address The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations) and U.S. Pharmacopeia <797> guidelines. In addition, our pre-filled syringes are color coded and pre-labeled for easier medication

management. Our delivery systems are marketed under the brand Optivantage Dual-Head (Optivantage DH) for CT, Optistar for MRI and Illumena for cardiac catheterization laboratories. All of our injectors can accept both pre-filled syringes and our disposable syringes for use with saline and contrast media. We sell our CMDS products primarily to hospitals and imaging centers through GPOs.

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The following are significant products in our CMDS product portfolio:

*Optiray* (ioversol injection) is a low osmolar, lower viscosity and nonionic organically bound solution of iodine with a broad range of indications in CT imaging procedures, including peripheral and coronary arteriography, angiography and venography. Optiray is available in a Radio Frequency Identification (RFID)-enabled Ultraject pre-filled syringe that, when combined with a RFID-enabled Optivantage DH CT Contrast Delivery System (a medical device used to synchronize the injection of contrast media with the CT scanner), provides a safer and more efficient method of delivering contrast media. Sales of our Optiray product represent 14%, 17% and 19% of our total net sales in fiscal 2013, 2012 and 2011, respectively. Optiray has been on the market for over 25 years. The high capital intensity in manufacturing API for Optiray products and our significant scale have contributed to the longevity of this product.

Optimark (gadoversetamide injection) is a non-ionic extracellular Gadolinium-Based Contrast Agent (GBCA) indicated for use with MRI in patients where abnormal vascularity of the brain or liver is suspected. It is the only GBCA approved by the FDA for administration by power injector and is available in pre-filled syringes to help reduce medication errors and improve patient safety. Nuclear Imaging

Our Nuclear Imaging business manufactures radioactive isotopes for the diagnosis and treatment of disease. Our nuclear radiopharmaceutical product offering includes both hot radioisotopes (primarily Tc-99m, used in approximately 82% of nuclear medicine imaging procedures) and cold kits (tagging agents that are paired with hot radioisotopes for diagnostic procedures). We have significant expertise in managing the highly regulated nature of the radioactive materials used to manufacture the isotope generators and the short half-life of isotopes, which precludes stockpiling and requires exacting execution along all aspects of the supply chain. We believe that our investment in Tc-99m generators in North America and Europe, our own Mo-99 processing facility and a very well-coordinated logistics network provides us with a competitive advantage. Our strategy for our Nuclear Imaging business is focused on bolstering the Tc-99m/Mo-99 supply chain through supplier diversification and our investments in generator manufacturing lines. We have entered into agreements to obtain Mo-99 from the Maria nuclear research reactor in Poland, the High Flux Reactor in the Netherlands and the BR2 reactor in Belgium, and are also able to purchase finished Mo-99 from other suppliers in the marketplace with whom we do not have long-term supply agreements. Going forward, we will continue to seek further diversification of our supplier base.

We intend to ultimately eliminate the use of HEU in favor of using LEU. We currently use HEU targets for the production of Mo-99. In 2004, the U.S. National Security Administration established its Global Threat Initiative to, as quickly as possible, identify, secure and remove or facilitate the disposition of vulnerable, high-risk nuclear and radiological materials around the world. Included as one of the stated initiatives is the conversion by research reactors and isotope production facilities to LEU from HEU. We are in the process of converting our Mo-99 production operation in the Netherlands to LEU targets. For a discussion of how Mo-99 is used in our business, refer to Raw Materials and Risk Factors. We primarily market our nuclear radiopharmaceutical products to nuclear radiopharmacies in the U.S. and to hospitals in Europe.

The following are significant products in our Nuclear Imaging product portfolio:

*Ultra-Technekow DTE* is a dry-ship, top eluting Tc-99m radioisotope generator that provides an on-site isotope source of Tc-99m solution that is combined by a nuclear pharmacist with various cold kit targeting agents to prepare an individualized radiopharmaceutical dose. The prepared Tc-99m radiopharmaceutical is used in procedures using SPECT. SPECT radiopharmaceutical scans account for approximately 81% of all radiopharmaceutical scans and are used in a number of applications, including myocardial perfusion imaging and bone scans. Tc-99m is a decay product of Mo-99, the parent isotope contained in the Tc-99m generator. We are one of only a limited number of manufacturers of Tc-99m generators in North America and Europe, and the only one on either

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continent that has its own Mo-99 processing facility, which provides significant cost and raw material supply advantages.

*Octreoscan* (kit for the preparation of indium In-111 pentetreotide) is a unique molecular imaging agent used for the localization of primary and metastatic neuroendocrine tumors bearing somatostatin receptors. The product was approved by the FDA in June 1994 and is sold primarily in the U.S. and Europe. There are three Orange Book-listed patents for the drug product and usage in detection of neuroendocrine tumors. The last patent expires in September 2017.

### **Industry Overview and Trends**

We believe our businesses are well positioned in attractive markets based on a broadening of access to healthcare globally, increased demand for pharmaceutical products from emerging markets and the medical industry s continued focus on diagnostic imaging for the early diagnosis of diseases.

We expect that the specialty pharmaceuticals market in the U.S. will likely grow in the low-to-mid single digits in the near-term, with the most successful companies being focused on innovation. With respect to branded drugs, most disease areas are addressed by products of a small group of companies that can create extensions of existing brands. Pain management represents the largest therapeutic prescription market in the U.S., with pain medications accounting for approximately one out of every ten dispensed prescriptions in 2012. Pain management is a time-tested therapeutic area, and pain products have been available on the U.S. market since the 1920s.

We believe our experience satisfying the regulatory requirements relating to raw materials for nuclear radiopharmaceuticals provides competitive advantages versus other potential competitors. Currently, imaging tends to be concentrated in developed markets due to its high capital-intensity requirements. However, there are opportunities for growth in emerging markets as governments build out their healthcare infrastructure.

### Competition

### Specialty Pharmaceuticals

Our Specialty Pharmaceuticals products compete with products manufactured by many other companies in highly competitive markets, primarily throughout the U.S. Our competitors vary depending upon therapeutic and product categories. Major competitors of our Specialty Pharmaceuticals segment include Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.), Endo Health Solutions Inc., Johnson & Johnson (including its Noramco, Inc. subsidiary), Johnson Matthey plc, Mylan Inc., Pfizer Inc., Purdue Pharma L.P. and Teva Pharmaceutical Industries Ltd., among others. Our secure sources of raw opioid material, vertically integrated manufacturing capabilities, broad offerings of API controlled substances and acetaminophen, comprehensive generic controlled substance product line and established relationships with retail pharmacies enable us to compete effectively with larger generics manufacturers. In addition, we believe that our experience with the FDA, DEA and Risk Evaluation and Mitigation Strategies ( REMS ) provides us the knowledge to successfully operate in this highly competitive and highly regulated environment.

The competitive landscape in the acquisition and in-licensing of pharmaceutical products has intensified in recent years as there has been a reduction in the number of compounds available and an increase in the number of companies and the collective resources bidding on available assets. The ability to effectively compete in product development, acquisitions and in-licensing is important to our long-term growth strategy. In addition to product development and acquisitions, other competitive factors in the pharmaceutical industry include product efficacy, safety, ease of use,

price, demonstrated cost-effectiveness, marketing effectiveness, service, reliability of supply, reputation and access to technical information.

The highly competitive environment of our Brands business requires us to continually seek out technological innovations and to market our products effectively. Most new products that we introduce must compete with other products already on the market, as well as other products that are later developed by

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competitors. For our branded products, we may be granted market exclusivity through either the FDA, the U.S. Patent Office or similar agencies internationally. Regulatory exclusivity is granted by the FDA for new innovations, such as new clinical data, a new chemical entity or orphan drugs, and patents are issued for inventions, such as composition of matter or method of use. While patents offer a longer period of exclusivity, there are more bases to challenge that exclusivity than with regulatory exclusivity. Once market exclusivity expires on our branded products, competition will likely intensify as generic forms of the product are launched. Manufacturers of generic pharmaceuticals typically invest far less in R&D than research-based pharmaceutical companies, causing generic versions to typically be significantly less expensive than the related branded products. The generic form may also be required in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies. If competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products can be subject to progressive price reductions, decreased sales volume or both. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our branded products offer not only medical benefits but also cost advantages, as compared with other forms of care.

In our Generics business, we face intense competition from other generic drug manufacturers, brand-name pharmaceutical companies through authorized generics, existing branded equivalents and manufacturers of therapeutically similar drugs. The competition varies depending on the specific product category and dosage strength, and we believe that our competitive advantages include our ability to introduce new generic versions of brand-name drug products, our formulation expertise and drug delivery technology, our access to controlled substance API, our quality and cost-effective production, our customer service and the breadth of our generic product line. Among the large generic controlled substance providers, we are the only generic manufacturer that has its own controlled substance API manufacturing capability, and we believe the vertical integration and production of our own API allows us to compete effectively against other pharmaceutical companies. New drugs and future developments in improved or advanced drug delivery technologies or other therapeutic techniques may provide therapeutic or cost advantages to competing products. The maintenance of profitable operations in generic pharmaceuticals depends, in part, on our ability to select, develop and timely launch new generic products and to manufacture such new products in a cost efficient, high-quality manner.

As a result of consolidation among wholesale distributors and rapid growth of large retail drug store chains, a small number of large wholesale distributors and retail drug store chains control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. This has resulted in customers gaining more purchasing power. Consequently, there is heightened competition among generic drug producers for the business of this smaller and more selective customer base.

In our API business, we believe that our competitive advantages include our manufacturing capabilities in controlled substances that enable high-speed, high-volume tableting, packaging and distribution. Additionally, we believe we offer customers reliability of supply and broad-based technical customer service.

### **Global Medical Imaging**

We compete primarily on the ability of our products to capture market share. While we believe that the number of procedures using contrast media will grow in emerging markets, due in part to increasing access to healthcare, we expect that our ability to compete with other providers of contrast media will be impacted by pricing pressures. We believe that our key product characteristics, such as proven efficacy, reliability and safety, coupled with our core competencies such as our efficient manufacturing processes and established distribution network, are important factors that distinguish us from our competitors.

The market for imaging agents is highly competitive. Major competitors in our Global Medical Imaging segment include, among others:

for contrast imaging agents: GE Healthcare, a division of General Electric Company, Bracco Imaging S.p.A., Bayer AG and Guerbet Group;

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for delivery systems: Nemoto & Co, Ltd.;

for CMDS: Bayer AG and Bracco Imaging S.p.A.;

for radiopharmaceutical generators sold in the U.S.: Lantheus Medical Imaging, Inc.;

for radiopharmaceutical generators sold in Europe: GE Healthcare, IBA Group, and POLATOM; and

for radiopharmaceutical SPECT cold kits: Lantheus Medical Imaging, Inc., GE Healthcare, Bracco Imaging S.p.A. and IBA Group.

Unlike some of our competition, we offer a full line of CMDS and radiopharmaceutical products. Our broad product portfolio allows us to be a complete source for most imaging agent needs.

Our current or future products could be rendered obsolete or uneconomical as a result of the competition described above and the factors described in Business Intellectual Property and Risk Factors. Our failure to compete effectively could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

### **Intellectual Property**

We own or license a number of patents in the U.S. and other countries covering certain products and have also developed brand names and trademarks for other products. Generally, our Brands business relies upon patent protection to ensure market exclusivity for the life of the patent. We consider the overall protection of our patents, trademarks and license rights to be of material value and act to protect these rights from infringement. However, our business is not materially dependent upon any single patent, trademark or license or any group of patents, trademarks or licenses.

The majority of an innovative product s commercial value is usually realized during the period in which the product has market exclusivity. In the branded pharmaceutical industry, an innovator product s market exclusivity is generally determined by two forms of intellectual property: patent rights held by the innovator company and any regulatory forms of exclusivity to which the innovator is entitled. In the U.S. and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there often are very substantial and rapid declines in the branded product s sales. The rate of this decline varies by country and by therapeutic category; however, following patent expiration, branded products often continue to have some market viability based upon the goodwill of the product name, which typically benefits from trademark protection or is based on the difficulties associated with replicating the product formulation or bioavailability.

Patents are a key determinant of market exclusivity for most branded pharmaceuticals. Patents provide the innovator with the right to exclude others from practicing an invention related to the product. Patents may cover, among other things, the active ingredient(s), various uses of a drug product, pharmaceutical formulations, drug delivery mechanisms, and processes for (or intermediates useful in) the manufacture of products. Protection for individual products extends for varying periods in accordance with the expiration dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its scope of coverage and the availability of meaningful legal remedies in the country.

Many developed countries provide certain non-patent incentives for the development of pharmaceuticals. For example, the U.S., E.U. and Japan each provide for a minimum period of time after the approval of certain new drugs during which the regulatory agency may not rely upon the innovator s data to approve a competitor s generic copy. Regulatory exclusivity is also available in certain markets as incentives for research on new indications, orphan drugs (drugs that demonstrate promise for the diagnosis or treatment of rare diseases or conditions) and medicines that may be useful in treating pediatric patients. Regulatory exclusivity is independent of any patent rights and can be particularly important when a drug lacks broad patent protection. However, most

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regulatory forms of exclusivity do not prevent a competitor from gaining regulatory approval prior to the expiration of regulatory exclusivity on the basis of the competitor s own safety and efficacy data on its drug, even when that drug is identical to that marketed by the innovator.

We estimate the likely market exclusivity period for each of our branded products on a case-by-case basis. It is not possible to predict with certainty the length of market exclusivity for any of our branded products because of the complex interaction between patent and regulatory forms of exclusivity, the relative success or lack thereof by potential competitors experience in product development and inherent uncertainties concerning patent litigation. There can be no assurance that a particular product will enjoy market exclusivity for the full period of time that we currently estimate or that the exclusivity will be limited to the estimate.

In addition to patents and regulatory forms of exclusivity, we also market products with trademarks. Trademarks have no effect on market exclusivity for a product, but are considered to have marketing value. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registrations of such trademarks are for fixed terms and subject to renewal as provided by the laws of the particular country.

### **Research and Development**

We devote significant resources to the research and development of products and proprietary drug delivery technologies. We incurred R&D expenses of \$165.7 million, \$144.1 million and \$141.5 million in fiscal 2013, 2012 and 2011, respectively, and \$39.0 million and \$38.4 million for the three months ended December 27, 2013 and December 28, 2012, respectively. We expect to continue to invest in R&D activities, as well as enter into license agreements to supplement our internal R&D initiatives. We intend to focus our R&D investments in the Specialty Pharmaceuticals segment, specifically investments to support our Brands business, where we believe there is the greatest opportunity for growth and profitability. Our low-risk, high productivity R&D approach will remain a key contributor to this growth. We currently expect our R&D investments to be in the range of 6% to 8% of annualized net sales. As noted in Our Business and Product Strategies, we market our products to pain specialists, anesthesiologists, neurologists and other physician specialists. In targeting future R&D spending, we focus on new product innovations that can be sold to these physician specialists.

The focus of our R&D within each of our businesses is noted below:

*Brands*. Our R&D strategy focuses on branded product development in the area of pain, other central nervous system areas, such as spasticity, and adjacent areas.

*Generics and API*. R&D within our Generics business is focused on developing ANDA products that incorporate DEA-controlled substances and difficult to replicate formulations. Our API R&D is focused on process improvements to our core products, which is focused on increasing manufacturing yields to reduce our costs. We also selectively add API products to our portfolio where we believe we have created a unique, cost-effective and competitive manufacturing process. While we patent some of these API process improvements, many more are kept as trade secrets.

*Global Imaging.* Our R&D efforts in our Global Medical Imaging segment are primarily focused on driving efficiency throughout CMDS. In our Nuclear Imaging business, our efforts relate to expanding our portfolio

of radioisotopes and better utilizing existing capacity. *Key Areas of Study* 

Our R&D group is comprised of a number of highly experienced, trained and skilled individuals with nearly 25% holding Ph.D. degrees, who have developed expertise in a number of platform technologies, including:

formulation of oral solids in novel ways to mimic patented delivery systems;

formulation of parenteral products to provide sustained blood levels of select small molecules;

linker technology to attach small molecules to radioisotopes; and

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abuse-deterrent characteristics for oral solids in both immediate-release as well as extended-release to limit the abuse and misuse of controlled substances.

While many of these programs are in pre-clinical development, we anticipate that some of these will form the basis of novel products in the future. However, there is no guarantee that any of the studies underway will lead to the development of a product or whether or when such product will be further developed, launched and become commercially viable.

#### Select Products in Development

We are presently developing a number of branded and generic products, some of which utilize novel drug-delivery systems, through a combination of internal and collaborative programs. As of December 27, 2013, we had two NDAs and five ANDAs awaiting review in the U.S. Our pipeline portfolio contains various products and product candidates that are reformulations of existing molecules for the treatment of pain and adjacent areas. The following are our most promising pipeline products:

*Xartemis XR*. Xartemis XR is a controlled-release, long-acting oral formulation of oxycodone hydrochloride and acetaminophen that we are pursuing an indication for treatment of moderate to severe acute pain. Xartemis XR was formulated as a low-dose product to fulfill an unmet clinical need in the market with potentially abuse-deterrent characteristics. The formulation uses the patented Depomed Acuform drug-delivery technology, which we licensed in 2009. In July 2013, the FDA accepted our Xartemis XR NDA, filed as MNK-795, and granted it priority review. This acceptance marks a major milestone for us and is further evidence of our ability to advance our pipeline in both branded and generic products. In November 2013, in response to additional data we submitted, the FDA extended their review of the Xartemis XR NDA by three months. If approved, we anticipate launching Xartemis XR during the second quarter of fiscal 2014.

*MNK-155*. MNK-155 is a controlled-release, long-acting oral formulation of hydrocodone and acetaminophen that we are pursuing an indication for treatment of moderate to severe acute pain. MNK-155 was formulated as a low-dose product to fulfill an unmet clinical need in the market with potentially abuse-deterrent characteristics. The formulation uses the patented Depomed Acuform drug-delivery technology. MNK-155 has completed Phase III clinical trials and our NDA is expected to be filed with the FDA during the second half of fiscal 2014.

*Pennsaid* 2%. Pennsaid 2% is a new 2% formulation of diclofenac topical solution which we anticipate will be indicated for the treatment of pain associated with osteoarthritis of the knee, and an extension of our Pennsaid franchise. This new formulation was studied using a twice-daily administration and is dispensed for topical usage by a new metered dose pump bottle. The NDA for Pennsaid 2%, originally filed as MNK-395, was approved by the FDA in January 2014. We launched this product in February 2014.

*Intrathecal Product Development*. Our acquisition of CNS Therapeutics in October 2012 provided us approved concentrations of Gablofen and a R&D pipeline that included an additional presentation and concentration of Gablofen, including the pre-filled syringes that were approved in January 2013. The R&D pipeline also included several investigational pain products, in various stages of development, which could provide an alternative to products that are only available today through compounding pharmacies.

Additionally, this R&D pipeline may present opportunities for development of products that may be eligible to receive orphan drug designation from the FDA.

*Methylphenidate ER 18 mg*. Methylphenidate ER, a generic version of the branded Concerta, is for the treatment of ADHD. In February 2013, we submitted a supplement to our approved ANDA to include the 18 mg dosage strength. The FDA has accepted this supplement and granted it priority review. In January 2014, we received a Complete Response Letter from the FDA requesting additional information, and we are working to address the request. If approved, we would then have all four dosage strengths available on the market, as we currently offer the 27 mg, 36 mg and 54 mg dosage strengths.

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## **Regulatory Matters**

## **Quality Assurance Requirements**

The FDA enforces regulations to ensure that the methods used in, and the facilities and controls used for, the manufacture, processing, packaging and holding of drugs and medical devices conform to cGMP. The cGMP regulations that the FDA enforces are comprehensive and cover all aspects of manufacturing operations, from receipt of raw materials to finished product distribution, and are designed to ensure that the finished products meet all the required identity, strength, quality and purity characteristics. The cGMP regulations for devices, called the Quality System Regulations, are also comprehensive and cover all aspects of device manufacture, from pre-production design validation to installation and servicing, insofar as they bear upon the safe and effective use of the device and whether the device otherwise meets the requirements of the U.S. Federal Food, Drug and Cosmetic Act (the FFDCA). Other regulatory authorities have their own cGMP rules. Ensuring compliance requires a continuous commitment of time, money and effort in all operational areas.

The FDA conducts pre-approval inspections of facilities engaged in the development, manufacture, processing, packaging, testing and holding of the drugs subject to NDAs and ANDAs. If the FDA concludes that the facilities to be used do not or did not meet cGMP, good laboratory practice (GLP) or good clinical practice (GCP) requirements, it will not approve the application. Corrective actions to remedy the deficiencies must be performed and are usually verified in a subsequent inspection. In addition, manufacturers of both pharmaceutical products and API used to formulate the drug also ordinarily undergo a pre-approval inspection, although the inspection can be waived when the manufacturer has had a passing cGMP inspection in the immediate past. Failure of any facility to pass a pre-approval inspection will result in delayed approval and could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The FDA also conducts periodic inspections of drug and device facilities to assess their cGMP status. If the FDA were to find serious cGMP non-compliance during such an inspection, it could take regulatory actions that could materially adversely affect our business, results of operations, financial condition and cash flows. Additionally, imported API and other components needed to manufacture products could be rejected by U.S. Customs and Border Protection, usually after conferring with the FDA. In the case of domestic facilities, the FDA could initiate product seizures or, in some instances, require product recalls and seek to enjoin a product semantary and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with cGMP requirements, sanctions may be imposed that include preventing that company from receiving the necessary licenses to export its products and classifying that company as an unacceptable supplier, thereby disqualifying that company from selling products to federal agencies.

## United States

In general, drug manufacturers operate in a highly regulated environment. In the U.S., we must comply with laws, regulations, guidance documents and standards promulgated by the FDA, the Department of Health and Human Services ( DHHS ), the DEA, the Environmental Protection Agency ( EPA ), the NRC, the Customs Service and state boards of pharmacy.

The FDA s authority to regulate the safety and efficacy of pharmaceuticals comes from the FFDCA. In addition to reviewing NDAs, for branded drugs, and ANDAs, for generic drugs, the FDA has the authority to ensure that pharmaceuticals introduced into interstate commerce are neither adulterated nor misbranded. Adulterated means that the product may cause or has caused injury to patients when used as intended because it fails to comply with current cGMP. Misbranded means that the labels of, or promotional materials for, the product contain false or misleading

information. Failure to comply with applicable FDA and other federal and state regulations could result in product recalls or seizures, partial or complete suspension of manufacturing or distribution, refusal to approve pending NDAs or ANDAs, monetary fines, civil penalties or criminal prosecution.

In order to market and sell a new prescription drug product in the U.S., a drug manufacturer must file with the FDA a NDA that shows the safety and effectiveness of (a) a new chemical entity that serves as the API, known as a 505(b)(1) NDA; or (b) a product that has significant differences from an already approved one, known as a 505(b)(2) NDA. Alternatively, in order to market and sell a generic version of an already approved drug product, a drug manufacturer must file an ANDA that shows that the generic version is therapeutically equivalent, or behaves almost the same when taken by a patient to the branded drug product and, therefore, is substitutable.

For all pharmaceuticals sold in the U.S., the FDA also regulates sales and marketing to ensure that drug product claims made by manufacturers are neither false nor misleading. Manufacturers are required to file copies of all product-specific promotional materials to the FDA s Office of Prescription Drug Promotion prior to their first use by sales representatives. In general, such advertising does not require FDA prior approval. Failure to implement a robust internal company review process and comply with FDA regulations regarding advertising and promotion increases the risk of enforcement action by either the FDA or the U.S. Department of Justice.

For both NDAs and ANDAs, the manufacture, marketing and selling of certain drug products may be limited by quota grants for controlled substances by the DEA. Refer to Drug Enforcement Administration for further information.

*NDA Process.* The path leading to FDA approval of a NDA for a new chemical entity begins when the drug product is merely a chemical formulation in the laboratory. In general, the process involves the following steps:

Completion of formulation, laboratory and animal testing in accordance with GLP that fully characterizes the drug product from a pre-clinical perspective and provides preliminary evidence that the drug product is safe to test in human beings;

Filing with the FDA an Investigational New Drug Application that will permit the conduct of clinical trials (testing in human beings under adequate and well-controlled conditions);

Designing and conducting clinical trials to show the safety and efficacy of the drug product in accordance with GCP;

Submitting the NDA for FDA review, which provides a complete characterization of the drug product;

Satisfactory completion of FDA pre-approval inspections regarding the conduct of the clinical trials and the manufacturing processes at the designated facility in accordance with cGMP;

If applicable, satisfactory completion of a FDA Advisory Committee meeting in which the Agency requests help from outside experts in evaluating the NDA;

Final FDA approval of the full prescribing information, labeling and packaging of the drug product; and

Ongoing monitoring and reporting of adverse events related to the drug product, implementation of a REMS program, if applicable, and conduct of any required Phase IV studies. Clinical trials are typically conducted in four sequential phases, although they may overlap. The four phases are as follows:

Phase I trials are typically small (less than 100 healthy volunteers) and are designed to determine the toxicity and maximum safe dose of the drug product.

Phase II trials usually involve 100 to 300 participants and are designed to determine whether the drug product produces any clinically significant effects in patients with the intended disease or condition. If the results of these trials show promise, then a larger Phase III trial may be conducted.

Phase III trials are often multi-institution studies that involve a large number of participants and are designed to show efficacy. Phase III (and some Phase II) trials are designed to be pivotal, or confirmatory trials. The goal of a pivotal trial is to establish the safety and efficacy of a drug product by eliminating biases and increasing statistical power.

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In some cases, the FDA requires Phase IV trials, which are usually performed after the NDA has been approved. Such post-marketing surveillance is intended to obtain more information about the risks of harm, benefits and optimal use of the drug product by observing the results of the drug product in a large number of patients.

A drug manufacturer may conduct clinical trials either in the U.S. or outside the U.S., but in all cases must comply with GCP, which includes (a) a legally effective informed consent process when enrolling participants; (b) an independent review by an Institutional Review Board to minimize and manage the risks of harm to participants; and (c) ongoing monitoring and reporting of adverse events related to the drug product.

In addition, a drug manufacturer may decide to conduct a clinical trial of a drug product on pediatric patients in order to obtain a form of marketing exclusivity as permitted under the Best Pharmaceuticals for Children Act (BPCA). Alternatively, the FDA may require a drug manufacturer, using its authority under the Pediatric Research Equity Act, to conduct a pediatric clinical trial. The goal of conducting pediatric clinical trials is to gather data on how drug products should best be administered to this patient population.

The path leading to FDA approval of a NDA for a drug product that has significant differences from an already approved one is somewhat shorter. The FDA requires a drug manufacturer to submit data from either already published reports or newly conducted studies that show the safety and efficacy of those differences. Significant differences include different dosage strengths or route of administration.

Under the U.S. Prescription Drug User Fee Act, the FDA has the authority to collect fees from drug manufacturers who submit NDAs for review and approval. These user fees help the FDA fund the drug approval process. For fiscal 2014, the user fee rate has been set at \$2,169,100 for a 505(b)(1) NDA and \$1,084,550 for a NDA not requiring clinical data, generally a 505(b)(2) NDA. We expense these fees as they are incurred. The average review time for a NDA is approximately six months for priority review and ten months for standard review.

ANDA Process. The path leading to FDA approval of an ANDA is much different from that of a NDA. By statute, the FDA waives the requirement for a drug manufacturer to complete pre-clinical studies and clinical trials and instead focuses on data from bioequivalence studies. Bioequivalence studies generally involve comparing the absorption rate and concentration levels of a generic drug in the human body to that of the branded drug or Reference Listed Drug (RLD). In the event that the generic drug behaves in the same manner in the human body as the RLD, the two drug products are considered bioequivalent. The FDA considers a generic drug therapeutically equivalent, and therefore substitutable, if it also contains the same active ingredients, dosage form, route of administration and strength.

In August 2013, it was reported that the average review time for an ANDA is about 35 months. In 2010, U.S. Congress passed into law the Generic Drug User Fee Act to address the FDA s backlog, which at the time was over 2,000 ANDAs. This legislation granted the FDA authority to collect, for the first time, user fees from generic drug manufacturers who submit ANDAs for review and approval, and the fees collected will help the FDA fund the drug approval process. For fiscal 2014, the user fee rate is set at \$63,860 for an ANDA and \$31,930 for a prior approval supplement to an ANDA. The FDA also will collect from generic drug manufacturers a separate one-time Drug Master File fee and separate annual manufacturing facility fees for API and finished drug products. These fees are expensed as incurred. The FDA anticipates that the approval process timeframe will not begin to improve until fiscal 2015.

Aside from the backlog described above, the timing of FDA approval of ANDAs depends on other factors, including whether an ANDA holder has challenged any listed patents to the RLD and whether the RLD is entitled to one or more periods of marketing exclusivity under the FFDCA (such as pediatric exclusivity under the BPCA). In general, the FDA will not approve (but will continue to review) an ANDA in which the RLD holder has sued, within 45 days

of receiving notice of the ANDA filing, the ANDA holder for patent infringement until either the litigation has been resolved or 30 months has elapsed, whichever is later.

*Patent and Non-Patent Exclusivity Periods.* A sponsor of a NDA is required to identify in its application any patent that claims the drug or a use of the drug subject to the application. Upon NDA approval, the FDA lists these patents in a publication referred to as the Orange Book. Any person that files a Section 505(b)(2) NDA, the type of NDA that relies upon the data in the application for which the patents are listed, or an ANDA to secure approval of a generic version of a previous drug, must make a certification in respect to listed patents. The FDA may not approve such an application for the drug until expiration of the listed patents unless the generic applicant certifies that the listed patents are invalid, unenforceable or not infringed by the proposed generic drug and gives notice to the holder of the NDA for the RLD of the bases upon which the patents are challenged, and the holder of the RLD does not sue the later applicant for patent infringement within 45 days of receipt of notice. If an infringement suit is filed, the FDA may not approve the later application until the earliest of: (a) 30 months after receipt of the notice by the holder of the NDA for the RLD; (b) entry of an appellate court judgment holding the patent invalid, unenforceable or not infringed; (c) such time as the court may order; or (d) the expiration of the patent.

One of the key motivators for challenging patents is the 180-day market exclusivity period (generic exclusivity) granted to the developer of a generic version of a product that is the first to make a Paragraph IV certification and that prevails in litigation with the manufacturer of the branded product over the applicable patent(s) or is not sued. For a variety of reasons, there are situations in which a company may not be able to take advantage of an award of generic exclusivity begins and ends is very complicated.

The holder of the NDA for the RLD may also be entitled to certain non-patent exclusivity during which the FDA cannot approve an application for a competing generic product or 505(b)(2) NDA product. Generally, if the RLD is a new chemical entity, the FDA may not accept for filing any application that references the innovator s NDA for five years from the approval of the innovator s NDA. However, this five-year period is shortened to four years where a filer s ANDA includes a Paragraph IV certification. In other cases, where the innovator has provided certain clinical study information, the FDA may accept for filing, but may not approve, an application that references the innovator s NDA for a period of three years from the approval of the innovator s NDA.

Certain additional periods of exclusivity may be available if the RLD is indicated for use in a rare disease or condition or is studied for pediatric indications.

*Risk Evaluation and Mitigation Strategies.* For certain drug products or classes, such as transmucosal immediate-release fentanyl products and extended-release and long-acting opioids, the FDA has the authority to require the manufacturer to provide a REMS that is intended to ensure that the benefits of a drug product (or class of drug products) outweigh the risks of harm. The FDA may require that a REMS include elements to ensure safe use to mitigate a specific serious risk of harm, such as requiring that prescriber have particular training or experience or that the drug product is dispensed in certain healthcare settings. The FDA has the authority to impose civil penalties on or take other enforcement action against any drug manufacturer who fails to properly implement an approved REMS program. Separately, a drug manufacturer cannot use an approved REMS program to delay generic competition.

In December 2011, the FDA approved a single, class-wide REMS program for transmucosal immediate-release fentanyl ( TIRF ) products (called the TIRF REMS Access Program ) in order to ease the burden on the healthcare system. TIRF products are opioids used to manage pain in adults with cancer who routinely take other opioid pain medicines around-the-clock. We were part of the original industry working group that collaborated to develop and implement the TIRF REMS Access Program. The goals of this program are to ensure patient access to important medications and mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors by: (a) prescribing and dispensing only to appropriate patients, including use only in opioid-tolerant patients; (b) preventing inappropriate conversion between fentanyl products; (c) preventing accidental exposure to children and others for whom such products were not prescribed; and (d) educating prescribers, pharmacists and patients on the

potential for misuse, abuse, addiction and overdose. This program started in March 2012 and requires manufacturers, distributors, prescribers, dispensers and patients to enroll in a real-time database that maintains a closed-distribution system.

In February 2009, the FDA requested that drug manufacturers help develop a single, shared REMS for extended-release and long-acting opioid products that contain fentanyl, hydromorphone, methadone, morphine, oxycodone and oxymorphone. In April 2009, the FDA announced that the REMS would be intended to ensure that the benefits of these drugs continue to outweigh the risks associated with: (1) use of high doses of long-acting opioids and extended-release opioid products in non-opioid-tolerant and inappropriately selected individuals; (2) abuse; (3) misuse; and (4) overdose, both accidental and intentional. We were part of the original industry working group that collaborated to develop and implement this REMS program. Upon FDA approval of Exalgo in March 2010, we implemented the product-specific REMS program that was developed internally while continuing to collaborate on the class-wide REMS program. In July 2012, the FDA approved a class-wide REMS program (called the Extended-Release and Long-Acting Opioid Analgesics REMS ) that affected more than 30 extended-release and long-acting opioid analgesics (both branded and generic products). This REMS program requires drug manufacturers to make available training on appropriate prescribing practices for healthcare professionals who prescribe these opioid analgesics and to distribute educational materials on their safe use to prescribers and patients.

As part of our ongoing commitment to the responsible prescribing, dispensing and safe use of prescription opioids beyond the FDA s REMS requirements, we launched the C.A.R.E.S. Alliance in September 2010. For further discussion on the C.A.R.E.S. Alliance, refer to Our Business and Product Strategies.

*Drug Enforcement Administration.* The DEA is the federal agency responsible for domestic enforcement of the CSA. The CSA classifies drugs and other substances based on identified potential for abuse. Schedule I controlled substances, such as heroin and LSD, have a high abuse potential and have no currently accepted medical use; thus, they cannot be lawfully marketed or sold. Opioids, such as oxycodone, oxymorphone, morphine, fentanyl and hydrocodone, are either Schedule II or III controlled substances. Consequently, the manufacture, storage, distribution and sale of these substances are highly regulated.

The DEA regulates the availability of API, products under development and marketed drug products that are Schedule II or III by setting annual quotas. Every year, we must apply to the DEA for manufacturing quota to manufacture API and procurement quota to manufacture finished dosage products. Given that the DEA has discretion to grant or deny our manufacturing and procurement quota requests, the quota the DEA grants may be insufficient to meet our commercial and R&D needs. To date in calendar 2013, manufacturing and procurement quotas granted by the DEA have been sufficient to meet our sales and inventory requirements on most products. During calendar 2012, the initial hydrocodone manufacturing and procurement quota grants we received from the DEA were below the amounts requested and were therefore insufficient to meet customer demand. While we were granted additional quota, these shortfalls did result in lost sales of hydrocodone products, the amount of which was not significant. Future delay or refusal by the DEA to grant, in whole or in part, our quota requests could delay or result in stopping the manufacture of our marketed drug products, new product launches or the conduct of bioequivalence studies and clinical trials.

In October 2013, the FDA announced its recommendation that the DEA reschedule hydrocodone combination products (such as Vicodin and our developmental product MNK-155) from Schedule III to Schedule II, thereby increasing regulatory controls on these drug products. The FDA issued its formal recommendation to the DHHS, who in turn issued a similar recommendation to the DEA in December 2013. In February 2014, the DEA issued its proposal to reschedule hydrocodone combination products from Schedule III to Schedule II. The DEA proposal is open for comment through April 28, 2014. At this time, it is too early to determine the degree of impact the hydrocodone rescheduling, if adopted, will have on our business.

DEA regulations make it extremely difficult for a manufacturer in the U.S. to import finished dosage forms of controlled substances manufactured outside the U.S. These rules reflect a broader enforcement approach by the DEA to regulate the manufacture, distribution and dispensing of legally produced controlled substances. Accordingly, drug

manufacturers who market and sell finished dosage forms of controlled substances in the U.S. typically manufacture or have them manufactured in the U.S.

The DEA also requires drug manufacturers to design and implement a system that identifies suspicious orders of controlled substances, such as those of unusual size, those that deviate substantially from a normal pattern and those of unusual frequency, prior to completion of the sale. A compliant SOM system includes well-defined due diligence, know your customer efforts and order monitoring.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Annual registration is required for any facility that manufactures, tests, distributes, dispenses, imports or exports any controlled substance. The facilities must have the security, control and accounting mechanisms required by the DEA to prevent loss and diversion. Failure to maintain compliance, particularly as manifested in loss or diversion, can result in regulatory action that could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also regulate controlled substances, and we, as well as our third-party API suppliers and manufacturers, are subject to such regulation by several states with respect to the manufacture and distribution of these products.

We and, to our knowledge, our third-party API suppliers, dosage form manufacturers, distributors and researchers have all necessary registrations, and we believe all registrants operate in conformity with applicable registration requirements, under controlled substance laws.

*Government Benefit Programs.* Statutory and regulatory requirements for Medicaid, Medicare, Tricare and other government healthcare programs govern provider reimbursement levels, including requiring that all pharmaceutical companies pay rebates to individual states based on a percentage of their net sales arising from Medicaid program-reimbursed products. The federal and state governments may continue to enact measures in the future aimed at containing or reducing payment levels for prescription pharmaceuticals paid for in whole or in part with government funds. We cannot predict the nature of such measures, which could have material adverse consequences for the pharmaceutical industry as a whole and, consequently, also for us. However, we believe we have provided for our best estimate of potential refunds based on current information available.

From time to time, legislative changes are made to government healthcare programs that impact our business. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003 created a new prescription drug coverage program for people with Medicare through a new system of private market drug benefit plans. This law provides a prescription drug benefit to seniors and individuals with disabilities in the Medicare program (Medicare Part D). Congress continues to examine various Medicare policy proposals that may result in pressure on the prices of prescription drugs in the Medicare program.

In addition, the Healthcare Reform Act provides for major changes to the U.S. healthcare system, which may transform the delivery and payment for healthcare services in the U.S. While some provisions of the Healthcare Reform Act have already taken effect, most of the provisions to expand access to healthcare coverage will not be implemented until 2014 and beyond. The combination of these measures, which include the elimination of lifetime caps and no rescission of policies or denial of coverage due to preexisting conditions, could expand health insurance coverage by an estimated 32 million people in the U.S., improving patients ability to obtain and maintain health insurance.

Since much of the implementation is yet to take place, there are still many challenges and uncertainties ahead. Such a comprehensive reform measure will require expanded implementation efforts on the part of federal and state agencies

embarking on rule-making to develop the specific components of their new authority. We intend to monitor closely the implementation of the Healthcare Reform Act and related legislative and regulatory developments. The overall impact of the Healthcare Reform Act reflects a number of uncertainties; however, we believe that the impact to our business will be largely attributable to changes in the Medicare Part D coverage

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gap, the imposition of an annual fee on branded prescription pharmaceutical manufacturers and increased rebates in the Medicaid Fee-For-Service Program and Medicaid Managed Care plans. There are a number of other provisions in the legislation that collectively are expected to have a small impact, including originator average manufacturers price for new formulations and the expansion of 340B pricing to new entities.

## Healthcare Fraud and Abuse Laws

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry. For example, in the U.S., there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations, including the U.S. Anti-Kickback Statute and similar state statutes, the U.S. Federal Sunshine Law and other parts of the Healthcare Reform Act, the False Claims Act and the Health Insurance Portability and Accountability Act of 1996. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws apply to hospitals, physicians and other potential purchasers of our products and are potentially applicable to us as both a manufacturer and a supplier of products reimbursed by federal healthcare programs. In addition, some states in the U.S. have enacted compliance and reporting requirements aimed at drug manufacturers.

We are also subject to the Foreign Corrupt Practices Act of 1977 and similar worldwide anti-bribery laws in non-U.S. jurisdictions which generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside of the U.S. are with governmental entities and are therefore subject to such anti-bribery laws. Our policies mandate compliance with these anti-bribery laws; however, we operate in many parts of the world that have experienced governmental corruption to some degree and, in certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not protect us from reckless or criminal acts committed by our employees or agents.

## **Compliance** Programs

In order to systematically and comprehensively mitigate the risks of non-compliance with regulatory requirements described within this section, we have developed what we believe to be a robust compliance program based on the April 2003 Office of the Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers, the U.S. Federal Sentencing Guidelines, the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, the Code of Ethics of the Advanced Medical Technology Association, the United Kingdom (U.K.) Anti-Bribery guidance, and other relevant government guidances and national or regional industry codes of behavior. We conduct ongoing compliance training programs for all employees and maintain a 24-hour ethics and compliance reporting hotline.

As part of our compliance program, we have implemented internal cross-functional processes to review and approve all product-specific promotional materials, presentations and external communications to address the risk of misbranding or mislabeling our products through our promotional efforts. For example, we have established programs to monitor promotional speaker activities and field sales representatives, which includes a ride along program for field sales representatives similar to those included in recent Corporate Integrity Agreements from the OIG in order to obtain first-hand observations of how these approved materials are used. We have also implemented a comprehensive controlled substances compliance program, including anti-diversion efforts that go beyond the DEA s SOM requirements and we regularly assist federal, state and local law enforcement and prosecutors in the U.S. by providing information and testimony on our products and placebos for use by the DEA and other law enforcement agencies in

investigations and at trial. As part of this program, we also work with some of our customers to help develop and implement what we believe are best practices for SOM and other anti-diversion activities.

We believe our compliance program design also addresses our FDA, healthcare anti-kickback and anti-fraud, and anti-bribery-related activities.

## **Outside the United States**

Outside the U.S., we must comply with laws, guidelines and standards promulgated by other regulatory authorities that regulate the development, testing, manufacturing, marketing and selling of pharmaceuticals, including, but not limited to, Health Canada, the Medicines and Healthcare Products Regulatory Agency in the U.K., the Irish Medicines Board, the European Medicines Agency and member states of the E.U., the State Food and Drug Administration in China, the Therapeutic Goods Administration in Australia, the New Zealand Medicines and Medical Devices Safety Authority, the Ministry of Health and Welfare in Japan, the European Pharmacopoeia of the Council of Europe and the International Conference on Harmonization. Although international harmonization efforts continue, many laws, guidelines and standards differ by region or country.

We currently market our products in Canada, in various countries in the E.U., and in the Latin American, Middle Eastern, African and Asia-Pacific regions. The approval requirements and process vary by country, and the time required to obtain marketing authorization may vary from that required for FDA approval. Certain drug products and variations in drug product lines also must meet country-specific and other local regulatory requirements. The following discussion highlights some of the differences in the approval process in other regions or countries outside the U.S.

*European Union*. Marketing authorizations are obtained either pursuant to a centralized or decentralized procedure. The centralized procedure, which provides for a single marketing authorization valid for all E.U. member states, is mandatory for the approval of certain drug products and is optional for novel drug products that are in the interest of patient health. Under the centralized procedure, a single marketing authorization application is submitted for review to the European Medicines Agency, which makes a recommendation on the application to the European Commission, who determines whether or not to approve the application. The decentralized procedure provides for concurrent mutual recognition of national approval decisions, and is available for products that are not subject to the centralized procedure.

The E.U. has also adopted directives and other laws that govern the labeling, marketing, advertising, supply, distribution and drug safety monitoring and reporting of drug products. Such directives set regulatory standards throughout the E.U. and permit member states to supplement such standards with additional requirements.

European governments also regulate drug prices through the control of national healthcare systems that fund a large part of such costs to patients. Many regulate the pricing of a new drug product at launch through direct price controls or reference pricing and, recently, some have also imposed additional cost-containment measures on drug products. Such differences in national pricing regimes may create price differentials between E.U. member states. Many European governments also advocate generic substitution by requiring or permitting prescribers or pharmacists to substitute a different company s generic version of a brand drug product that was prescribed, and patients are unlikely to take a drug product that is not reimbursed by their government.

*Japan.* The Pharmaceutical and Medical Devices Agency (PMDA) is responsible for reviewing marketing authorizations of drug products. The PMDA may require bridging studies (a clinical trial with a smaller sub-population than the original clinical trials) to demonstrate that clinical trial data obtained in trials conducted outside of Japan are applicable to Japanese patients. After completing a comprehensive review, the PMDA reports its findings to the Ministry of Health, Labour and Welfare, which either approves or denies the application.

Japan s national health insurance system maintains a Drug Price List that specifies which drug products are eligible for reimbursement and the Ministry of Health, Labour and Welfare sets pricing for such drug products. In general, the Japanese government introduces a round of price cuts every other year and mandates price

reductions for specific drug products. However, new drug products that are judged innovative or useful, indicated for pediatric use, or target orphan diseases may be eligible for premium prices. Similar to other countries, the Japanese government also advocates the prescribing and use of generic drugs, where available.

*Emerging Markets*. Many emerging markets continue to evolve their regulatory review and oversight processes. At present, such countries typically require prior regulatory approval or marketing authorization from large, developed markets (such as the U.S.) before they will initiate or complete their review. Some countries also require the applicant to conduct local clinical trials as a condition of marketing authorization. Many emerging markets continue to implement measures to control drug product prices, such as implementing direct price controls or advocating the prescribing and use of generic drugs.

## Environmental

Our operations, like those of other pharmaceutical companies, involve the use of substances regulated under environmental laws, primarily in manufacturing processes and, as such, we are subject to numerous federal, state, local and non-U.S. environmental protection and health and safety laws and regulations. We cannot assure you that we have been or will be in full compliance with environmental, health and safety laws and regulations at all times. Certain environmental laws assess strict (*i.e.*, can be imposed regardless of fault) and joint and several liability on current or previous owners of real property and current or previous owners or operators of facilities for the costs of investigation, removal or remediation of hazardous substances or materials at such properties or at properties at which parties have disposed of hazardous substances. We have, from time to time, received notification from the EPA and from state environmental agencies in the U.S. that conditions at a number of sites where the disposal of hazardous substances requires investigation, cleanup and other possible remedial actions. These agencies may require that we reimburse the government for costs incurred at these sites or otherwise pay for the cost of investigation and cleanup of these sites including compensation for damage to natural resources. We have projects underway at a number of current and former manufacturing facilities to investigate and remediate environmental contamination resulting from past operations, as further described in Business Legal Proceedings and Note 18 of the notes to our annual consolidated and combined financial statements included elsewhere in this prospectus.

Environmental laws are complex, change frequently and generally have become more stringent over time. We believe that our operations currently comply in all material respects with applicable environmental laws and regulations, and have planned for future capital and operating expenditures to comply with these laws and to address liabilities arising from past or future releases of, or exposures to, hazardous substances. However, we cannot assure you that our costs of complying with current or future environmental protection, health and safety laws and regulations will not exceed our estimates or have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Further, we cannot assure you that we will not be subject to additional environmental claims for personal injury or cleanup in the future based on our past, present or future business activities. While it is not feasible to predict the outcome of all pending environmental matters, it is reasonably possible that there will be a need for future provisions for environmental costs that, in management s opinion, are not likely to have a material adverse effect on our financial condition, but could be material to the results of operations in any one accounting period.

Certain radiological licenses at certain manufacturing sites owned by us require the establishment of decommissioning programs which will require remediation in accordance with regulatory requirements upon cessation of operations at these sites.

### **Raw Materials**

We contract with various third-party manufacturers and suppliers to provide us with raw materials used in our products, finished goods and certain services. If, for any reason, we are unable to obtain sufficient quantities of any of the raw materials or components required for our products, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

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The active ingredients in the majority of our current pharmaceutical products and products in development, including oxycodone, oxymorphone, morphine, fentanyl, methylphenidate and hydrocodone, are listed by the DEA as Schedule II or III substances under the CSA. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation and the DEA limits both the availability of these active ingredients and the production of these products. As discussed in Regulatory Matters, we must annually apply to the DEA for procurement and production quotas in order to obtain and produce these substances. The DEA has complete discretion to adjust these quotas from time to time during the calendar year and, as a result, our procurement and production quotas may not be sufficient to meet commercial demand or to conduct bioequivalence studies and clinical trials. Any delay or refusal by the DEA in granting, in whole or in part, our quota requests for controlled substances could delay or result in the stoppage of the manufacture of our pharmaceutical products, our clinical trials or product launches and could require us to allocate product among our customers.

Our radiopharmaceutical product offering includes hot radioisotopes including Mo-99, a critical ingredient of our Ultra-Technekow DTE Tc-99m generators. Mo-99 is produced in nuclear research reactors utilizing HEU or LEU targets. These targets, either tubular or flat and of varying sizes, are fabricated from HEU or LEU and, in either case, aluminum. The targets are placed in or near the core of the nuclear reactor where fission reactions occur resulting in the production of Mo-99 and other isotopes. This process, which takes approximately six days, is known as target irradiation. There are currently eight reactors around the world producing the global supply of Mo-99. We have agreements to obtain Mo-99 from three of these reactors and we rely predominantly on two of these reactors for our Mo-99 supply. These reactors are subject to scheduled and unscheduled shutdowns which can have a significant impact on the amount of Mo-99 available for processing. Mo-99 produced at these reactors is then finished at one of five processing sites located throughout the world, including our processing facility located in the Netherlands. At the processing facility, the targets are dissolved and chemically separated. In this process, the Mo-99 is isolated as a radiochemical. We transport finished Mo-99 from our processing facility in the Netherlands to our facility in Maryland Heights, Missouri, where it, together with Mo-99 received from other third-party processors, is loaded into our Tc-99m generators. Mo-99 has a 66-hour half-life and degrades into, among other things, Tc-99m, which has a half-life of only six hours. The radiopharmacies or hospitals prepare dosages from the Tc-99m generators for use in SPECT imaging medical procedures.

In November 2012, the HFR in the Netherlands, one of two primary reactors we utilize, experienced an unscheduled shutdown. We were able to receive increased target irradiations at the two other reactors and purchased additional Mo-99 from other sources to continue meeting customer orders; however, the additional Mo-99 we procured from alternative sources came at a higher than normal cost. The HFR resumed production in June 2013.

In October 2013, the HFR experienced another unscheduled shutdown. In addition, our own Mo-99 processing facility in the Netherlands also experienced a shutdown. The HFR resumed production in late February 2014. Our Mo-99 processing facility remains shut down. Until it resumes production, we expect to fulfill customer orders through processing of Mo-99 from alternative sources at higher costs. Ongoing increased raw material and manufacturing costs will limit our ability to return the Global Medical Imaging segment to historical operating margins.

# Sales, Marketing and Customers

## Sales and Marketing

We market our branded, generic and CMDS products to physicians, pharmacists, pharmacy buyers, radiologists and radiology technicians. We distribute these products to major drug wholesalers, retail pharmacy chains, hospital networks and governmental agencies. In addition, we contract with GPOs and managed care organizations to improve access to our products. We sell and distribute API directly or through distributors to other pharmaceutical companies.

In the U.S., we market and distribute our nuclear imaging products to radiopharmacies which, in turn, supply hospitals and standalone imaging centers with patient-customized doses. Outside the U.S., we market and distribute our nuclear imaging products to hospitals.

We often negotiate with parties that enter into supply contracts for the benefit of their member facilities, including GPOs, integrated delivery networks, large and medium size retail pharmacy chains, nuclear pharmacy chains, wholesalers and, solely outside the U.S., with governments through a tender process.

For further information on our sales and marketing strategies, refer to Our Businesses and Product Strategies.

#### **Customers**

Net sales to distributors that accounted for more than 10% of our total net sales in fiscal 2013, 2012 and 2011 were as follows:

		Fiscal Year		
	2013	2012	2011	
Cardinal Health, Inc.	18%	19%	19%	
McKesson Corporation	15%	14%	13%	
Amerisource Bergen Corporation	9%	9%	10%	

No other customer accounted for 10% or more of our net sales in the past three fiscal years.

#### **Manufacturing and Distribution**

We presently have ten manufacturing sites, including seven located in the U.S., as well as sites in Canada, Ireland and the Netherlands, which handle production, assembly, quality assurance testing, packaging and sterilization of our products. We estimate that our manufacturing production by region in fiscal 2013 (as measured by cost of production) was as follows:

U.S.	79%
Europe	13%
Canada	8%

We maintain distribution centers in 17 countries. In addition, in certain countries outside the U.S. we utilize third-party distribution centers. Products generally are delivered to these distribution centers from our manufacturing facilities and then subsequently delivered to the customer. In some instances, product, such as nuclear medicine, is delivered directly from our manufacturing facility to the customer. We contract with a wide range of transport providers to deliver our products by road, rail, sea and air.

### Backlog

At September 27, 2013, the backlog of firm orders was less than 1% of net sales. We anticipate that substantially all of the backlog as of September 27, 2013 will be shipped during fiscal 2014.

### Seasonality

There are no significant seasonal aspects to our business; however, DEA quotas are allocated in each calendar year to companies and may impact our sales until the DEA grants additional quotas, if any. Impacts from quota limitations are most commonly experienced during the third and fourth calendar quarters, which represent our fourth and first fiscal

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quarters, respectively.

## Employees

At September 27, 2013, we had approximately 5,500 employees, approximately 4,100 of which are based in the U.S. Certain of these employees are represented by unions or work councils. We believe that we generally have a good relationship with our employees, and with the unions and work councils that represent certain employees.

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## **Properties**

Our offices in the U.S. are located in a facility in Hazelwood, Missouri, which we own. As of September 27, 2013, we owned a total of 12 facilities in four countries. Our owned facilities consist of approximately 2.9 million square feet, and our leased facilities consist of approximately 0.6 million square feet. We presently have ten manufacturing sites, six of which are used by our Global Medical Imaging segment, three of which are used by our Specialty Pharmaceuticals segment and one of which is shared by both segments. We have a manufacturing site in each of Canada, Ireland and the Netherlands and seven manufacturing sites in the U.S. We believe all of these facilities are well-maintained and suitable for the operations conducted in them.

## Legal Proceedings

We are subject to various legal proceedings and claims, including patent infringement claims, product liability matters, environmental matters, employment disputes, contractual disputes and other commercial disputes, including those described below. We believe that these legal proceedings and claims likely will be resolved over an extended period of time. Although it is not feasible to predict the outcome of these matters, we believe, given the information available as of December 27, 2013, that their ultimate resolution will not have a material adverse effect on our financial condition, results of operations and cash flows.

## **Governmental Proceedings**

On November 30, 2011 and October 22, 2012, we received subpoenas from the United States Drug Enforcement Administration requesting production of documents relating to our suspicious order monitoring programs. We are complying as required by the terms of the subpoenas. While it is not possible at this time to determine with certainty the outcome of these proceedings, we believe, given the information available as of December 27, 2013, that the ultimate resolution will not have a material adverse effect on our financial condition, results of operations and cash flows.

## Patent/Antitrust Litigation

*Tyco Healthcare Group LP, et al. v. Mutual Pharmaceutical Company, Inc.* We filed a patent infringement suit in the U.S. District Court for the District of New Jersey against Mutual Pharmaceutical Co., Inc., et al. (collectively, Mutual ) on March 20, 2007 pursuant to procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984, after Mutual submitted an Abbreviated New Drug Application to the U.S. Food and Drug Administration (FDA ) seeking to sell a generic version of our 7.5 mg Restoril sleep aid product. Mutual also filed antitrust and unfair competition counterclaims. The patents at issue have since expired or been found invalid. On January 18, 2013, the trial court issued an opinion and order granting our motion for summary judgment regarding Mutual s antitrust and unfair competition counterclaims. On May 1, 2013, Mutual appealed this decision to the U.S. Court of Appeals for the Federal Circuit and oral arguments were heard February 6, 2014. While it is not possible at this time to determine with certainty the ultimate outcome of the counterclaims, we believe, given the information available as of December 27, 2013, that the ultimate resolution of the claims will not have a material adverse effect on our financial condition, results of operations and cash flows.

## **Pricing Litigation**

*State of Utah v. Actavis US, Inc., et al.* We, along with numerous other pharmaceuticals companies, are defendants in this matter which was filed May 8, 2008, and is pending in the Third Judicial Circuit of Salt Lake County, Utah. The State of Utah alleges, generally, that the defendants reported false pricing information in connection with certain drugs

that are reimbursable under Medicaid, resulting in overpayment by state Medicaid programs for those drugs, and is seeking monetary damages and attorneys fees. We believe that we have meritorious defenses to these claims and are vigorously defending against them. While it is not possible at this time to determine with certainty the outcome of the case, we believe, given the information available as of December 27, 2013, that the ultimate resolution will not have a material adverse effect on our financial condition, results of operations and cash flows.

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### **Environmental Remediation and Litigation Proceedings**

We are involved in various stages of investigation and cleanup related to environmental remediation matters at a number of sites, including those described below. The ultimate cost of site cleanup and timing of future cash outlays is difficult to predict, given the uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations and alternative cleanup methods. We concluded that, as of December 27, 2013, it was probable that we would incur remedial costs in the range of \$44.5 million to \$80.3 million. We also concluded that, as of December 27, 2013, the best estimate within this range was \$44.5 million, of which \$5.8 million was included in accrued and other current liabilities and the remainder was included in environmental liabilities on the unaudited condensed consolidated balance sheet at December 27, 2013.

Crab Orchard National Wildlife Refuge Superfund Site, near Marion, Illinois. We are a successor in interest to International Minerals and Chemicals Corporation ( IMC ). Between 1967 and 1982, IMC leased portions of the Additional and Uncharacterized Sites ( AUS ) Operable Unit at the Crab Orchard Superfund Site ( the Site ) from the government and manufactured various explosives for use in mining and other operations. In March 2002, the Department of Justice, the U.S. Department of the Interior and the EPA (together, the Government Agencies ) issued a special notice letter to General Dynamics Ordnance and Tactical Systems, Inc. (General Dynamics), one of the other potentially responsible parties ( PRPs ) at the Site, to compel General Dynamics to perform the remedial investigation and feasibility study ( RI/FS ) for the AUS Operable Unit. General Dynamics negotiated an Administrative Order on Consent with the Government Agencies to conduct an extensive RI/FS at the Site under the direction of the U.S. Fish and Wildlife Service. General Dynamics asserted in August 2004 that we are jointly and severally liable, along with approximately eight other lessees and operators at the AUS Operable Unit, for alleged contamination of soils and groundwater resulting from historic operations, and has threatened to file a contribution claim against us and other parties for recovery of its costs incurred in connection with the RI/FS activities being conducted at the AUS Operable Unit. We and other PRPs who received demand letters from General Dynamics have explored settlement alternatives, but have not reached settlement to date. We and other PRPs are awaiting completion of the RI/FS by General Dynamics before the initiation of formal PRP negotiations to address resolution of these alleged claims. While it is not possible at this time to determine with certainty the ultimate outcome of this case, we believe, given the information available as of December 27, 2013, that the final resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on our financial condition, results of operations and cash flows.

*Mallinckrodt Veterinary, Inc., Millsboro, Delaware.* We previously operated a plant in Millsboro, Delaware ( the Millsboro Site ) that manufactured various animal healthcare products. In 2005, the Delaware Department of Natural Resources and Environmental Control found trichloroethylene ( TCE ) in the Millsboro public water supply at levels that exceeded the federal drinking water standards. Further investigation to identify the TCE plume in the ground water indicated that the plume has extended to property owned by a third party near the Millsboro Site. We, and other former owners, assumed responsibility for the Millsboro Site cleanup under the Alternative Superfund Program administered by the EPA. We and other PRPs entered into an Administrative Order on Consent ( AOC ) with the EPA on May 10, 2010, which was subsequently amended in November 2010 and January 2011, to investigate the potential source of TCE contamination and to evaluate options to abate, mitigate or eliminate the release or threat of release of hazardous substances at the Millsboro Site. We, along with the other parties, continue to conduct the studies and prepare remediation plans in accordance with the amended AOC. While it is not possible at this time to determine with certainty the ultimate outcome of this matter, we believe, given the information available as of December 27, 2013, that the final resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on our financial condition, results of operations and cash flows.

*Coldwater Creek, Saint Louis County, Missouri.* We are named as a defendant in 14 tort complaints filed February 2012 and January 2014 with numerous plaintiffs pending in the U.S. District Court for the Eastern District of Missouri. These cases allege personal injury for alleged exposure to radiological substances present in Coldwater Creek in Missouri. Plaintiffs lived in various locations in Saint Louis County, Missouri near Coldwater Creek. Radiological residues which may have been present in the creek have been remediated by the

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U.S. Army Corps of Engineers. We believe that we have meritorious defenses to these complaints and are vigorously defending against them. We are unable to estimate a range of reasonably possible losses for the following reasons: (i) the proceedings are in early stages; (ii) we have not received and reviewed complete information regarding the plaintiffs and their medical conditions; and (iii) there are significant factual issues to be resolved. While it is not possible at this time to determine with certainty the ultimate outcome of these cases, we believe, given the information available as of December 27, 2013, that the ultimate resolution of all known claims will not have a material adverse effect on our financial condition, results of operations and cash flows.

*Lower Passaic River, New Jersey.* We and approximately 70 other companies comprise the Lower Passaic Cooperating Parties Group ( the CPG ), and are parties to a May 2007 AOC with the EPA to perform a RI/FS of the lower seventeen miles of the Lower Passaic River in New Jersey ( the River ). Our potential liability stems from former operations at Lodi and Belleville, New Jersey. In June 2007, the EPA released a draft Focused Feasibility Study ( FFS ) which addressed various early action remediation alternatives for the River. The EPA has not released the final FFS. As an interim step related to the 2007 AOC, the CPG voluntarily entered into an AOC on June 18, 2012, with the EPA for remediation actions focused solely at mile 10.9 of the River. Our estimated costs related to the RI/FS and focused remediation action at mile 10.9, based on an interim allocation, are immaterial and have been accrued.

At this time, we cannot reasonably estimate our liability related to the remediation efforts, excluding the RI/FS and remediation actions at mile 10.9, as the RI/FS is ongoing, the ultimate remedial approach and associated cost has not yet been determined, and the parties that will participate in funding the remediation and their respective allocations are not yet known. While it is not possible at this time to determine with certainty the ultimate outcome of this matter, we believe, given the information available as of December 27, 2013, that the ultimate resolution will not have a material adverse effect on our financial condition, results of operations and cash flows. However; in the event of adverse determinations related to this matter, it is possible that the ultimate liability resulting from this matter and the impact to our results of operations and cash flows could become material.

# **Products Liability Litigation**

Beginning with lawsuits brought in July 1976, we are also named as a defendant in personal injury lawsuits based on alleged exposure to asbestos-containing materials. A majority of the cases involve product liability claims based principally on allegations of past distribution of products containing asbestos. A limited number of the cases allege premises liability based on claims that individuals were exposed to asbestos while on our property. Each case typically names dozens of corporate defendants in addition to us. The complaints generally seek monetary damages for personal injury or bodily injury resulting from alleged exposure to product scontaining asbestos. Our involvement in asbestos cases has been limited because we did not mine or produce asbestos. Furthermore, in our experience, a large percentage of these claims have never been substantiated and have been dismissed by the courts. We have not suffered an adverse verdict in a trial court proceeding related to asbestos claims and intend to continue to defend these lawsuits. When appropriate, we settle claims; however, amounts paid to settle and defend all asbestos claims have been immaterial. As of December 27, 2013, there were approximately 11,500 asbestos-related cases pending against us. We estimate pending asbestos claims and claims that were incurred but not reported and related insurance recoveries.

We estimate our liability for pending and future claims based on claims experience over the past five years and covers claims either currently filed or expected to be filed over the next seven years. We believe that we have adequate amounts recorded related to these matters. While it is not possible at this time to determine with certainty the ultimate outcome of these asbestos-related proceedings, we believe, given the information available as of December 27, 2013, that the final outcome of all known and anticipated future claims, after taking into account amounts already accrued, along with recoveries from insurance, will not have a material adverse effect on our financial condition, results of

operations and cash flows.

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# **Other Matters**

We are a defendant in a number of other pending legal proceedings related to present and former operations, acquisitions and dispositions. Given the information available as of December 27, 2013, we do not expect the outcome of these proceedings, either individually or in the aggregate, to have a material adverse effect on our financial condition, results of operations and cash flows.

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### MANAGEMENT

#### **Executive Officers of Mallinckrodt plc**

Set forth below are the names, ages as of February 28, 2014, and current positions of our executive officers.

Name	Age	Title			
Mark Trudeau	52	President, Chief Executive Officer and Director			
Matthew Harbaugh	43	Senior Vice President and Chief Financial Officer			
Peter Edwards	52	Senior Vice President and General Counsel			
Hugh O Neill	50	Senior Vice President and President of U.S. Specialty Pharmaceuticals			
Stephen Merrick	53	Senior Vice President and President, Commercial Operations, International			
Gary Phillips	47	Senior Vice President and Chief Strategy Officer			
Mario Saltarelli	53	Senior Vice President and Chief Science Officer			
Ian Watkins	51	Senior Vice President and Chief Human Resources Officer			
Meredith Fischer	61	Senior Vice President, Communications and Public Affairs			
Sandra L. Hatten	56	Senior Vice President, Quality and Regulatory Compliance			
Set forth below is a brief description of the position and business experience of each of our executive officers.					

*Mark Trudeau* is our President and Chief Executive Officer, and also serves on our board of directors. Mr. Trudeau joined the Pharmaceuticals segment of Covidien in February 2012 as a Senior Vice President and President of its Pharmaceuticals business. Mr. Trudeau previously worked for Bayer HealthCare Pharmaceuticals LLC USA, the U.S. healthcare business of Bayer AG, where he served as Chief Executive Officer, and simultaneously served as President of Bayer HealthCare Pharmaceuticals business. In addition, Mr. Trudeau served as Interim President of the global specialty medicine business unit from January to August 2010. Prior to joining Bayer in 2009, Mr. Trudeau headed the Immunoscience Division at Bristol-Myers Squibb. During his ten-plus years at Bristol-Myers Squibb, he served in multiple senior roles, including President of the Asia/Pacific region, President and General Manager of Canada and General Manager/Managing Director in the U.K. Mr. Trudeau was also with Abbott Laboratories, serving in a variety of executive positions, from 1988 to 1998. Mr. Trudeau holds a Bachelor s degree in chemical engineering and a M.B.A., both from the University of Michigan.

*Matthew Harbaugh* is our Senior Vice President and Chief Financial Officer. Mr. Harbaugh previously served as Vice President, Finance of Covidien s Pharmaceuticals business, a position he held since July 2008. He also served as Interim President of Covidien s Pharmaceuticals business from November 2010 to January 2012. Mr. Harbaugh joined Covidien s Pharmaceuticals business in August 2007 as its Vice President and Controller, Global Finance for the Global Medical Imaging business. Mr. Harbaugh was a Lead Finance Executive with Cerberus Capital Management, L.P. from April 2007 until August 2007. Mr. Harbaugh worked for Monsanto from 1997 to 2007 serving in senior U.S. roles in treasury, investor relations, financial planning and analysis and strategy, in addition to two international assignments in Canada and Argentina.

*Peter Edwards* is our Senior Vice President and General Counsel. Mr. Edwards joined Covidien s Pharmaceuticals business in May 2010 as Vice President and General Counsel. Mr. Edwards previously worked for the Solvay Group in Brussels, Belgium, where he served as Executive Vice President and General Counsel for the global pharmaceuticals business from June 2007 until April 2010.

*Hugh O Neill* is our Senior Vice President and President of U.S. Specialty Pharmaceuticals. Prior to joining Mallinckrodt in September 2013, Mr. O Neill worked at Sanofi-Aventis for ten years where he held various commercial leadership positions including Vice President of Commercial Excellence from June 2012 to July 2013, General Manager, President of Sanofi-Aventis Canada from June 2009 to May 2012, Vice President Market Access and Business Development from 2006 to 2009. Mr. O Neill joined Sanofi in 2003 as its Vice President, United States Managed Markets. Mr. O Neill previously served in a variety of positions of increasing responsibility for Sandoz Pharmaceuticals, Forest Laboratories, Novartis Pharmaceuticals and Pfizer.

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*Stephen Merrick* is our Senior Vice President and President of Commercial Operations, International. Mr. Merrick joined Covidien s Pharmaceuticals business in February 2013 as Vice President and President of Commercial Operations, International. Mr. Merrick was employed by Bristol-Myers Squibb Company, where he served as Vice President, Strategic Projects Intercontinental Region from September 2012 until February 2013, President and General Manager Brazil from December 2009 until September 2012 and as Vice President Distributor Markets and Geographic Optimization from November 2007 until December 2009.

*Gary Phillips* is our Senior Vice President and Chief Strategy Officer and joined Mallinckrodt in October 2013. Most recently, Dr. Phillips had served as head of Global Health and Healthcare Industries for the World Economic Forum in Geneva, Switzerland from January 2012 to September 2013. Prior to that, Dr. Phillips served as President of Reckitt Benckiser Pharmaceuticals North America from 2011 to 2012, as Head, Portfolio Strategy, Business Intelligence and Innovation at Merck Serono from 2008 to 2011, and as President of US Pharmaceuticals and Surgical and Bausch & Lomb from 2002 to 2008. Dr. Phillips has also held positions of leadership at Novartis Pharmaceuticals, Wyeth-Ayerst and Gensia Pharmaceuticals.

*Mario Saltarelli* is our Senior Vice President and Chief Science Officer. Prior to joining Mallinckrodt in October 2013, Dr. Saltarelli had served as Senior Vice President, R&D at Shire plc since September 2012 and as its Senior Vice President Clinical Development and Medical Affairs from January 2011 to September 2012. From 2004 to 2011, Dr. Saltarelli served as Divisional Vice President of Abbott Laboratories. From 1997 to 2004, he held positions of responsibility at Pfizer, and, prior to that, academic posts in the Department of Neurology at the Emory University School of Medicine in Atlanta.

*Ian Watkins* is our Senior Vice President and Chief Human Resources Officer. Mr. Watkins joined Covidien s Pharmaceuticals business in September 2012 as the Chief Human Resources Officer. Mr. Watkins served as Vice President, Global Human Resources at Synthes, Inc. from June 2007 to September 2012, which was recently acquired by Johnson & Johnson. Mr. Watkins served as Senior Vice President, Human Resources from 2003 to 2006 for Andrx Corporation, which is now part of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.).

*Meredith Fischer* is our Senior Vice President, Communications and Public Affairs. Ms. Fischer joined Covidien s Pharmaceuticals business in February 2013 as Vice President, Communications and Public Affairs. Ms. Fischer was employed by Bayer Corporation from December 2001 until February 2013, where she served as Vice President of Communications and Public Policy for Bayer HealthCare and Bayer HealthCare Pharmaceuticals, North America. In that role, Ms. Fischer supported Bayer HealthCare s U.S. pharmaceutical and animal health divisions and the company s global medical care and consumer care businesses.

*Sandra Hatten* became our Senior Vice President, Quality and Regulatory Compliance in February 2014. Ms. Hatten joined Covidien s pharmaceuticals business in October 2010 as its Director of Quality R&D. She served as the Director of Quality, St. Louis Plant from May 2011 until September 2011 and as Senior Director of Quality API Operations from September 2011 to September 2012. She was appointed interim Vice President of Quality in September 2012 and became Vice President of Quality in February 2013. Ms. Hatten was Vice President of Quality Assurance for KV Pharmaceuticals from August 2007 until August 2010. She was Director of Site Quality and Compliance for Catalent Pharmaceutical Solutions from March 2006 until August 2007. Previously, Ms. Hatten served as Director of Quality from December 2000 to March 2006 for Perrigo Company plc.

#### **Board of Directors of Mallinckrodt plc**

The following table sets forth information with respect to those persons who serve on the board of directors of Mallinckrodt plc.

Name	Age	Title
Melvin D. Booth	68	Chairman of the Board
Mark C. Trudeau	52	President, Chief Executive Officer and Director
David R. Carlucci	59	Director
J. Martin Carroll	64	Director
Diane H. Gulyas	57	Director
Nancy S. Lurker	56	Director
JoAnn A. Reed	58	Director
Kneeland C. Youngblood, M.D.	58	Director
Joseph A. Zaccagnino	67	Director

Mr. Booth has been Chairman of the board and a director since June 2013. He is also a member of our Audit Committee. Mr. Booth has been a director of Catalent Pharma Solutions since 2010 and a director of eResearch Technologies since 2012. Mr. Booth has also been a strategic advisor in life sciences to Genstar Capital (a private equity firm) since 2005. Mr. Booth s previous public company board experience includes serving as Lead Director of Millipore, a life science research company, from 2004 to 2010, and as a member of the boards of PRA International from 2004 to 2013, MedImmune from 1998 to 2005 and of Human Genome Sciences from 1995 to 1998. Mr. Booth was President of MedImmune from 1998 until his retirement at the end of 2003. Mr. Booth was President of Human Genome Sciences from 1995 to 1998. He held a variety of domestic and international positions with Syntex from 1981 to 1995, including serving as President of its U.S. pharmaceuticals business. Mr. Booth has been active in U.S. pharmaceutical industry organizations and is a past Chairman of the Pharmaceuticals Manufacturers Association of Canada. Mr. Booth received a B.S. degree in accounting from Northwest Missouri State University where he was also awarded an honorary Doctor of Science degree. He is also a Certified Public Accountant. Mr. Booth s qualifications to serve on our board include his significant experience in leadership positions at pharmaceutical companies.

Mr. Carlucci has been a director since June 2013 and is Chair of our Human Resources and Compensation Committee. Mr. Carlucci was President and Chief Operating Officer of IMS Health from October 2002 until January 2005, when he was named Chief Executive Officer and President. He became Chairman the following year. Mr. Carlucci retired from IMS Health in December 2010. Mr. Carlucci held several senior executive level positions at IBM from 1976 to 2002, including responsibilities for operations in the U.S., Canada, and Latin America. Mr. Carlucci has been a director and Chairman of the Human Resources and Compensation Committee for MasterCard International since 2006. Mr. Carlucci also served as a member of the advisory board of Mitsui USA, one of the world s most diversified comprehensive trading, investment and service companies. Mr. Carlucci received a B.A. in political science from the University of Rochester. Mr. Carlucci s qualifications to serve on our board include his significant experience as an executive and/or board member of publicly-traded and private companies.

Mr. Carroll has been a director since June 2013 and is Chair of our Compliance Committee. Mr. Carroll served as President and Chief Executive Officer of Boehringer Ingelheim Corporation and of Boehringer Pharmaceuticals, Inc. from 2003 until 2012 and as a director of Boehringer Ingelheim Corporation from 2003 until December 2012. Mr. Carroll joined the organization in 2002 as President of Boehringer Pharmaceuticals, Inc. Mr. Carroll worked at Merck & Company, Inc. from 1976 to 2001. From 1972 to 1976, Mr. Carroll served in the United States Air Force where he attained the rank of Captain. Mr. Carroll also serves as a director of Vivus, Inc. Mr. Carroll received a B.A.

in accounting & economics from the College of the Holy Cross and a M.B.A. from Babson College. Mr. Carroll s qualifications to serve on our board include his significant experience in leadership positions at pharmaceutical companies.

Ms. Gulyas has been a director since June 2013 and is a member of our Audit Committee and Human Resources and Compensation Committee. Ms. Gulyas has worked at E. I. du Pont de Nemours and Company since 1978 and has been the President of DuPont s Performance Polymers division since 2009. She is also the Vice Chairman of the DuPont-Teijin Films global joint venture. From 2009 until 2012, Ms. Gulyas served as a director and as a member of the Finance Committee of Navistar International Corporation, a leading manufacturer of commercial trucks, buses, RVs, defense vehicles and engines. Ms. Gulyas received her B.S. in chemical engineering from the University of Notre Dame. Ms. Gulyas qualifications to serve on our board include her extensive executive experience with chemical and manufacturing companies.

Ms. Lurker has been a director since June 2013 and is a member of our Human Resources and Compensation Committee. Ms. Lurker has been serving as a director and Chief Executive Officer of PDI Inc. since 2008. PDI, Inc. is a leading provider of outsourced commercial services to established and emerging pharmaceutical, biotechnology and healthcare companies in the United States. Prior to joining PDI, Ms. Lurker served as Senior Vice President and Chief Marketing Officer of Novartis Pharmaceuticals Corporation from 2006 to 2008. Prior to that, she was President and Chief Executive Officer of ImpactRx, Inc. from 2003 to 2006. From 1998 to 2003, Ms. Lurker served as Group Vice President Global Primary Care Products for Pharmacia Corporation. She was also a member of Pharmacia s U.S. Executive Management Committee from 1998 to 2003. Ms. Lurker began her career at Bristol-Myers Squibb, where she worked for 14 years. Ms. Lurker also has served as a director of Auxilium Corporation since 2011. Ms. Lurker served as a director of ConjuChem Biotechnologies, Inc. from 2004 to 2006 and as a director of Elan Corporation from 2005 to 2006. Ms. Lurker received a B.S. magna cum laude in biology from Seattle Pacific University and a M.B.A. from the University of Evansville. Ms. Lurker s qualifications to serve on our board include her significant experience in leadership positions at pharmaceutical companies.

Ms. Reed has been a director since June 2013 and is Chair of our Audit Committee. Ms. Reed is a healthcare services consultant. Ms. Reed served as an advisor to the Chief Executive Officer of Medco Health Solutions from April 2008 to April 2009. From 2002 to March 2008, Ms. Reed served as Senior Vice President, Finance and Chief Financial Officer of Medco Health Solutions. From 1992 to 2002, she served as Senior Vice President, Finance of Medco Health Solutions. She joined Medco Containment Services, Inc. in 1988. Ms. Reed has been a director of Health Management Associates, Inc. since 2013, a director of American Tower Corporation since 2007, a director of Waters Corporation since 2006 and a trustee of St. Mary s College of Notre Dame since 2006. Ms. Reed received a B.B.A. in business administration from St. Mary s College. She received her M.B.A. in finance and international marketing cum laude from Fordham University. Ms. Reed s qualifications to serve on our board include her experience as a healthcare services consultant and her financial expertise experience and knowledge of financial statements, corporate finance and accounting matters.

Dr. Youngblood has been a director since June 2013. He is a member of our Compliance and Nominating and Governance Committees. Dr. Youngblood is a founding partner of Pharos Capital Group, a private equity firm that focuses on providing growth and expansion capital/buyouts in healthcare, business services and opportunistic investments. Dr. Youngblood served as a director of the Gap Inc. from 2006 to 2012, a director of Starwood Hotels and Resorts from 2001 to 2012, a director of Burger King Corporation from 2004 to 2010 and a director of the iStar Financial from 1998 to 2001. Dr. Youngblood has been serving as a director of Energy Future Holdings Corp, an electric utility provider, since 2007. Dr. Youngblood is a physician by training, with over 15 years of experience in emergency medicine. He is also a member of the Council on Foreign Relations. Dr. Youngblood earned a B.A. in politics from Princeton University and an M.D. from the University of Texas Southwestern Medical School. Dr. Youngblood s qualifications to serve on our board include his extensive experience in healthcare practice, policy and business.

Mr. Zaccagnino has been a director since June 2013. He is Chair of our Nominating and Governance Committee and a member of our Compliance Committee. Mr. Zaccagnino has been a director of Covidien plc since it was spun-off from Tyco International in 2007 and serves on its Compliance and Transactions Committees and as Chairman of the Nominating and Governance Committee. Mr. Zaccagnino has served as

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President, Chief Executive Officer and director of Yale New Haven Health System and its flagship Yale-New Haven Hospital from 1991 until his retirement in 2005. He has also served as a director of NewAlliance Bancshares, Inc. from 1991 until it was acquired in 2010. Mr. Zaccagnino has served on the board of the National Committee for Quality Healthcare from 1995 until 2005, and was elected Chairman of the Board in 2003. From 1999 until 2006 he served as a director and from 2004 to 2006 as Chairman of the Board of VHA Inc., a provider member cooperative of community owned health systems and their physicians which provides supply chain and group purchasing services through their subsidiaries, Novation and Provista. Mr. Zaccagnino received a B.S. (business administration) from the University of Connecticut and a M.P.H. (healthcare management) from Yale University School of Medicine. Mr. Zaccagnino s qualifications to serve on our board include his broad healthcare management and governance experience and his knowledge of healthcare policy and regulation, patient care delivery and financing and of clinical research and medical technology assessment, all of which will provide our board with unique insights and a keen perspective on the complexities of the healthcare sector and on the priorities of and challenges facing our company and the purchasers of our products.

#### **Independence of Directors**

A majority of our board of directors is comprised of directors who are independent as defined by the rules of the NYSE and the corporate governance guidelines to be adopted by the board. The governance guidelines adopted by the board include criteria adopted by the board to assist it in making determinations regarding the independence of its members. The criteria, summarized below, are consistent with the NYSE listing standards regarding director independence. To be considered independent, the board must determine that a director does not have a material relationship, directly or indirectly, with Mallinckrodt. In assessing independence, the board considers all relevant facts and circumstances. In particular, when assessing the materiality of a director s relationship with the Company, the board considers the issue not just from the standpoint of the director, but also from that of the persons or organizations with which the director has an affiliation. A director will not be considered independent if he or she, at the time of determination:

is, or has been within the prior three years, an employee of Mallinckrodt or its subsidiaries;

has an immediate family member who is, or has been within the prior three years, an executive officer of Mallinckrodt or its subsidiaries;

is a current partner or employee of our auditor;

has an immediate family member who is a current partner of our auditor or who is an employee of our auditor and personally works on our audit;

has been, or has an immediate family member who has been, within the prior three years, a partner or employee of our auditor who personally worked on our audit during that time;

is, or has an immediate family member who is, or has been within the prior three years, employed as an executive officer of a public company that has or had on the compensation committee of its board an executive officer of Mallinckrodt (during the same period of time);

has, or has an immediate family member who has, received more than \$120,000 in direct compensation from Mallinckrodt, other than director and committee fees or other forms of deferred compensation for prior service (provided such compensation is not contingent in any way on continued service), in any 12-month period within the prior three years;

is a current employee, or has an immediate family member who is a current executive officer, of a company that has made payments to, or received payments from, Mallinckrodt for property or services in an amount which, in any of the prior three fiscal years, exceeds the greater of \$1 million or 2% of such other company s consolidated gross revenues; or

is, or his or her spouse is, an executive officer, director or trustee of a charitable organization to which Mallinckrodt s contributions, not including our matching of charitable contributions by employees, exceed, in any single fiscal year within the prior three years, the greater of \$1 million or 2% of such organization s total charitable receipts during that year.

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The board has considered the independence of its members in light of these independence criteria. In connection with its independence considerations, the board has reviewed Mallinckrodt s relationships with organizations with which our directors are affiliated and has determined that such relationships, other than that with Covidien, from whom we spun in June 2013, were established in the ordinary course of business. The board has determined that none of these current business relationships are material to us, any of the organizations involved, or our directors. Based on these considerations, the board has determined that each of our directors, other than Mark C. Trudeau, our President and Chief Executive Officer, satisfies the criteria and is independent. These independent directors are: Melvin D. Booth, David R. Carlucci, J. Martin Carroll, Diane H. Gulyas, Nancy S. Lurker, JoAnn A. Reed, Kneeland C. Youngblood, M.D. and Joseph A. Zaccagnino. Each independent director is expected to notify the chair of the Nominating and Governance Committee, as soon as reasonably practicable, of changes in his or her personal circumstances that may affect the board s evaluation of his or her independence.

#### **Director Nominations Process**

The Nominating and Governance Committee is responsible for developing the general criteria, subject to approval by the full Board, for use in identifying, evaluating and selecting qualified candidates for election or re-election to the board. The Nominating and Governance Committee periodically reviews with the board the appropriate skills and characteristics required of board members in the context of the then-current make-up of the board. Final approval of director candidates is determined by the full board, and invitations to join the board are extended by the Chairman of the Board on behalf of the entire board.

The Nominating and Governance Committee, in accordance with our corporate governance guidelines, seeks to create a board that is strong in its collective knowledge and has a diversity of backgrounds, skills and experience with respect to accounting and finance, management and leadership, vision and strategy, business operations, business judgment, industry knowledge, corporate governance and global markets. When the Committee reviews a potential new candidate, the Committee looks specifically at the candidate s qualifications in light of the needs of the board and Mallinckrodt at that time, given the then-current mix of director attributes.

As described in our Corporate Governance Guidelines:

directors should be individuals of the highest ethical character and integrity;

directors should have demonstrated management ability at senior levels in successful organizations, including as the chief executive officer of a public company or as the leader of a large, multifaceted organization, including government, educational and other non-profit organizations;

each director should have the ability to provide wise, informed and thoughtful counsel to senior management on a range of issues and be able to express independent opinions, while at the same time working as a member of a team;

directors should be free from any conflict of interest or business or personal relationship that would interfere with the duty of loyalty owed to the Company; and

directors should be independent of any particular constituency and be able to represent all shareholders of the Company.

The Committee assesses independence and also monitors compliance by the members of the board with the requisite qualifications under NYSE listing standards for populating the Audit, Human Resources and Compensation Committee and Nominating and Governance Committees. Directors may not serve on more than four public company boards of directors (including Mallinckrodt) or, if the director is employed as CEO of a publicly-traded company, no more than three public company boards of directors (including Mallinckrodt) or, if cluding Mallinckrodt). No person may stand for election as a director after reaching age 72.

Our articles of association contain provisions that address the process by which a shareholder may nominate an individual to stand for election to the board of directors and establish certain qualifications for service as a director. The Nominating and Governance Committee s charter includes procedures by which the Committee will consider nominations submitted by shareholders.

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The Nominating and Governance Committee will consider suggestions for director candidates from board members and, in its discretion, may employ a third-party search firm to assist in identifying candidates for director. In evaluating candidates for director, the Committee will use the guidelines described above, and will evaluate shareholder candidates in the same manner as candidates proposed from all other sources.

### **Majority Vote for Election of Directors**

Directors are elected by the affirmative vote of a majority of the votes cast by shareholders at the annual general meeting of shareholders (present in person or by proxy) and serve for one-year terms. Any nominee for director who does not receive a majority of the votes cast is not elected to the board and the position that would have been filled by such nominee will become vacant. Given that Irish law does not recognize the concept of a holdover director, incumbent directors who do not receive a majority of the votes cast at the annual general meeting are not re-elected to the board, and immediately following the annual general meeting, will no longer be members of the board.

Irish law does require, however, a minimum of two directors at all times. In the event that an election results in either only one or no directors receiving the required majority vote, either the nominee or each of the two nominees receiving the greatest number of votes in favor of his or her election shall, in accordance with the Company s Articles of Association, hold office until his or her successor shall be elected.

### **Transactions with Related Persons**

The board s Nominating and Governance Committee is responsible for the review and, if appropriate, approval or ratification of related-person transactions involving Mallinckrodt or its subsidiaries and related persons. Under SEC rules, a related person is a director, nominee for director, executive officer or a beneficial owner of 5% or more of Mallinckrodt s shares, and their immediate family members. Our board of directors has adopted written policies and procedures that apply to any transaction or series of transactions in which the Company or a subsidiary is a participant, the amount involved exceeds \$120,000 and a related person has a direct or indirect material interest.

Mallinckrodt personnel in the legal and finance departments review transactions involving related persons. If they determine that a related person could have a material interest in such a transaction, the transaction is forwarded to the Nominating and Governance Committee for review. The Nominating and Governance Committee determines whether the related person has a material interest in a transaction and may, in its discretion, approve, ratify or take other action with respect to the transaction. The Nominating and Governance Committee reviews all material facts related to the transaction and takes into account, among other factors it deems appropriate, whether the transaction is on terms no less favorable to the Company than terms generally available to an unaffiliated third-party under the same or similar circumstances, the extent of the related person s interest in the transaction and, if applicable, the availability of other sources of comparable products or services.

As discussed elsewhere in this prospectus, until our separation from Covidien in June 2013, the Company constituted the Pharmaceuticals business of Covidien. In connection with the separation, we entered into various agreements with Covidien, including a separation and distribution agreement, a transition services agreement, a tax matters agreement and an employee matters agreement. These agreements, which we have filed with the SEC, are described in more detail in our Annual Report on Form 10-K for the fiscal year ended September 27, 2013, and in other documents we have filed with the SEC.

#### **Committees of the Board of Directors**

Our board of directors has the following standing committees: an Audit Committee, a Compensation and Human Resources Committee, a Nominating and Governance Committee and a Compliance Committee. Our board of directors has adopted a written charter for each of these committees, which are posted on our website, www.mallinckrodt.com.

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### Audit Committee

The Audit Committee monitors the integrity of our financial statements, the independence and qualifications of the independent auditors, the performance of our internal auditors and independent auditors, our compliance with certain legal and regulatory requirements and the effectiveness of our internal controls. The Audit Committee is responsible for selecting, retaining, evaluating, setting the remuneration of and, if appropriate, recommending the termination of our independent auditors. The members of the Audit Committee are Ms. Reed, Mr. Booth and Ms. Gulyas, each of whom has been determined by the board to be independent under SEC rules and NYSE listing standards applicable to audit committee members. Additionally, Ms. Reed is an audit committee financial expert under SEC rules and the NYSE listing standards applicable to audit committees. Ms. Reed serves as the Chair of the Audit Committee.

# **Compensation and Human Resources Committee**

The Compensation and Human Resources Committee reviews and approves compensation and benefits policies and objectives, determines whether our officers and employees are compensated according to those objectives and carries out the board s responsibilities relating to the compensation of our executives. The members of the Compensation and Human Resources Committee are Mr. Carlucci, Ms. Gulyas and Ms. Lurker, each of whom has been determined by the board to be independent under SEC rules and NYSE listing standards applicable to compensation committee members. Mr. Carlucci serves as the Chair of the Compensation and Human Resources Committee.

### Nominating and Governance Committee

The Nominating and Governance Committee is responsible for identifying individuals qualified to become board members, recommending to the board the director nominees for election at the Annual General Meeting, developing and recommending to the board any updates to our corporate governance guidelines, and taking a general leadership role in our corporate governance. The members of the Nominating and Governance Committee are Mr. Zaccagnino, Mr. Carroll and Dr. Youngblood, each of whom has been determined by the board to be independent under NYSE listing standards. Mr. Zaccagnino serves as the Chair of the Nominating and Governance Committee.

# **Compliance** Committee

The Compliance Committee assists the board in fulfilling its oversight responsibility with respect to regulatory, healthcare compliance and public policy issues that affect us. The members of the Compliance Committee are Mr. Carroll, Dr. Youngblood and Mr. Zaccagnino, each of whom has been determined by the board to be independent under NYSE listing standards. Mr. Carroll serves as the Chair of the Compliance Committee.

# **Compensation Committee Interlocks and Insider Participation**

Prior to the separation on June 28, 2013, Mallinckrodt was not an independent company, and did not have a compensation committee or any other committee serving a similar function. Prior to the separation, decisions as to the compensation of those who currently serve as our executive officers were made by Covidien.

Since the completion of the separation, Mallinckrodt s Compensation and Human Resources Committee has been and is currently comprised of Mr. Carlucci and Mses. Gulyas and Lurker. None of these individuals has been at any time an officer or employee of Mallinckrodt. During fiscal 2013, Mallinckrodt had no compensation committee

interlocks meaning that it was not the case that an executive officer of ours served as a director or member of the compensation committee of another entity and an executive officer of the other entity served as a director or member of our compensation committee.

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#### **Board Leadership Structure**

Currently, the positions of Chairman of the Board and Chief Executive Officer are held by separate people. The Chairman of the Board provides leadership to the board and works with the board to define its structure and activities in the fulfillment of its responsibilities. The Chairman of the Board sets the board agendas with board and management input, facilitates communication among directors, provides an appropriate information flow to the board and presides at meetings of the board of directors and shareholders. The Chairman of the Board works with other board members to provide strong, independent oversight of the company s management and affairs. Future modification of the board leadership structure will be made at the sole discretion of our board of directors. A more detailed description of the role and responsibilities of the Chairman of the Board is set forth in our Corporate Governance Guidelines.

#### **Corporate Governance Guidelines**

The board has adopted governance guidelines which are designed to assist the Company and the board in implementing effective corporate governance practices. The governance guidelines, which are reviewed annually by the Nominating and Governance Committee, address, among other things:

director responsibilities;

composition and selection of the board, including qualification standards and independence guidelines;

majority voting for directors;

the role of the Chairman of the Board or of an independent Lead Director;

board committee establishment, structure and guidelines;

officer and director stock ownership requirements;

meetings of non-employee directors;

director orientation and continuing education;

board access to management and independent advisors;

communication with directors;

board and committee self-evaluations;

succession planning and management development reviews;

CEO performance reviews;

recoupment, or claw-back , of executive compensation; and

ethics and conflicts of interest. The governance guidelines are posted on our website at *www.mallinckrodt.com*.

### **Code of Ethics**

We have adopted the Mallinckrodt Guide to Business Conduct, which applies to all of our employees, officers and directors and meets the requirements of a code of ethics as defined by SEC regulations. The Guide to Business Conduct also meets the requirements of a code of business conduct and ethics under the listing standards of the NYSE. The Guide to Business Conduct is posted on our website, *www.mallinckrodt.com*. We will disclose any material amendments to the Guide to Business Conduct, as well as any waivers for executive officers or directors, on our website.

#### **Board Risk Oversight**

Our board of directors oversees an enterprise-wide approach to risk management designed to support the achievement of organizational objectives, including strategic objectives, to improve long-term organizational

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performance and enhance shareholder value. A fundamental part of risk management is not only understanding the risks we face and what steps management is taking to manage those risks, but also understanding what level of risk is appropriate for us. The involvement of the full board of directors in setting our business strategy is a key part of its assessment of management s appetite for risk and the determination of what constitutes an appropriate level of risk for the Company. In this process, risk is assessed throughout the business, focusing on three primary areas of risk: financial risk, legal/compliance risk and operational/strategic risk.

While the board of directors has the ultimate oversight responsibility for the risk management process, various committees of the board also have responsibility for risk management. In particular, the Audit Committee focuses on financial risk, including internal controls, and receives an annual risk assessment report from our internal auditors. Our Compliance Committee assists the board of directors in fulfilling its oversight responsibility with respect to regulatory, healthcare compliance and public policy issues that affect us and work closely with our legal and regulatory groups. In addition, in setting compensation, the Human Resources and Compensation Committee strives to create incentives that encourage a level of risk-taking behavior consistent with our business strategy. Finally, the Company s Compliance Committee conducts an annual assessment of the risk management process and reports its findings to the board.

### **Communications with the Board of Directors**

The board has established a process for interested parties to communicate with members of the board. If you have a concern, question or complaint regarding our compliance with any policy or law, or would otherwise like to contact the board, you may reach the board via email at board.directors@mallinckrodt.com. A direct link to this email address can be found on our website. You may also submit communications in writing or by phone. Please refer to the board of directors contact information that can be found at http://www.mallinckrodt.com/Company\_Contacts/. All concerns and inquiries are received and reviewed promptly by the Office of the General Counsel. Any significant concerns relating to accounting, internal controls or audit matters are reviewed with the Audit Committee.

All concerns will be addressed by the Office of the General Counsel, unless otherwise instructed by the Audit Committee or the Chairman of the board. The status of all outstanding concerns is reported to the Chairman of the Board and the Audit Committee on a quarterly basis, and any concern that is determined to (1) pose an immediate threat to the Company or (2) concern a senior Company official (any executive officer or any direct report to the President and Chief Executive Officer) is immediately communicated to the Chair of the Audit Committee. The Chairman of the Board or the Audit Committee may determine that certain matters should be presented to the full board and may direct the retention of outside counsel or other advisors in connection with any concern addressed to them. The Mallinckrodt Guide to Business Conduct prohibits any employee from retaliating against anyone for raising or helping to resolve an integrity question.

# **Application of Non-U.S. Corporate Governance Codes**

Our corporate governance guidelines and general approach to corporate governance as reflected in our memorandum and articles of association and our internal policies and procedures are guided by U.S. practice and applicable federal securities laws and regulations and NYSE requirements. Although we are an Irish public limited company, we are not subject to the listing rules of the Irish Stock Exchange or the listing rules of the U.K. Listing Authority and we are therefore not subject to, nor have we adopted, the U.K. Corporate Governance Code or any other non-statutory Irish or U.K. governance standards or guidelines. While there are many similarities and overlaps between the U.S. corporate governance standards applied by us and the U.K. Corporate Governance Code and other Irish/U.K. governance standards applied and the U.K. Corporate Governance Code and other Irish/U.K. governance standards or guidelines, there are differences, in particular relating to the extent of the authorization to issue share capital and effect share repurchases that may be granted to the board and the criteria for determining the independence

of directors.

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# **Board of Directors of MIFSA**

Set forth below is information as of January 14, 2014 with respect to the directors of MIFSA:

*Marie Dhersin-Luporsi* Ms. Luporsi, age 33, is the managing director of MIFSA. Ms. Luporsi has served as a financial controller for MIFSA and Mallinckrodt Group Sarl since 2013.

*John E. Einwalter* Mr. Einwalter, age 45, serves on MIFSA s board of directors. Mr. Einwalter has served as Vice President and Treasurer of Mallinckrodt plc since the Company separated from Covidien plc in 2013.

*Alan Catterson* Mr. Catterson, age 52, serves on MIFSA s board of directors. Mr. Catterson has served as the financial controller for MIFSA and Mallinckrodt Group Sarl since 2013.

*Rene Beltjens* Mr. Beltjens, age 52, serves on MIFSA s board of directors. Mr. Beltjens is Deputy Chairman of the Alter Domus Group in Luxembourg. He has served as a director since 2013.

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### **COMPENSATION OF NON-EMPLOYEE DIRECTORS**

The Board of Directors has approved a compensation structure for non-employee directors consisting of equity awards, an annual cash retainer and, for some positions, supplemental cash retainers.

The cash retainers are paid in four quarterly installments at the end of each quarter. The annual cash retainer for all directors is \$100,000, with the non-executive Chairman receiving a supplemental cash retainer of \$50,000, the chairs of the Audit Committee and the Human Resources and Compensation Committee each receiving a supplemental cash retainer of \$20,000, the chairs of the Compliance Committee and the Nominating and Governance Committee each receiving a supplemental cash retainer of \$10,000 and each member of a committee required by NYSE rules (excluding committee chairs) receiving a supplemental cash retainer of \$5,000.

In addition, at the time of our 2014 Annual General Meeting, each non-employee director will be granted restricted units with a value of \$180,000 and the non-executive Chairman will be granted additional restricted units with a value of \$90,000. These awards fully vest on the date of the 2015 Annual General Meeting.

Directors are also reimbursed for reasonable out-of-pocket expenses incurred in attending meetings of our Board of Directors, committee meetings and shareholder meetings. Directors are provided with private aircraft in order to travel to and from such meetings.

Given that we were a publicly-traded company for only one quarter of fiscal 2013, our Board members received a prorated cash retainer and a prorated annual equity grant for fiscal 2013. A prorated annual equity grant will not be granted to any new director who commences serving less than three months prior to the vesting date.

#### **Director Share Retention and Ownership Guidelines**

As set forth in our Corporate Governance Guidelines, all non-employee directors are required to hold Mallinckrodt shares with a market value of at least five times the annual cash retainer. In determining a director s ownership, shares held directly as well as shares underlying restricted units subject to time-based vesting are included. Shares underlying unexercised stock options are not included in the calculation. Until the required ownership level is achieved, the non-employee directors are required to retain net after tax shares received upon vesting of restricted units from the Company.

The following table provides information concerning the compensation paid by us to each of our non-employee directors for the fiscal year ended September 27, 2013. Compensation for Mark C. Trudeau, our President and Chief Executive Officer, is shown in the Summary Compensation Table on page 138. Mr. Trudeau receives no compensation for his services as a director.

#### 2013 Director Compensation Table

	<b>Fees Earned</b>			
	or Paid in	Stock	Other	
	Cash	Awards <sup>(1)</sup>	Compensation <sup>(2)</sup>	
Name	(\$)	(\$)	(\$)	Total (\$)
(a)	(b)	(c)	( <b>g</b> )	( <b>h</b> )
Melvin D. Booth	\$ 38,750	\$ 196,103	\$ 40,000	\$274,853

David R. Carlucci	\$ 30,000	\$ 130,735	\$ 20,000	\$ 180,735
J. Martin Carroll	\$ 28,750	\$ 130,735	\$ 20,000	\$ 179,485
Diane H. Gulyas	\$ 27,500	\$ 130,735	\$ 20,000	\$178,235
Nancy S. Lurker	\$ 26,250	\$ 130,735	\$ 20,000	\$ 176,985
JoAnn A. Reed	\$ 30,000	\$ 130,735	\$ 20,000	\$180,735
Kneeland C. Youngblood, M.D.	\$ 26,250	\$ 130,735	\$ 20,000	\$ 176,985
Joseph A. Zaccagnino	\$ 27,500	\$ 130,735	\$ 20,000	\$178,235

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- (1) The amounts in column (c) reflect the aggregate grant date fair value of restricted units granted in fiscal 2013, calculated in accordance with Accounting Standards Codification 718. The grant date fair value does not necessarily correspond to the actual value that will be recognized by each director, which will likely vary based on a number of factors, including our financial performance, stock price fluctuations and applicable vesting. As of September 27, 2013, each current director listed in the table above, other than Mr. Booth, had 3,034 restricted units outstanding. As of September 27, 2013, Mr. Booth had 4,551 restricted units outstanding. No stock options were granted to non-employee directors in fiscal 2013.
- (2) Consists of a one-time pre-separation payment from Covidien.

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# COMPENSATION DISCUSSION AND ANALYSIS

#### **Executive Summary**

Effective June 28, 2013, the last day of our third fiscal quarter, we separated from Covidien and became the parent company that owns and operates Covidien s former Pharmaceuticals business. Throughout this Compensation Discussion and Analysis, we refer to this separation as the separation, the period before separation as pre-separation and the period after separation as post-separation. Covidien s compensation programs applied to the named executive officers during the first three quarters of our 2013 fiscal year, and the compensation Committee ) applied to the named executive officers during the fourth quarter of our 2013 fiscal year. Accordingly, this discussion and analysis describes the compensation programs established by Covidien pre-separation, but will focus on the compensation programs approved by the Compensation Committee for the fourth quarter of our 2013 fiscal year.

The Compensation Committee has adopted an integrated executive compensation program that is intended to align our named executive officers interests with those of our shareholders and to promote the creation of shareholder value without encouraging excessive or unnecessary risk-taking. Additionally, the Compensation Committee has tied a majority of our named executive officers compensation to a number of key performance measures that contribute to or reflect shareholder value. Specifically, in addition to a base salary, our named executive officers compensation program that is based on the Company s attainment of objective pre-established financial performance metrics and long-term equity awards consisting of stock options, performance units and restricted units.

# Fiscal 2013 Business Highlights

Despite a challenging market environment, the Company finished fiscal 2013 with solid operating performance, meeting its publicly stated goals of growing sales faster than the Specialty Pharmaceuticals market and expanding its core product portfolio. The Company reported financial results for fiscal year 2013 of operational growth of 7.8%, adjusted EBITDA margin of 18.0% and adjusted diluted earnings per share of \$3.13. In addition to becoming an independent public company, the Company also was successful in beginning to shift its mix of business to the Specialty Pharmaceuticals business which for fiscal year 2013 accounted for 57%, up from 50% in fiscal 2012 of net sales. The Company also launched three product dosages of Methylphenidate ER and filed two New Drug Applications, one of which, for Xartemis XR, has been granted priority review by the U.S. Food and Drug Administration.

# Key Fiscal 2013 Compensation Decisions

As a result of our positive financial results for fiscal 2013, payouts under the 2013 Annual Incentive Plan to our named executive officers at the corporate level were made at 133% of target performance level. The Company s operating income and sales growth exceeded the 2013 Annual Incentive Plan target performance level.

On July 1, 2013, the Compensation Committee approved grants of initial equity awards, which consisted of an equal mix of non-qualified stock options and restricted units, to certain of Mallinckrodt s executives, including certain of the named executive officers. This grant was intended to strengthen named executive officers alignment with shareholders and continue to motivate and retain named executive officers during the initial stages of a public launch.

# **Policies and Practices to Support Effective Governance**

The Compensation Committee has adopted the following compensation practices, which are intended to support effective governance and alignment with shareholder interests:

We have established significant share ownership guidelines to reinforce the alignment of management and shareholder interests.

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We have an executive recoupment policy that allows us to recover performance-based cash and equity incentive compensation paid to executives in various circumstances.

We do not provide excise tax gross-up provisions in our change in control plan or for any perquisites that we offer.

We use an independent compensation consultant.

Our Insider Trading Policy prohibits employees, including directors and named executive officers, from entering into puts, calls, cashless collars, options or similar rights and obligations involving Mallinckrodt securities, other than the exercise of a Company-issued stock option.

#### Introduction

Pre-separation, Covidien established the compensation programs applicable to those serving as executive officers of Covidien s Pharmaceuticals business. Following the separation, the Compensation Committee reviewed these compensation programs in connection with its consideration of what programs to implement post-separation. The Compensation Committee s analysis included consideration of, among other things:

our post-separation status as a stand-alone company, rather than as part of a larger conglomerate;

our specific businesses; and

a compensation philosophy which places a significant emphasis on performance-based compensation. For purposes of the following Compensation Discussion and Analysis and executive compensation disclosures, the individuals listed below are referred to collectively as our named executive officers. They are our President and Chief Executive Officer, our Chief Financial Officer, our three other most highly compensated executive officers, based on fiscal 2013 compensation, and two additional individuals for whom disclosure would have been required but for the fact that they were no longer serving as executive officers at the end of fiscal 2013.

Mark Trudeau, President and Chief Executive Officer.

Matthew Harbaugh, Senior Vice President and Chief Financial Officer.

Ian Watkins, Senior Vice President and Chief Human Resources Officer.

Peter G. Edwards, Senior Vice President and General Counsel.

Stephen Merrick, Senior Vice President and President, Commercial Operations (International).

Stefano Carchedi, Former Senior Vice President and President, Commercial Operations (North America).

David Silver, Former Senior Vice President, Portfolio Management, Strategy and Business Development and Licensing.

The following sections of this Compensation Discussion and Analysis describe our compensation philosophy, policies and practices as they applied to our named executive officers listed above during fiscal 2013.

#### **Executive Compensation Philosophy**

For fiscal 2013, Mallinckrodt and the Compensation Committee adopted a compensation philosophy designed to attract, retain and motivate its executive officers. The core principles of that compensation philosophy are as follows:

Compensation should strongly align the interests of executive officers and shareholders.

Compensation policies and practices should support effective governance.

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Compensation should be based on a total rewards perspective with an explicit role for each element.

Compensation should be competitive, but not excessive, in order to attract and retain talented executive officers who can achieve Mallinckrodt s long-term strategic goals and create shareholder value.

Compensation should support Mallinckrodt s business strategy in the areas of customer focus, globalization, operational excellence and innovation, as well as Mallinckrodt s talent strategy.

The reward elements should be balanced, with an emphasis on performance-based compensation.

Compensation goals and practices should be transparent and easy to communicate, both internally and externally.

Target setting is a key activity and should be done in a rigorous manner resulting in targets that reflect stretch, yet are achievable.

There are three major components to Mallinckrodt s executive compensation program: base salary, annual incentive compensation, and long-term incentive awards. All of these components are designed to work together and the Compensation Committee views the executive compensation program as an integrated total compensation program. The mix of compensation elements varies based on a named executive officer s position and responsibilities.

*Base salary*. Base salary is intended to reflect the market value of the executive officer s role, with differentiation for strategic significance, individual capability and experience.

*Annual incentive compensation.* Annual incentive compensation in the form of a market-competitive, performance-based cash bonus opportunity is designed to focus executive officers on pre-set objectives each year and drive specific behaviors that foster short- and long-term growth and profitability.

*Long-term incentive compensation*. Long-term incentive compensation, which consists of awards of stock options, restricted units and performance units, is designed to recognize executive officers for their contributions to Mallinckrodt, to highlight the strategic significance of each executive s role, to promote retention and to align the interests of executive officers with the interests of shareholders in long-term growth and stock performance, rewarding executive officers for shareholder value creation.

In addition, Mallinckrodt also provides certain other benefits, consisting of retirement benefits, (including both qualified and non-qualified plans), health and welfare benefits, an executive physical program, an employee stock purchase plan and change in control and severance benefits which are intended to be competitive with Mallinckrodt s peer companies.

#### How Executive Pay Decisions Are Made

As noted above, during fiscal 2013, the named executive officers participated in Covidien s executive compensation programs pre-separation. Consequently, our initial compensation policies are largely the same as those adopted by Covidien. In determining executive compensation packages for fiscal 2013, Covidien sought to strike an appropriate

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balance between fixed and variable compensation and between short- and long-term compensation. Additionally, Covidien reviewed available market data and set target compensation at levels consistent with an executive s experience. Any adjustments pre-separation were conservative to provide our Compensation Committee flexibility to review and make their own adjustments, if any, post-separation. Because Mallinckrodt believes that making a significant portion of its named executive officers compensation variable and long-term supports its pay-for-performance executive compensation philosophy, many of the post-separation compensation adjustments were provided in the form of long-term incentive compensation (i.e., equity awards). Mallinckrodt believes this encourages strategies and levels of risk-taking that correlate with the long-term best interests of Mallinckrodt and its shareholders. Mallinckrodt emphasizes share-based compensation, in

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combination with executive share ownership guidelines, to promote long-term ownership, long-term shareholder perspective and responsible practices, encouraging significant and sustainable performance over the longer term. Mallinckrodt s initial long-term incentive compensation program replicates the Covidien program and includes a mix of vehicles to mitigate the risk of over-emphasis on any one element and includes a cap on performance units. The equity awards include claw-back provisions which apply to certain monetary gains on equity grants realized by executives whose employment is terminated for cause. Finally, in assessing the contributions of a particular named executive officer, both Covidien and the Compensation Committee look not only to results-oriented performance, but also to how those results were achieved whether the decisions and actions leading to the results were consistent with company values and the long-term impact of those decisions. Based on these principles, Covidien and, where applicable, the Compensation Committee established the compensation payable to the named executive officers as described below.

Covidien utilizes a Talent and Leadership Review (TLR) process to manage its talent and organizational capability with the goal of maximizing organizational excellence and business success. As part of the TLR process, each employee s manager, in conjunction with a human resources representative, assigns to each employee a rating on two discrete dimensions: leadership competencies and results. For fiscal 2013, three possible ratings could be assigned in each of these two dimensions: exceptional, effective and not yet effective. These performance ratings impact base salary decisions, as well as decisions regarding the individual award target established for the employee pursuant to the annual incentive plan and the value of long-term incentive compensation awards. The TLR process applied to Mr. Trudeau, Mr. Harbaugh and Mr. Edwards all other NEOs did not participate in the Covidien TLR process for fiscal year 2013.

As new hires during fiscal year 2013, Mr. Watkins , Mr. Merrick s and Mr. Carchedi s compensation was not established through the TLR process. To establish the compensation opportunities for Mr. Watkins, Mr. Merrick and Mr. Carchedi, Covidien considered a market study prepared by its compensation committee s independent compensation consultant, Steven Hall and Partners. This market study included information regarding base salary, annual cash incentive awards and the value of equity awards and compiled data derived from the 2011 Towers Watson U.S. General Industry survey. Covidien s independent compensation consultant weighted the survey job matches based on company revenue and industry in order to utilize survey data for companies of similar size to Mallinckrodt. Covidien then established Mr. Watkins , Mr. Merrick s and Mr. Carchedi s compensation opportunities based on the results of that process.

In connection with the separation, Frederic W. Cook & Co, Inc. ( Cook & Co. ) was retained prior to the separation and the Compensation Committee specifically requested a report from Cook & Co. assessing the competitiveness of the compensation of our Chief Executive Officer and other named executive officers when compared to compensation paid to similarly situated officers of companies in our new, post-separation peer group, as described in more detail on page 129. The following discusses the decision-making criteria for each component of compensation.

*Base Salary*. With respect to named executive officers, base salary for fiscal 2013 pre-separation was based on individual performance and an assessment of the value of the individual to Covidien. In November, 2012, Covidien s compensation committee approved a salary increase from \$650,000 to \$682,500 for Mr. Trudeau. Similarly, based in part upon the recommendation of Mallinckrodt s CEO and considering each named executive s officer s post-separation level of responsibility, Covidien s management approved an increase in Mr. Harbaugh s base salary from \$293,486 to \$400,000, an increase in Mr. Watkins base salary from \$375,000 to \$380,000, an increase in Mr. Edwards base salary from \$335,140 to \$375,000 and an increase in Mr. Silver s base salary from \$299,227 to \$308,204.

Post-separation, our Compensation Committee, based in part upon the recommendation of Mallinckrodt s CEO and considering each named executive officer s post-separation level of responsibility, experience and market data for

similar positions at companies in our peer group in July 2013, approved an increase in Mr. Harbaugh s base salary from \$400,000 to \$440,000, an increase in Mr. Watkins base salary from \$380,000

to \$400,000, an increase in Mr. Edwards s base salary from \$375,000 to \$400,000, an increase in Mr. Merrick s base salary from \$325,000 to \$370,000, and an increase in Mr. Carchedi s base salary from \$375,000 to \$425,000.

The Compensation Committee, based in part upon the recommendation of its independent compensation consultant, Cook & Co., and input from the full Board and considering the post-separation level of responsibility and market data for similar positions at companies in our peer group, approved an increase in Mr. Trudeau s base salary from \$682,500 to \$900,000 in July 2013.

*Annual Incentive Compensation.* During fiscal 2013, each named executive officer participated in the Covidien 2013 Annual Incentive Plan (Covidien 2013 AIP), which is a component of the Covidien Stock and Incentive Plan. At the beginning of the fiscal year pre-separation, the Covidien Compensation Committee established performance measures and goals, which included various core financial and strategic focus metrics, performance targets for each metric, including minimum threshold performance requirements to earn an award, and maximum performance goals. Post-separation, the Compensation Committee established an additional overall funding metric to supplement the existing metrics inherited from the Covidien 2013 AIP and to provide the Compensation Committee flexibility to assess the quality of the individual performance results as well as other factors related to the separation. As discussed under the heading 2013 Annual Incentive Awards below, each named executive officer had core financial metrics of sales growth and operating income and each named executive officer other than Mr. Trudeau had a strategic focus component which was based on core competencies and individual performance goals, while Mr. Trudeau as strategic focus component was based on gross margin and inventory metrics. Individual award targets, expressed as a percentage of base salary, were initially set by Covidien for each named executive officer based on the executive s level of responsibility and performance review.

Pre-separation, Covidien management, based in part upon the recommendation of Mallinckrodt s CEO and considering each named executive officer s post-separation level of responsibility and market data for similar positions at companies in our peer group, approved increases to the target bonus opportunities for the annual incentive plan as percentages of annual base salary for Mr. Harbaugh from 50% to 60%; and Mr. Edwards from 45% to 50% in December 2012.

Post-separation, the Compensation Committee, based in part upon the recommendation of Mallinckrodt s CEO and considering each named executive officer s post-separation level of responsibility and market data for similar positions at companies in our peer group, approved further increases to the target bonus opportunities for the annual incentive plan as percentages of annual base salary as follows: Mr. Harbaugh from 60% to 70%; Mr. Edwards from 50% to 60%; Mr. Merrick from 55% to 60%; and Mr. Carchedi from 55% to 60% in July 2013. The Compensation Committee, based in part upon the recommendation of Cook & Co., input from the full Board and considering the post-separation level of responsibility and market data for similar positions at companies in our peer group, approved an increase to the target bonus opportunity for the annual incentive plan as a percentage of annual base salary for Mr. Trudeau from 80% to 100% in July 2013.

After the close of the fiscal year, the Compensation Committee received a report from management regarding the performance of Mallinckrodt against the pre-established performance goals. Awards were based on each named executive officer s individual award target percentage and Mallinckrodt s performance relative to the specific performance goals, as certified by the Compensation Committee, and, with respect to named executive officers other than Mr. Trudeau, considering attainment of each officer s individual performance goals.

*Long-Term Incentive Compensation.* During fiscal 2013, named executive officers were eligible to receive long-term incentive compensation awards pursuant to the Covidien Stock and Incentive Plan pre-separation, and then post-separation under the Mallinckrodt Pharmaceuticals Stock and Incentive Plan. In establishing the value of the

fiscal 2013 long-term incentive compensation awards for each named executive officer other than Mr. Trudeau, Covidien s management considered individual performance, including TLR performance ratings, the officer s total compensation and mix of compensation for the previous fiscal year, the resulting compensation

mix projected for fiscal 2013, the officer s level of responsibility and previous equity grants. Mr. Merrick, who started after the fiscal 2013 long-term incentive award planning was completed, received a pro-rated long-term incentive award based on his target long-term incentive component as previously approved by Covidien in connection with his commencement of employment with Covidien. Post-separation, the Compensation Committee, based in part upon the recommendation of Mallinckrodt s CEO and considering each named executive officer s post-separation level of responsibility and market data for similar positions at companies in our peer group, approved an increase to the long-term incentive compensation award targets as percentages of annual base salary as follows: Mr. Harbaugh from 70% to 175%; Mr. Watkins from 80% to 120%; Mr. Edwards from 70% to 120%; Mr. Merrick from 70% to 160% and Mr. Carchedi from 70% to 160% in July 2013. The Compensation Committee, based in part upon the recommendation of Cook & Co., input from the full Board and considering Mr. Trudeau s post-separation level of responsibility and market data for similar positions at companies in our peer group, approved an increase to the long-term incentive compensation award target as a percentage of annual base salary to the long-term incentive commendation of Cook & Co., input from the full Board and considering Mr. Trudeau s post-separation level of responsibility and market data for similar positions at companies in our peer group, approved an increase to the long-term incentive compensation award target as a percentage of annual base salary for Mr. Trudeau from 200% to 400%.

Compensation Consultant. The Compensation Committee utilizes the services of independent compensation consultants from time to time and has the sole authority to retain, compensate and terminate any such compensation consultants. Steven Hall & Partners, Covidien s independent compensation consultant prepared a number of studies comparing the pre-separation compensation of our named executive officers with compensation of similarly-situated executive officers in peer group companies. In anticipation of the separation, the Compensation Committee reconsidered the use of a Covidien-retained compensation consultant and decided to retain a different compensation consultant. Accordingly, in April 2013, subject to the separation of Mallinckrodt from Covidien, the Compensation Committee directly engaged Cook & Co. as its independent compensation consultant. The Compensation Committee has assessed the independence of Cook & Co. and determined that the compensation consultant is independent and that no conflicts of interest exist currently or existed during fiscal 2013. Cook & Co. reports directly to the Compensation Committee and does not provide services to, or on behalf of, any other part of our business. Cook & Co. also has been retained by the Nominating and Governance Committee as its independent compensation consultant in all matters relating to non-employee director compensation. A representative of Cook & Co. reviews Compensation Committee materials, attends Compensation Committee meetings, assists the Compensation Committee with program design, generally provides advice to the Compensation Committee as compensation issues arise and provides recommendations on certain specific aspects of our compensation programs.

*Peer Group.* When reviewing compensation programs for the named executive officers, the Compensation Committee considers the compensation practices of specific peer companies in the same industry of reasonably similar size to us, as well as compensation data from general industry published surveys. Our initial specific peer group was established by Covidien pre-separation with the assistance of the Covidien compensation committee s independent compensation consultant, Steven Hall & Partners. With the assistance of Cook & Co., the Compensation Committee analyzed this peer group to determine whether the peer group was appropriate for us as a stand-alone company post-separation. Based on this analysis, the Compensation Committee concluded that the members of the group should be expanded for greater statistical significance and representation of the market for which we compete for executive talent. In refining its peer group selection, the Compensation Committee considered various factors, including the industry sector, revenue, net income, market capitalization and number of employees. The following table sets forth the post-separation peer group approved by the Compensation Committee:

Mylan Inc. Actavis Inc. (formerly Watson Pharmaceuticals, Inc.) Shire plc Hospira, Inc.

Hologic, Inc. Vertex Pharmaceuticals Incorporated Regeneron Pharmaceuticals, Inc. Alexion Pharmaceuticals, Inc. Forest Laboratories, Inc. Perrigo Company Valeant Pharmaceuticals International, Inc. Endo Health Solutions, Inc. Warner Chilcott Ltd. Cubist Pharmaceuticals, Inc. United Therapeutics Corporation Salix Pharmaceuticals, Ltd. Jazz Pharmaceuticals plc Impax Laboratories, Inc.

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### **2013** Annual Incentive Awards

Mallinckrodt s payment of fiscal 2013 annual incentive awards to the named executive officers was subject to the achievement of core financial and strategic focus metrics established pursuant to the Covidien 2013 AIP. For fiscal 2013, there were two core financial metrics which were weighted 35% each and which accounted for, in the aggregate, 70% of the performance multiplier. The strategic focus metrics accounted for the remaining 30% of the performance multiplier. The following describes the core financial and strategic focus metrics applicable to each named executive officer for fiscal 2013 as well as the process employed by Mallinckrodt to calculate the performance multiplier and final payouts to named executive officers under the 2013 AIP.

*Core Financial Metrics*. The two core financial metrics for fiscal 2013, established pre-separation by Covidien and ratified by the Compensation Committee, were operating income and sales growth for the Pharmaceuticals business of Covidien. While operating income was measured on a Company wide basis for all named executive officers, sales growth was measured on a Company wide basis for named executive officers other than Messrs. Merrick and Carchedi who were measured against the sales growth targets for their respective divisions.

*Strategic Focus Metrics*. The strategic focus metrics for Mr. Trudeau, established pre-separation by Covidien and ratified by the Compensation Committee, were gross margin and net inventory for the pharmaceutical segment. The strategic focus component for the other named executive officers was represented by their individual performance rating. Under the Covidien performance management process, the performance rating was based on core competencies established by Covidien and individual performance goals approved by the manager of each named executive officer, pre-separation, according to the process described below.

At the start of fiscal 2013, Covidien established six core competencies which were company-wide initiatives utilized to assess a portion of certain employees performance during fiscal 2013. Also at the start of fiscal 2013, corporate goals were established by Mr. Trudeau and the members of his executive team for the Company.

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The following chart summarizes the 2013 AIP design, including the performance targets and performance scores for the core financial metrics for each named executive officer as well as the performance target and performance scores for the strategic focus metrics for Mr. Trudeau. Please refer to the discussion that immediately follows this chart for more detail regarding the calculation of the performance multiplier for the strategic focus component for named executive officers other than Mr. Trudeau, as well as the final payout under the 2013 AIP for each named executive officer.

### Fiscal 2013 Annual Incentive Plan Design Summary

		D	anformanal	Dowf	annanaa	Performance	Weighted
Executive Officer	Performance Metric	r Weight	Target <sup>(1)</sup> (dollars in	R	esults	Multiplier	Multiplier
Mark Trudeau	Operating Income	35%	\$ 377.6	\$	376.3	96.64%	33.82%
	Sales Growth	35%	6.8%	+	8.2%	169.37%	59.28%
	Gross Margin	15%	46.5%		44.8%	59.93%	8.99%
	Net Inventory	15%	\$350.0	\$	356.2	91.10%	13.67%
Performance Multi	plier Total						115.76%
Matthew Harbaugh	Operating Income	35%	\$377.6	\$	376.3	96.64%	N/A
Ian Watkins							
Peter Edwards	Sales Growth	35%	6.8%		8.2%	169.37%	N/A
David Silver							
Performance Multi	plier for Core Financial Metri	cs Only				133.0%	N/A
Stephen Merrick	Operating Income	35%	\$377.6	\$	376.3	96.64%	N/A
	Sales Growth International	35%	8.6%		-0.6%	0%	N/A
<b>Performance Multi</b>	plier for Core Financial Metri	cs Only				48.32%	N/A
Stefano Carchedi	Operating Income	35%	\$377.6	\$	376.3	96.64%	N/A
	Sales Growth North America	35%	6.6%		11.9%	200%	N/A
Performance Multi	plier for Core Financial Metrie	cs Only				148.32%	N/A

(1) The performance metrics used for compensation purposes include non-GAAP financial measures which exclude the effects of anticipated one-time, generally non-recurring items which the Compensation Committee believes may mask the underlying operating results and/or business trends of the business segment. The categories of these anticipated extraordinary items are identified at the beginning of the fiscal year when the performance measure is approved and, for the Mallinckrodt 2013 AIP, included certain restructuring charges, revenue adjustments related to businesses exited or sold, acquisitions, goodwill or other intangible asset impairment charges, shareholder and other litigation charges, certain legacy tax matters and costs related to separation.

For the 2013 AIP, the performance targets were calculated as follows:

Operating income is the operating income of Mallinckrodt as Covidien s Pharmaceutical business pre-separation and on a consistent basis post-separation, calculated using the currency exchange rate applied in setting our annual operating plan in order to eliminate the effect of currency exchange rate fluctuations.

Sales growth is the total change in net trade sales of Mallinckrodt as Covidien s Pharmaceutical business pre-separation and on a consistent basis post-separation for fiscal 2013 in U.S. dollars, calculated using fiscal 2012 currency exchange rates divided by fiscal 2012 net trade sales.

Gross margin is gross margin dollars of Mallinckrodt as Covidien s Pharmaceutical business pre-separation and on a consistent basis post-separation, divided by net sales dollars, where gross margin dollars is calculated by adjusting sales primarily for product costs, variances in plant, freight costs, royalties, warehousing, inventory adjustments and currency exchange rate fluctuations.

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Net Inventory is the balance sheet Inventories excluding Global Medical Imaging inventory at distribution centers located outside of the United States and Canada.

Our sales growth exceeded the 2013 AIP target performance level, while operating income, gross margin and net inventory did not meet the target performance level. Payout under the 2013 AIP to Mr. Trudeau was made at 115.76% of target performance level (i.e., by application of a performance multiplier of 115.76%).

With respect to the other named executive officers, pool funding under the 2013 AIP was determined solely on the results of the core financial metrics. For Messrs. Harbaugh, Watkins, Edwards and Silver it was based on a performance multiplier of 133%, which represents an equal weighting of the 96.64% and 169.37% performance multipliers for the operating income and sales growth core financial metrics, respectively. For Messrs. Merrick and Carchedi, it was based on the equal weighting of the Company operating income and the sales growth metric for their respective divisions. A preliminary payout was determined using a weighted average of 70% based on the core financial metrics performance multiplier and 30% based upon the strategic focus component multiplier.

As stated above, the strategic focus metrics for named executive officers other than Mr. Trudeau consisted of core competencies established by Covidien and individual performance goals approved by each named executive officer s pre-separation manager.

For fiscal 2013, the individual performance goals approved for the named executive officers other than Mr. Trudeau included certain corporate level objectives, primarily related to the successful achievement of the Company s separation from Covidien and establishment of Mallinckrodt as a newly independent public company and certain business level objectives, primarily related to the successful achievement in advancing the Company s product pipeline, as well as the achievement of certain objectives focused on operational excellence and customer satisfaction.

Immediately after the conclusion of fiscal 2013, the Chief Executive Officer conducted a performance evaluation for each executive officer by assessing the executive officer s performance during fiscal 2013 against each of the six core competencies and individual performance goals. During this process, each named executive officer s individual performance rating was categorized as exceeding, achieving, partially achieving or not achieving the stated objective. The Chief Executive Officer then determined a strategic focus component performance modifier based on the performance rating and the schedule below:

		Strategic Focus Component
Performance Rating	Target	Performance Modifier
Exceeding	150%	125% 175%
Achieving	100%	75% 125%
Partially Achieving	50%	25% 75%
Not Achieving	0	0%

Once the strategic focus component performance modifier was determined, Mallinckrodt calculated a preliminary payout for each named executive officer based on both the core financial metrics and the strategic focus component. The Chief Executive Officer then reviewed the preliminary payout and adjusted, if appropriate, the amount of the payout based on individualized performance, additional contributions by the named executive officer that were not captured within the parameters of the core competencies or individual performance goals, and the amount of the payout calculated solely based on the core financial metrics in order to align more closely the final payout with our financial performance and available pool funding.

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The following chart lists the performance multiplier for the core financial metrics only, the payout based only on the performance multiplier for the core financial metrics (CFM), the performance multiplier for both the CFM and the strategic focus metrics (SFM), the preliminary payout amount determined by application of the performance multiplier for both the CFM and the final payout made to each named executive officer. The chart also lists, for Mr. Trudeau, the performance multiplier applicable to his payout and his final payout amount.

Executive Officer	Pa Performance Multiplier for CFM Only	Pe N	Based on CF erformance Multiplier Only (Funded Amount)	M Performance Multiplier for CFM and SFM	B C Per	inary Payout ased on FM and SFM formance fultiplier	Final 2013 Annual Incentive Payout
Mark Trudeau	N/A		N/A	1.1576x		N/A	\$ 885,564
Matthew Harbaugh		\$	365,764	1.46x	\$	400,410	\$402,021
Ian Watkins		\$	319,212	1.41x	\$	338,648	\$ 331,021
Peter Edwards		\$	279,311	1.31x	\$	274,267	\$ 280,020
Stephen Merrick		\$	67,044	0.64x	\$	88,556	\$ 90,000
David Silver		\$	122,978	1.23x	\$	113,823	\$113,823
Stefano Carchedi		\$	354,578	1.11x	\$	266,134	\$ 266,000

From time to time, the Compensation Committee may also grant discretionary bonuses to reward employees for performance that has greatly exceeded the employee 's objectives and goals or the employee has made a unique contribution to the Company during the year or when other factors and circumstances warrant. The Compensation Committee approved a one-time special discretionary bonus award to Mark Trudeau, our President and Chief Executive Officer, to recognize his leadership and work related to the separation from Covidien, including the advancement of strategic initiatives in fiscal 2013 to position Mallinckrodt for success as an independent public company. The special discretionary bonus award in the amount of \$100,000 was approved on November 21, 2013 by the Compensation Committee, subject to the completion by Deloitte & Touche LLP s audit of the Company s consolidated and combined financial statements.

### **Long-Term Incentive Awards**

The Compensation Committee uses annual long-term incentive compensation to deliver competitive total direct compensation opportunities that recognize employees for their contributions to the Company and align named executive officers with shareholders in focusing on long-term growth and stock performance.

For the 2013 fiscal year, our long-term incentive compensation program consisted of grants of restricted units and non-qualified stock options, some of which were awarded by Covidien pre-separation in November 2012 (and granted in December 2012) and some of which were granted by the Compensation Committee in connection with the separation in July 2013. The off-cycle, initial post-separation grants in July 2013, which consisted of an equal mix of non-qualified stock options and restricted units, were made pursuant to our Stock and Incentive Plan, which became effective in July 2013 (see Initial Equity Grant discussion on pages 134 and 135). The Compensation Committee believes that the 50/50 mix of options and restricted units for the Initial Equity grants was appropriate to balance upside reward and downside value risk. Going forward, we expect to issue annual equity grants on the first NYSE trading day of the second quarter of each fiscal year. In November 2013, the Compensation Committee awarded the named executive officers fiscal 2014 annual equity grants, which consisted of a mix of non-qualified stock options (weighted 40%), restricted units (weighted 20%), and performance units (weighted 40%). Consistent with the timing

described above, these awards were issued on January 2, 2014.

The Compensation Committee determines equity awards by establishing a dollar value for each named executive officer and then converting this dollar value to equity based on grant-date fair values.

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By using this value approach, the number of stock options and restricted units will vary from year to year based on, among other things, our stock price at the time of grant, even though the awards may have the same dollar value under the Compensation Committee s valuation methodologies.

### **Outstanding Performance Units (pre-separation)**

Prior to the separation, named executive officers had previously received from Covidien performance units with performance-based vesting based on relative total shareholder return for each of the fiscal 2011 2013 performance period (the Fiscal 2011 Performance Units ) and the fiscal 2012 2014 performance period (the Fiscal 2012 Performance Units ). In connection with the separation, the ending date for the performance period was accelerated to the date of the separation and, in November 2013, the Compensation Committee certified the results for each of these awards and determined that 200% of the Fiscal 2011 Performance Units are eligible for vesting, subject to continued time-based vesting through December 2013, and 168% of the Fiscal 2012 Performance Units are eligible for vesting, subject to continued time-based vesting through December 2014.

### Fiscal 2013 Annual Equity Grants (pre-separation)

Prior to the separation, named executive officers were eligible to receive long-term incentive compensation awards, consisting of restricted units and non-qualified stock options on Covidien ordinary shares, pursuant to the Covidien Stock and Incentive Plan during fiscal 2013. Upon separation from Covidien, all outstanding equity awards held by active employees of the Company were converted into like-kind equity awards of the Company. Such equity awards were converted at equivalent value determined using the intrinsic value method. The original vesting provisions remained in effect for all equity awards.

*Restricted units*. Restricted units represent unissued ordinary shares; we do not issue stock until the applicable vesting requirements are satisfied. When the vesting requirements are satisfied, the executive receives ordinary shares without restriction. Restricted units granted to named executive officers during fiscal 2013 vest one-quarter annually beginning on the first anniversary of the grant date.

*Non-qualified stock options*. Non-qualified stock options generally permit a named executive officer to purchase ordinary shares at a per-share exercise price equal to the fair market value of ordinary shares on the date of grant. Fair market value is equal to the closing price of ordinary shares as reported on the NYSE on the grant date. Options granted to named executive officers during the 2013 fiscal year generally have a 10 year term and vest one-quarter annually beginning on the first anniversary of the grant date.

### **Initial Equity Grant**

On July 1, 2013, the Compensation Committee approved grants of initial equity awards to certain of Mallinckrodt s executives, including the following grants to the named executive officers of Mallinckrodt:

	Grant
	Date
Name	Fair Value
Mark Trudeau	\$7,203,333
Matthew Harbaugh	\$ 770,357
Ian Watkins	\$ 480,253

Peter Edwards	\$ 480,253
Stephen Merrick	\$ 592,304
Stefano Carchedi	\$ 680,355

In establishing the dollar value for the July 2013 grants, the Compensation Committee reviewed comparable information from the newly established peer group, as well as information relating to equity grants made by companies in a similar spin-off situation. The Compensation Committee reviewed research prepared by Steven

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Hall and Partners and validated by Cook & Co., which indicated that equity awards listed in proxy statements for named executive officers in the first year after a spin-off were generally two to three times higher than equity grants made prior to the spin-off, with the two times level more prevalent. The research noted that the higher awards at the time of spin-off typically resulted in reduced award levels for the following year. Accordingly, after considering accounting cost, equity overhang and run-rate issues, the Compensation Committee granted initial awards with a value approximately one times the intended post-separation annual grant value for each named executive officer (two times for the CEO). The size of Mr. Trudeau s initial equity grant was based on the terms of the February 1, 2012 letter agreement between Mr. Trudeau and Covidien, which provided that upon a spin-off of the Pharmaceuticals business, the spun-off entity would issue an initial equity award equal to at least two times a competitive annualized equity grant value for the CEO of a comparable company.

The objectives of the initial equity grant were to:

strengthen named executive officers alignment with shareholders; and

continue to motivate and retain named executive officers during the initial stages of a public launch. For each individual, approximately 50% of the value of the grants was awarded in the form of restricted units and 50% of the value was awarded in the form of stock options. Each restricted unit award (except for Mr. Trudeau s restricted unit award) and stock option award under these initial equity grants will vest in two equal amounts on each of July 1, 2016 and 2017. The stock option awards have an exercise price of \$44.00 per share and a 10-year term. Mr. Trudeau s restricted unit award vests in its entirety on July 1, 2018.

### **Other Benefits**

Each of the benefits described below was chosen to support Mallinckrodt s philosophy of providing a total rewards perspective to compensating its employees. Collectively, these benefits are intended to be competitive with Mallinckrodt s peer companies.

*Retirement Benefits.* Covidien maintains six defined benefit pension plans for the benefit of U.S. employees associated with its Pharmaceuticals business. These pension plans have been frozen with respect to all future benefit accruals. No named executive officer is eligible to participate in any of these defined benefit plans because all such plans were frozen before each executive officer commenced employment with Mallinckrodt or Covidien. However, the named executive officers are eligible to participate in the Mallinckrodt Retirement Savings and Investment Plan (Mallinckrodt Retirement Savings Plan), which is Mallinckrodt s 401(k) plan available to all eligible U.S. employees, and the Mallinckrodt Supplemental Savings and Retirement Plan (Mallinckrodt Supplemental Savings Plan), Mallinckrodt s non-qualified deferred compensation plan in which executive officers and other senior employees may participate. The Mallinckrodt Supplemental Savings Plan provides benefits that participants, including our named executive officers, can receive above and beyond Internal Revenue Code limitations. For more information regarding the Mallinckrodt Supplemental Savings Plan, see Executive Compensation Non-Qualified Deferred Compensation.

*Health and Welfare Benefits.* The health and welfare benefits Mallinckrodt provides to the named executive officers are offered to all eligible U.S.-based employees and include medical, dental, prescription drug, vision, life insurance, accidental death and dismemberment, business travel accident, personal and family accident, flexible spending accounts, short- and long-term disability coverage and an employee assistance program.

*Perquisites*. Although Mallinckrodt does not have a perquisite program, it maintains an executive physical program which offers comprehensive and coordinated annual physical examinations to certain senior-level employees. This program is available to Mr. Trudeau and all other senior executive officers, including the other named executive officers.

*Employee Stock Purchase Plan.* Effective October 1, 2013, Mallinckrodt began maintaining a broad-based employee stock purchase plan that provides eligible employees, including the named executive officers, with the

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opportunity to purchase Mallinckrodt ordinary shares. Eligible employees authorize payroll deductions to be made for the purchase of Mallinckrodt ordinary shares and Mallinckrodt provides a 15% matching contribution (25% for employees who did not receive an initial equity grant post-separation the 25% match is limited to fiscal year 2014 after which the match will be 15%) on up to \$25,000 of an employee s payroll deductions in any calendar year. All shares are purchased on the open market by a designated broker and are required to be held by participants for 12 months after purchase.

*Severance Benefits*. Mallinckrodt maintains an executive severance plan which provides benefits to Mallinckrodt senior executives upon an involuntary termination of employment for any reason other than cause, permanent disability or death. Severance benefits, in the form of base salary continuation, bonus and health benefits are generally payable for 18 months (24 months for our President and Chief Executive Officer) following a qualifying termination of employment. Receipt of these benefits is conditioned upon the named executive officer signing a release of any claims against Mallinckrodt.

*Change in Control Benefits.* Mallinckrodt maintains a change in control plan which provides benefits to certain Mallinckrodt senior executives upon an involuntary termination of employment or good reason resignation that occurs during a period shortly before and continuing after a change in control (a double trigger arrangement). Benefits are generally payable following a qualifying termination of employment in a lump-sum cash payment equal to 1.5 times (2 times for our President and Chief Executive Officer) the sum of the executive s base salary and the average of the executive s bonus for the previous three fiscal years. Additional benefits provided upon a change in control termination include full vesting of outstanding equity awards, continued subsidy for health plan premiums for an 18-month period (24 months for our President and Chief Executive Officer) and outplacement services. Receipt of change in control severance benefits is conditioned upon the executive signing a release of any claims against Mallinckrodt. The plan does not provide excise tax gross-ups.

### **Share Ownership Guidelines**

To reinforce the alignment of management and shareholder interests, the Compensation Committee established share ownership guidelines. Under these guidelines, named executive officers are expected to hold equity with a value expressed as a multiple of base salary as follows:

President and Chief Executive Officer	5 times base salary
Other Named Executive Officers	3 times base salary

In determining an executive s ownership, shares held directly as well as shares underlying restricted units are included. Shares underlying unexercised stock options and unvested performance units are not included in the calculation. Until the required ownership level is achieved, the executives are required to retain at least fifty percent of net profit shares. Net profit shares are shares remaining after payment of the exercise price, if applicable, and taxes upon the exercise of stock options, vesting of restricted stock, and earn-out of performance shares. Mallinckrodt s Insider Trading Policy prohibits employees, including named executive officers, from engaging in transactions in puts, calls, cashless collars, options or similar rights and obligations involving Mallinckrodt securities, other than the exercise of a Mallinckrodt-issued stock option.

### **Deductibility of Executive Compensation**

The Compensation Committee has generally intended to structure Mallinckrodt s executive compensation in a manner designed to qualify for deductibility under Section 162(m) of the Code when consistent with Mallinckrodt s overall

compensation program objectives, while also maintaining maximum flexibility in the design of Mallinckrodt compensation programs and in making appropriate payments to named executive officers.

### **Compensation Committee Report on Executive Compensation**

The Compensation Committee is responsible for the oversight of the Company s compensation programs on behalf of the Board of Directors. In fulfilling these responsibilities, the Compensation Committee has reviewed and discussed with management the Compensation Discussion and Analysis set forth in this Proxy Statement.

Based on the review and discussions referred to above, the Compensation Committee recommended to the Board of Directors that the Compensation Discussion and Analysis be included in the Company s Proxy Statement for the 2014 Annual General Meeting of Shareholders, which will be filed with the Securities and Exchange Commission.

#### Human Resources and Compensation Committee

David R. Carlucci, Chairman

Diane H. Gulyas

Nancy S. Lurker

### **Executive Compensation Tables**

#### **Summary Compensation**

As noted previously, during fiscal year 2013, we separated from Covidien. The information included in the Summary Compensation Table below reflects fiscal year 2013 compensation earned by our chief executive officer, chief financial officer and the three other most highly compensated executive officers in fiscal 2013 for services rendered to Covidien and its subsidiaries before separation (September 28, 2012 to June 27, 2013) and for services rendered to Mallinckrodt and its subsidiaries after separation (June 28, 2013 to September 27, 2013). The table also includes information for two additional individuals for whom disclosure would have been required but for the fact that they were no longer serving as executive officers on September 27, 2013. We refer to these seven individuals collectively as our named executive officers. For a more complete understanding of the table, please read the narrative following the table.

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### SUMMARY COMPENSATION TABLE

					Stock		Option	Pens	eferre	valu ed ed			
ame and Principal Position	<b>(B</b> )	Salary (\$) (C)	Bonus (\$) (D)	A	Awards (\$) (E)	A	Awards C (\$) (F)	Compensa <b>fi</b> e (\$) (G)	-		npensation (\$) (I)		Total (\$) (J)
Iark C. Trudeau resident and Chief Executive officer	2013 2012	\$ 723,942 \$ 420,000	\$ 100,000 \$ 225,000	\$4 \$	4,315,055 945,965	\$4 \$	4,931,881 623,096	\$ 885,564 \$ 507,252		\$ \$	84,347 109,730		11,040,789 2,831,044
fatthew K. Harbaugh enior Vice President and thief Financial Officer	2013 2012	\$ 380,554 \$ 334,723	\$ \$	\$ \$	581,814 428,537	\$ \$	820,031 364,707	\$ 402,021 \$ 205,543		\$ \$	33,283 34,295		2,217,703 1,367,804
an J. Watkins enior Vice President and hief Human Resources Officer	2013	\$ 383,269	\$ 50,000	\$	390,047	\$	454,413	\$331,021		\$	536,578	\$	2,145,328
eter G. Edwards enior Vice President and General Counsel	2013 2012	\$ 367,410 \$ 322,827	\$ \$	\$ \$	408,343 149,465	\$ \$	460,007 81,535	\$ 280,020 \$ 181,825		\$ \$	32,954 23,522	\$ \$	1,548,734 759,174
tephen Merrick enior Vice President and resident, Commercial perations (International)	2013	\$217,885	\$	\$	390,830	\$	429,695	\$ 90,000		\$	204,502	\$	1,332,912
tefano R. Carchedi ormer Senior Vice President nd President, Commercial perations (North America)	2013	\$ 357,692	\$ 75,000	\$	471,257	\$	523,872	\$266,000		\$	130,875	\$	1,824,696
avid E. Silver ormer Senior Vice President, ortfolio Management, trategy, and Business evelopment and Licensing	2012	\$ 296,881		\$	132,088 211,517	\$	115,335	\$ 149,998		\$	,124,851 21,985	\$	1,645,295 795,716

Bonus (Column B) The amounts reported in Column B represent, for Mr. Trudeau, a one-time special discretionary bonus to recognize his leadership and work related to our separation from Covidien, including the advancement of strategic initiatives during the year to position the Company for success as an independent public company and for Messrs. Watkins and Carchedi, a one-time bonus in connection with the commencement of their employment during fiscal 2013.

*Stock Awards (Column E) and Option Awards (Column F)* These columns represent the aggregate grant date fair value, computed in accordance with Accounting Standards Codification 718 (ASC 718), of restricted units and stock option awards issued to each of our named executive officers during the 2013 fiscal year as well as the incremental value for the grants of Covidien equity that converted to Mallinckrodt equity as of the date of the separation. The incremental value for the grants of Covidien equity that converted to Mallinckrodt equity is for Mr. Trudeau: \$632,590; Mr. Harbaugh: \$347,377; Mr. Watkins: \$73,845; Mr. Edwards: \$167,624; Mr. Carchedi: \$63,634 and Mr. Silver: \$12,400. Further information regarding the 2013 awards is included in the Fiscal 2013 Grants of Plan-Based Awards Table, the Outstanding Equity Awards at 2013 Fiscal Year-End Table and the *Compensation Discussion and Analysis* (CD&A), beginning on page 124.

Amounts in these columns do not correspond to the actual value that may be recognized by the named executive officers, which may be higher or lower based on a number of factors, including the Company s performance, stock price fluctuations and applicable vesting. For additional information relating to assumptions made in the valuation for current year awards reflected in these columns, see Note 14 to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended September 27, 2013.

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*Non-Equity Incentive Plan Compensation (Column G)* The amounts reported in Column G represent annual incentive cash awards paid to the named executive officers under our 2013 Annual Incentive Plan. For information regarding the calculation of these awards, see the CD&A, beginning on page 124.

*Change in Pension Value and Non-Qualified Deferred Compensation Earnings (Column H)* No named executive officer is eligible to participate in a Mallinckrodt or Covidien defined benefit pension plan because all such plans were frozen before each executive officer commenced employment with Covidien.

All Other Compensation (Column I) The amounts reported in Column I represent the aggregate dollar amount for each named executive officer for employer contributions to the Retirement Savings Plan (including contributions by Covidien to the Covidien Retirement Savings Plan pre-separation), employer credits to the Supplemental Savings Plan (including contributions by Covidien to the Covidien Supplemental Savings and Retirement Plan pre-separation), relocation benefits, and tax reimbursements attributable to relocation benefits. The following table shows the specific amounts included in Column I of the Summary Compensation Table for fiscal 2013.

### ALL OTHER COMPENSATION

(	Contributions Retiremen	s to to	Perquisites and al Other	Re				
Name and Principal Position (A)	Savings n Plan (B)	Savings Plan (C)	Personal Benefits (D)	Severance Benefits (E)	Relocation Benefits (F)	Relocation Benefits (G)		Total (H)
Mark C. Trudeau President and Chief Executive Officer	\$ 15,300	\$ 65,797	\$ 3,250				\$	84,347
Matthew K. Harbaugh Senior Vice President and Chief Financial Officer	\$ 14,949	\$ 18,334					\$	33,283
Ian J. Watkins Senior Vice President and Chief Human Resources Officer	\$ 17,302	\$ 1,638			\$ 513,747	\$ 3,891	\$	536,578
Peter G. Edwards Senior Vice President, General Counsel	\$ 16,034	\$ 16,921					\$	32,954
Stephen Merrick Senior Vice President and President, Commercial Operations (International)	\$ 12,325				\$ 167,268	\$ 24,909	\$	204,502
Stefano R. Carchedi Former Senior Vice President and President, Commercial Operations (North America)	\$ 17,896	\$ 1,835			\$ 67,495	\$ 43,649	\$	130,875
David E. Silver	\$ 11,126	\$ 11,954		\$ 1,101,772			\$ 1	1,124,851

Former Senior Vice President, Portfolio Management, Strategy, and Business Development and Licensing **Perquisites & Other Personal Benefits (Column D)** 

Mr. Trudeau. The amount in Column D includes an annual physical under the Company s executive physical program.

#### **Severance Benefits (Column E)**

*Mr. Silver*. The amount in Column E reflects severance cash payments received in fiscal year 2013 under the Mallinckrodt Pharmaceuticals Severance Plan for U.S. Officers and Executives. It also includes a \$1,000,000 termination bonus as part of a retention agreement between Mr. Silver and the Company.

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### **Grants of Plan-Based Awards**

The following table provides information concerning the annual incentive cash awards and equity incentive awards granted to each of our named executive officers in fiscal 2013, including equity awards granted by Covidien in fiscal 2013 pre-separation.

AIP is the annual incentive cash award payable pursuant to our 2013 Annual Incentive Plan.

RSUs are restricted unit awards subject to time-based vesting.

Options are nonqualified stock options subject to time-based vesting. The table does not show equity awards granted by Covidien prior to fiscal year 2013 which were converted into Mallinckrodt equity awards in connection with the separation. For a more complete understanding of the table, please read the related narrative.

### FISCAL 2013 GRANTS OF PLAN-BASED AWARDS

Name (A)	Grant Date (B)	Date of Committee Action	Un	ate Future der Non-Ec ntive Plan A Target (\$) (D)	quity	Shares of Stock or	f Awards:E Number of Securities Underlying	Base Price of	rGrant Date Fair Value of Stock and Option Awards (\$) (I)
<b>Mark C. Trudeau</b> AIP RSUs Options	12/3/2012 7/1/2013 12/3/2012 7/1/2013	11/14/2012 11/14/2012	\$ 133,875	\$ 765,000	\$ 1,530,000	17,138 81,819	77,750 234,437	\$41.73 \$44.00	\$ 715,019 \$ 3,600,036 \$ 1,048,189 \$ 3,603,297
<b>Matthew</b> K. Harbaugh AIP RSUs	12/3/2012	11/14/2012	\$ 68,750	\$ 275,000	\$ 550,000	3,517			\$ 146,746

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Options	7/1/2013 12/3/2012 7/1/2013	11/14/2012				8,750	15,958 25,072	\$ 41.73 \$ 44.00	\$ \$ \$	385,000 209,647 385,357
<b>Ian J. Watkins</b> AIP RSUs Options	12/3/2012 7/1/2013 12/3/2012 7/1/2013	11/14/2012 11/14/2012	\$ 60,000	\$ 240,000	\$ 480,000	3,596 5,455	16,303 15,630	\$41.73 \$44.00	\$ \$ \$	150,027 240,020 214,180 240,233
<b>Peter G.</b> <b>Edwards</b> AIP RSUs Options	12/3/2012 7/1/2013 12/3/2012 7/1/2013	11/14/2012 11/14/2012	\$ 52,500	\$210,000	\$ 420,000	2,729 5,455	12,384 15,630	\$ 41.73 \$ 44.00	\$ \$ \$ \$	113,873 240,020 162,692 240,233
<b>Stephen</b> <b>Merrick</b> AIP RSUs Options	3/1/2013 7/1/2013 3/1/2013 7/1/2013	2/28/2013 2/28/2013	\$ 34,688	\$ 138,750	\$ 277,500	2,057 6,728	9,328 19,276	\$ 46.08 \$ 44.00	\$ \$ \$	94,798 296,032 133,423 296,272
<b>Stefano R.</b> <b>Carchedi</b> AIP RSUs Options	1/2/2013 7/1/2013 1/2/2013 7/1/2013	12/20/2012 12/20/2012	\$ 59,766	\$ 239,063	\$ 478,125	3,100 7,728	14,061 22,142	\$ 42.33 \$ 44.00	\$ \$ \$	131,225 340,032 183,549 340,323
<b>David E.</b> Silver AIP RSUs Options	12/3/2012 12/3/2012	11/14/2012 11/14/2012	\$ 23,115	\$ 92,461	\$ 184,922	2,278	10,335	\$ 52.53	\$ \$	119,688 28,015

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*Non-Equity Incentive Plan Awards (Columns C through E)* The amounts reported in Columns C through E reflect threshold, target and maximum award amounts for fiscal 2013 that were set by Covidien in fiscal year 2013 under its Annual Incentive Plan, but were paid post-separation pursuant to our 2013 Annual Incentive Plan, which is an element of our 2013 Stock and Incentive Plan. The actual amounts earned by each named executive officer pursuant to such awards are set forth in Column G of the Summary Compensation Table.

*Stock Awards and Option Awards (Columns F and G)* On December 3, 2012 and January 2, 2013, Covidien granted stock options and restricted units to employees, including certain named executive officers which vest one-quarter annually beginning on the first anniversary of the grant date. All Covidien awards are presented on a post-conversion basis; that is, grants of Covidien equity that were converted into Mallinckrodt equity have been reported as Mallinckrodt equity in this table. Mr. Silver terminated his employment with Covidien s Pharmaceutical business pre-separation, and as such, Mr. Silver s awards were not converted into Mallinckrodt equity awards. The grants issued by us on July 1, 2013 include stock options and restricted units, which (except for Mr. Trudeau s restricted stock unit award which will vest in its entirety on July 1, 2018) will vest in two equal amounts on each of July 1, 2016 and 2017.

*Grant Date Fair Value of Stock and Option Awards (Column I)* This column represents the aggregate grant date fair value, computed in accordance with ASC 718 of restricted units and stock option awards issued to each of our named executive officers during the 2013 fiscal year as well as the incremental value for the 2013 fiscal year grants of Covidien equity that converted to Mallinckrodt equity as of the date of the separation. The incremental value for the 2013 fiscal year grants of Covidien equity that converted to Mallinckrodt equity is for Mr. Trudeau: \$352,195; Mr. Harbaugh: \$72,282; Mr. Watkins: \$73,845; Mr. Edwards: \$56,092; Mr. Merrick \$45,471 and Mr. Carchedi: \$63,634.

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#### **Outstanding Equity Awards at Fiscal Year-End**

The following table provides information regarding outstanding stock option awards and unvested restricted unit and performance unit awards held by each named executive officer as of September 27, 2013. All Covidien awards are presented on a post-conversion basis; that is, grants of Covidien equity that were converted into Mallinckrodt equity have been reported as Mallinckrodt equity in this table. For a more complete understanding of the table, please read the footnotes that follow the table. Unless otherwise specified, the market value of outstanding stock awards in the table is calculated by multiplying the number of unvested restricted or performance units by \$43.57, the closing price of our stock on September 27, 2013.

### **OUTSTANDING EQUITY AWARDS AT 2013 FISCAL YEAR-END**

Name	Underlying Unexercise Options (#)	Option Number of Securities Underlying Inexercised Options (#) mexercisable	Awards Option Exercise Price (\$)		res or Unit of Stock That	s o Un Tha	ן וו וויket Value	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$)
Name (A)	Exercisable (B)	(C)	(\$) (E)	Date (F)	(#) (G)		(\$) (H)	(\$) (I)	( <b>5</b> ) ( <b>J</b> )
Mark C. Trudeau	17,904	53,712 <sup>(1)</sup> 77,750 <sup>(3)</sup>	\$ 37.8500 \$ 41.7300	01/31/2022	$18,359^{(2)} \\ 17,284^{(4)}$	\$ \$	799,902 753,064		\$
		234,437 <sup>(5)</sup>	\$44.0000	06/30/2023	81,819 <sup>(6)</sup>		3,564,854		
Matthew K Harbaugh	7,474 10,539 1,726	$\begin{array}{c} 3,166^{(7)} \\ 7,477^{(9)} \\ 31,623^{(11)} \\ 5,186^{(13)} \\ 15,958^{(3)} \\ 25,072^{(5)} \end{array}$	\$ 34.5000 \$ 31.1200 \$ 33.6700 \$ 37.8500 \$ 41.7300 \$ 44.0000	11/30/2019 11/30/2020 11/30/2021 01/31/2022 12/02/2022 06/30/2023	$\begin{array}{c} 413^{(8)}\\ 897^{(10)}\\ 6,307^{(12)}\\ 1,160^{(14)}\\ 3,545^{(4)}\\ 8,750^{(6)}\end{array}$	\$	17,994 39,082 274,796 50,541 154,456 381,238	3,600 <sup>(21)</sup> 3,681 <sup>(22)</sup>	\$ 156,852 \$ 160,376
Ian J. Watkins		16,303(3)	\$41.7300	12/02/2022	3,626 <sup>(4)</sup>	\$	157,983		\$

			0 0						
		15,630 <sup>(5)</sup>	\$44.0000	06/30/2023	5,455(6)	\$	237,674		
Peter G. Edwards	1,996	1,998 <sup>(15)</sup> 7,007 <sup>(9)</sup>	\$29.8900 \$31.1200	05/31/2020	516 <sup>(16)</sup> 844 <sup>(10)</sup>	\$ \$	22,482	3,372 <sup>(21)</sup> 4,202 <sup>(22)</sup>	\$ 146,918 \$ 183.067
		8,326 <sup>(11)</sup> 12,384 <sup>(3)</sup> 15,630 <sup>(5)</sup>	\$ 33.6700 \$ 41.7300 \$ 44.0000	11/30/2020 11/30/2021 12/02/2022 06/30/2023	$936^{(12)}$ 2,751 <sup>(4)</sup> 5,455 <sup>(6)</sup>	\$ \$ \$	36,773 40,782 119,861 237,674	4,202(22)	\$ 183,067
Stephen Merrick		9,328 <sup>(17)</sup> 19,276 <sup>(5)</sup>	\$ 46.0800 \$ 44.0000	02/28/2023 06/30/2023	2,065 <sup>(18)</sup> 6,728 <sup>(6)</sup>	\$ \$	89,972 293,139		\$
Stefano R. Carchedi		14,061 <sup>(19)</sup> 22,142 <sup>(5)</sup>	\$42.3300 \$44.0000	01/01/2023 06/30/2023	3,112 <sup>(20)</sup> 7,728 <sup>(6)</sup>	\$ \$	135,590 336,709		\$
David E. Silver	2,690 2,936 3,118 2,583	<ul><li>(7)</li><li>(9)</li><li>(11)</li><li>(3)</li></ul>	\$43.4400 \$39.1800 \$42.3900 \$52.5300	06/28/2016 06/28/2016 06/28/2016 06/28/2016		\$		1,411 <sup>(22)</sup>	\$ 86,015

### Footnotes

Unless otherwise specified, stock option and restricted unit awards vest one-quarter annually, beginning on the first anniversary of the grant date.

- (1) Represents stock options granted on February 1, 2012 to Mr. Trudeau in connection with his commencement of employment with Covidien.
- (2) Represents restricted units granted on February 1, 2012 to Mr. Trudeau in connection with his commencement of employment as President of Covidien s Pharmaceuticals business; 6,296 of which vest fifty percent on each the <sup>n</sup>/<sub>2</sub> and 3<sup>rd</sup> anniversaries of the grant date and 12,063 of which vest one-third on each the 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> anniversaries of the grant date.
- (3) Represents stock options granted on December 3, 2012. For Mr. Silver, the stock options represent a right-to-buy Covidien shares as he terminated prior to the separation from Covidien and his outstanding awards were not converted to Mallinckrodt awards.
- (4) Represents restricted units granted on December 3, 2012.
- (5) Represents stock options granted on July 1, 2013 in connection with the separation from Covidien which vest fifty percent on each the 3<sup>rd</sup> and 4<sup>th</sup> anniversaries of the grant date.

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- (6) Represents restricted units granted on July 1, 2013 in connection with the separation from Covidien which vest fifty percent on each the 3<sup>rd</sup> and 4<sup>th</sup> anniversaries of the grant date; except for the grant to Mr. Trudeau which vests in full on the 5<sup>th</sup> anniversary of the grant date.
- (7) Represents stock options granted on December 1, 2009. For Mr. Silver, the stock options represent a right-to-buy Covidien shares as he terminated prior to the separation from Covidien and his outstanding awards were not converted to Mallinckrodt awards.
- (8) Represents restricted units granted on December 1, 2009.
- (9) Represents stock options granted on December 1, 2010. For Mr. Silver, the stock options represent a right-to-buy Covidien shares as he terminated prior to the separation from Covidien and his outstanding awards were not converted to Mallinckrodt awards.
- (10) Represents restricted units granted on December 1, 2010.
- (11)Represents stock options granted on December 1, 2011. For Mr. Silver, the stock options represent a right-to-buy Covidien shares as he terminated prior to the separation from Covidien and his outstanding awards were not converted to Mallinckrodt awards.
- (12) Represents restricted units granted on December 1, 2011.
- (13)Represents stock options granted on February 1, 2012 to Mr. Harbaugh as a supplemental award.
- (14) Represents restricted units granted on February 1, 2012 to Mr. Harbaugh as a supplemental award.
- (15)Represents stock options granted on June 1, 2010 to Mr. Edwards in connection with his commencement of employment with Covidien.
- (16)Represents restricted units granted on June 1, 2010 to Mr. Edwards in connection with his commencement of employment with Covidien.
- (17)Represents stock options granted on March 1, 2013 to Mr. Merrick in connection with his commencement of employment with Covidien.
- (18)Represents restricted units granted on March 1, 2013 to Mr. Merrick in connection with his commencement of employment with Covidien.
- (19)Represents stock options granted on January 2, 2013 to Mr. Carchedi in connection with his commencement of employment with Covidien.
- (20) Represents restricted units granted on January 2, 2013 to Mr. Carchedi in connection with his commencement of employment with Covidien.
- (21)Represents performance units granted on December 1, 2010 that vest at the end of the fiscal 2011 2013 performance cycle. In connection with the separation, the ending date for the performance period was accelerated to the date of the separation and the amounts reported in this column are based on achievement of maximum performance (200%) and are subject to time-based vesting for the balance of the performance cycle.
- (22) Represents performance units granted on December 1, 2011 that vest at the end of the fiscal 2012 2014 performance cycle. In connection with the separation, the ending date for the performance period was accelerated to the date of the separation and the amounts reported in this column are based on achievement through the separation date (168%) and are subject to time-based vesting for the balance of the performance cycle. For Mr. Silver, the number of shares were additionally prorated to reflect his separation on June 28, 2013 and the market value in the table is calculated by multiplying the number of unvested performance units by \$60.96, the closing price of Covidien s stock on September 27, 2013.

#### **Option Exercises and Stock Vested**

The following table provides information regarding the number of Covidien stock options that were exercised by named executive officers during fiscal 2013 before separation and the value realized from the exercise of such awards. The table also provides information regarding the vesting of Covidien restricted stock during fiscal 2013 before separation. The number of shares with respect to these Covidien stock options and Covidien restricted stock is presented on a pre-conversion basis; that is, exercises and vesting of Covidien options or restricted stock are reported as Covidien shares because these exercises and vesting events occurred pre-separation. Post-separation, no named

executive officer exercised any Company stock options or became vested in any Mallinckrodt restricted units and performance unit awards (including Covidien restricted units and performance unit awards that converted to Mallinckrodt restricted units and performance unit awards at separation) during fiscal 2013.

### FISCAL 2013 OPTION EXERCISES AND STOCK VESTED

	1	Awards	Stock Awards				
	Number of Shares Acquired on Exercise	Value Realized on Exercise	Number of Shares Acquired on Vesting	Value Realized on Vesting			
Name	(#)	(\$)	(#)		(\$)		
(A)	<b>(B</b> )	(C)	<b>(D</b> )		<b>(E)</b>		
Mark C. Trudeau		\$	5,176	\$	324,276		
Matthew K. Harbaugh	4,590	\$ 72,293	4,774	\$	283,535		
Ian J. Watkins		\$		\$			
Peter G. Edwards	4,550	\$ 61,605	903	\$	54,532		
Stephen Merrick		\$		\$			
Stefano R. Carchedi		\$		\$			
David E. Silver	10,161	\$ 143,534	6,812	\$	408,245		

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### **Pension Benefits**

No named executive officer is eligible to participate in a Mallinckrodt or Covidien defined benefit pension plan because all such plans were frozen before each executive officer commenced employment with Covidien.

#### **Non-Qualified Deferred Compensation**

The following table provides information with respect to fiscal 2013 non-qualified deferred compensation for each named executive officer. For more information regarding information contained in the table and the material terms of our non-qualified deferred compensation plan, please read the related narrative and footnotes that follow the table.

### FISCAL 2013 NON-QUALIFIED DEFERRED COMPENSATION

Name	Executive Contributions in Last FY (#)		Registrant Contributions in Last FY (\$)		Aggregate Earnings in Last FY (\$)		Aggregate Withdrawals / Distributions	Aggregate Balance at Last FYE (\$)	
(A)		<b>(B)</b>		(C)		<b>(D)</b>	<b>(E)</b>		<b>(F)</b>
Mark C. Trudeau	\$	29,750	\$	65,797	\$	21,404		\$	181,701
Matthew K. Harbaugh			\$	18,334	\$	16,366		\$	88,106
Ian J. Watkins			\$	1,638	\$	15		\$	1,654
Peter G. Edwards			\$	16,921	\$	2,692		\$	33,913
Stephen Merrick									
Stefano R. Carchedi			\$	1,835	\$	18		\$	1,853
David E. Silver			\$	11,954	\$	25,647		\$	130,248

*Executive Contributions in Last Fiscal Year (Column B)* The amounts reported in Column B include amounts deferred by the named executive officers during the 2013 fiscal year under the Covidien plc Supplemental Savings and Retirement Plan ( Covidien Supplemental Savings Plan ) pre-separation and under our Supplemental Savings Plan post-separation. Each executive officer participated in the Covidien Supplemental Savings Plan pre-separation and participates in our Supplemental Savings Plan post-separation. We refer to both the Covidien Supplemental Savings Plan and our Supplemental Savings Plan in the narrative to this table as the Supplemental Savings Plan. Of the amounts reported in this column, the following amounts reflect deferrals from fiscal 2013 base salary that also are reported in Column C (Salary) of the Summary Compensation Table for 2013: Mr. Trudeau, \$29,750.

**Registrant Contributions in Last Fiscal Year (Column C)** The amounts reported in Column C include amounts that Covidien credited to the Covidien Supplemental Savings Plan on behalf of the named executive officers during the 2013 fiscal year pre-separation and that we credited to our Supplemental Savings Plan on behalf of the named executive officers post-separation. These amounts are included in the amounts set forth in Column I of the Summary Compensation Table for fiscal 2013 and are specifically broken out in the footnote to Column D of the All Other Compensation Table.

Aggregate Earnings in Last Fiscal Year (Column D) The amounts reported in Column D include earnings credited to the named executive officer s account in the Supplemental Savings Plan. Earnings on amounts credited to the Supplemental Savings Plan are determined by investment selections made by each named executive officer in investment alternatives that generally mirror investment choices offered under the Retirement Savings Plan (our 401(k) plan).

Aggregate Balance at Last Fiscal Year End (Column F) Upon separation, amounts credited to each executive officer s account in the Covidien Supplemental Savings Plan were transferred to and credited under our Supplemental Savings Plan. As a result, the amount reported in Column F for each executive officer includes the executive officer s total balance in our Supplemental Savings Plan as of September 27, 2013.

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*Supplemental Savings Plan.* Under the Supplemental Savings Plan, participants, including named executive officers, may defer up to 50% of their base salary and 100% of their annual bonus. We provide matching credits based on the participant s deferred base salary and bonus at the same rate such participant is eligible to receive matching contributions under the Retirement Savings Plan and Company credits on any cash compensation (i.e., base and bonus) that the participant earns during a calendar year in excess of applicable IRS limits (\$255,000 for 2013). Participants are fully vested in matching and Company credits (including earnings on such credits) upon completion of two years of service. The Supplemental Savings Plan is a non-qualified deferred compensation plan that is maintained as an unfunded top-hat plan and is designed to comply with Internal Revenue Code Section 409A. Amounts credited to the Supplemental Savings Plan as participant deferrals or Company credits may also be credited with earnings (or losses) based upon investment selections made by each participant from investments that generally mirror investments offered under the Retirement Savings Plan. Participants may elect whether they will receive a distribution of their Supplemental Savings Plan account balances upon termination of employment or at a specified date. Distributions can be made in a lump sum or in up to 15 annual installments.

Under the Retirement Savings Plan, the Company makes an automatic contribution of three percent (3%) of an employee s eligible pay, irrespective of whether the employee contributes to such plan. Additionally, we match fifty cents (\$0.50) for every one dollar (\$1.00) employees contribute, up to the first six percent (6%) of eligible pay.

### **Potential Payments upon Termination**

*Severance Plan.* For all of the named executive officers, severance benefits are payable pursuant to the Mallinckrodt Severance Plan for U.S. Officers and Executives. Under the Severance Plan, benefits are payable to eligible executives, including named executive officers, upon an involuntary termination of employment for any reason other than cause, permanent disability or death. Post-termination benefits consist of:

continuation of base salary for a period of 18 months (24 months for the Chief Executive Officer);

payment of 1.5 times the average of the executive s bonus for the previous three fiscal years, paid over a period of 18 months (two times the average of the previous three fiscal year bonuses, paid over a period of 24 months for the Chief Executive Officer);

continuation of health and dental benefits at active employee rates for a period of up to 18 months (24 months for the Chief Executive Officer);

12 months accelerated vesting of unvested stock options;

12 months to exercise vested stock options (unless a longer period is provided in the applicable award agreement);

outplacement services, in our discretion, for up to 12 months; and

payment of a pro-rata portion of the executive s annual incentive cash award for the fiscal year during which such executive s employment terminates.

Upon a termination of employment other than for cause, including an involuntary termination of employment where the executive becomes eligible for severance benefits, executives, including named executive officers, forfeit all unvested restricted unit and performance unit awards and any stock options which do not vest within 12 months after the executive s employment termination date.

*Change in Control Plan.* For all named executive officers, change in control severance benefits are payable pursuant to the Mallinckrodt Change in Control Severance Plan for Certain U.S. Officers and Executives. Under the Change in Control Plan, benefits are payable to eligible executives, including named executive officers, only if the plan s double trigger requirements are satisfied, meaning that, in order to receive any of the following benefits, the executive must experience an involuntary termination of employment or good reason resignation during a period that begins 60 days before and ends 2 years after a change in control. Post-termination benefits consist of:

a single lump sum payment equal to 18 months of the executive s base salary (24 months for the Chief Executive Officer);

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a single lump sum payment equal to 1.5 times the average of the executive s bonus for the previous three fiscal years (2 times the average of the previous three fiscal year bonuses for the Chief Executive Officer);

continuation of health and dental benefits at active employee rates for a period of up to 18 months (24 months for the Chief Executive Officer);

full vesting of unvested stock options;

12 months to exercise vested stock options (unless a longer period is provided in the applicable option agreement);

full vesting of unvested restricted unit awards which are subject solely to time-based vesting;

full vesting of unvested performance unit awards if, and to the extent that, the Compensation Committee determines that the applicable performance criteria have been or will be attained or would have been attained during the 18-month period after the executive s employment terminates (24-month period for the Chief Executive Officer);

outplacement services, in our discretion, for up to 12 months; and

payment of a pro-rata portion of the executive s annual incentive cash award for the fiscal year during which such executive s employment terminates.

The payment of benefits under our Severance Plan and our Change in Control Plan is conditioned upon the executive executing a general release in favor of the Company and is subject to the terms of the Non-Competition, Non-Solicitation, and Confidentiality Agreement by and between the executive and the Company, under which the executive agreed not to disclose confidential Company information at any time and not to compete with the Company nor solicit our employees or customers, for a period of one year following termination of employment. We may cancel benefits that are payable or seek to recover benefits previously paid if the executive does not comply with these provisions or violates the release of claims. Payments may be delayed until six months after termination of employment if necessary to comply with Internal Revenue Code Section 409A.

Upon a termination of employment for cause, executives, including named executive officers, are not eligible for severance benefits under our Severance Plan or our Change in Control Plan and forfeit all unvested stock options, restricted unit and performance unit awards. In addition, the stock option, restricted unit and performance unit awards include a claw-back feature pursuant to which we may recover the amount of any profit the named executive officer realized upon the exercise of options, or the vesting of any restricted unit or performance unit award, during the 12-month period that occurs immediately prior to the executive officer s involuntary termination of employment for cause. For purposes of our Severance Plan and our Change in Control Plan, as well as the claw-back feature discussed in the preceding sentence, cause means substantial failure or refusal of the named executive officer to perform the duties and responsibilities of his job as required by the Company, violation of any fiduciary duty owed to the Company, conviction of a felony or misdemeanor, dishonesty, theft, violation of Company rules or policy, including a

violation of our Guide to Business Conduct, or other egregious conduct that has or could have a serious and detrimental impact on the Company and its employees.

*Other Termination Benefits.* The terms of our annual incentive plan and equity plan provide for certain benefits upon a named executive officer s termination of employment due to death, disability or retirement. For this purpose, normal retirement occurs where an executive officer terminates employment after attaining age 60 and the sum of the executive s age and years of service equals at least 70. Under the annual incentive plan, named executive officers are eligible to receive a pro-rated annual incentive cash award based on the number of days that the executive officer was employed by the Company during the fiscal year upon death, disability or normal retirement. Under the equity plan, named executive officers are eligible to receive full vesting of stock options, restricted units and performance units upon death, disability or normal retirement.

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*Retention Agreements.* The following describes the benefits that Covidien agreed to provide to certain named executive officer as part of its retention program, and which we have assumed as part of the separation.

*Mr. Harbaugh*. The retention agreements entered into with Mr. Harbaugh provides that Mr. Harbaugh is eligible to receive a spin bonus or termination bonus. The spin bonus, which is payable on the six-month anniversary of the completion of the separation if Mr. Harbaugh remains continuously employed by us through such anniversary date, equals \$139,755. The termination bonus, which is payable if, before the six-month anniversary of the completion of the separation, we involuntarily terminate Mr. Harbaugh s employment, or he resigns from employment for good reason, or if he dies or becomes permanently disabled, equals \$750,000.

*Mr. Edwards*. The retention agreement entered into with Mr. Edwards provides that Mr. Edwards is eligible to receive a spin bonus or termination bonus. The spin bonus, which is payable on the six-month anniversary of the completion of the separation if Mr. Edwards remains continuously employed by us through such anniversary date, equals \$157,951. The termination bonus, which is payable if, before the six-month anniversary of the completion of the separation, we involuntarily terminate Mr. Edwards employment, Mr. Edwards resigns from employment for good reason, or Mr. Edwards dies or becomes permanently disabled, equals \$500,000.

All of the retention agreements discussed above require the forfeiture of retention benefits in the event that Mallinckrodt terminates the named executive officer s employment for cause. The retention agreements also subject the payment of retention benefits to the named executive officer complying with the Mallinckrodt Guide to Business Conduct (or successor guide to business conduct), preserving confidentiality on the terms and conditions of any transaction or the status of any negotiations relating to any transaction, and cooperating with efforts surrounding a sale or spin-off transaction.

For purposes of the Severance Plan, the Change in Control Plan and the retention agreements, cause means substantial failure or refusal of the named executive officer to perform the duties and responsibilities of his job as required by Mallinckrodt, violation of any fiduciary duty owed to Mallinckrodt, conviction of a felony or misdemeanor, dishonesty, theft, violation of Mallinckrodt rules or policy, including a violation of the Mallinckrodt Guide to Business Conduct, or other egregious conduct that has or could have a serious and detrimental impact on Mallinckrodt and its employees.

For purposes of the Change in Control Plan and the retention agreements, good reason means any retirement or termination of employment by the named executive officer that is not initiated by Mallinckrodt and that is caused by any one or more of the following events, in each case, without the named executive officer s written consent: (i) assignment to the named executive officer of any duties inconsistent in any material respect with the named executive officer s authority, duties or responsibilities as in effect immediately prior to the change in control or effective date of the retention agreement, as applicable; (ii) a material diminution in the authority, duties or responsibilities of the supervisor to whom the named executive officer is required to report as in effect immediately prior to the change in control or effective date of the retention agreement, as applicable; (iii) a material change in the geographic location at which the named executive officer must perform services to a location which is more than 50 miles from the named executive officer s principal place of business immediately preceding the change in control or effective date of the retention agreement, as applicable; (iv) a material reduction in the named executive officer s compensation and benefits, taken as a whole, as in effect immediately prior to the change in control or effective date of the retention agreement, as applicable; (v) solely with respect to the Change in Control Plan, Mallinckrodt s failure to obtain a satisfactory agreement from any successor to assume and agree to perform Mallinckrodt s obligations to the named executive officer under such plan; or (vi) a material diminution in the budget over which the named executive officer retains authority. Additionally, good reason will only exist if the named executive officer provides written notice stating the good reason event, Mallinckrodt does not cure such event, and the named executive officer

terminates employment within a certain period of time after the end of the cure period.

The table below reflects the amount of compensation that would become payable to each of our named executive officers, other than Messrs. Carchedi and Silver, under existing plans if the named executive officer s

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employment had terminated on September 27, 2013, the last day of our 2013 fiscal year, given the named executive s service levels as of such date and, if applicable, based on our closing stock price as of that date, which was \$43.57. These benefits are in addition to benefits available prior to the occurrence of any termination of employment, including under then-exercisable stock options, and benefits available generally to salaried employees, such as distributions under the Retirement Savings Plan.

The actual amounts that would be paid upon a named executive officer s termination of employment or in connection with a change in control can be determined only at the time of any such event. Due to a number of factors that may affect the amount of any benefits provided upon the events discussed below, actual amounts paid or distributed may be higher or lower than indicated in the table. Factors that could affect these amounts include the timing during the year of any such event, our stock price, the executive s age and years of service, the attained level of performance for performance units, and any additional agreements or arrangements we may enter into in connection with any change in control or termination of employment. We have not included Messrs. Carchedi and Silver in these tables, as benefits payable to each of them are described below under Separation Agreements. For a more complete understanding of the table, please read the narrative disclosures that follow the table.

## POTENTIAL PAYMENTS UPON TERMINATION

Name and Termination Scenario (A)	Cash Severance (B)	Bonus <sup>(1)</sup> (C)	Option Awards (D)		Welfare Benefits and Outplacemen (F)	
Mark C. Trudeau						
Involuntary Termination (other than						
for cause)	\$3,321,756	\$765,000	\$138,175	\$	\$ 54,390	\$4,360,418 <sup>(2)</sup>
Death or Disability		\$765,000	\$450,293	\$5,117,819		\$6,414,209 <sup>(2)</sup>
Change in Control Termination	\$3,321,756	\$765,000	\$450,293	\$ 5,117,819	\$ 54,390	\$9,790,355 <sup>(2)</sup>
Matthew K. Harbaugh						
Involuntary Termination (other than						
for cause)	\$ 1,691,943	\$275,000	\$ 196,834	\$	\$ 47,023	\$ 2,210,800
Death or Disability	\$ 750,000	\$275,000	\$ 493,899	\$1,265,883		\$2,784,781
Change in Control Termination	\$1,691,943	\$275,000	\$ 493,899	\$1,265,883	\$ 47,023	\$3,773,748
Ian J. Watkins						
Involuntary Termination (other than						
for cause)	\$ 960,000	\$240,000	\$ 7,498	\$	\$ 47,023	\$1,273,461 <sup>(2)</sup>
Death or Disability		\$240,000	\$ 29,998	\$ 395,659		\$ 684,597 <sup>(2)</sup>
Change in Control Termination	\$ 960,000	\$240,000	\$ 29,998	\$ 395,659	\$ 47,023	\$1,691,620 <sup>(2)</sup>
Peter G. Edwards						
Involuntary Termination (other than						
for cause)	\$1,332,322	\$210,000	\$ 98,408	\$	\$ 47,023	\$ 1,687,753
Death or Disability	\$ 500,000	\$210,000	\$ 196,997	\$ 822,427		\$1,729,425
Change in Control Termination	\$1,332,322	\$210,000	\$ 196,997	\$ 822,427	\$ 47,023	\$2,608,770
Stephen Merrick						
Involuntary Termination (other than						
for cause)	\$ 867,188	\$138,750	\$ 4,291	\$	\$ 47,023	\$1,069,577 <sup>(2)</sup>
Death or Disability		\$138,750	\$ 17,164	\$ 383,111		\$ 551,350 <sup>(2)</sup>

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Change in Control Termination	\$	868,151	\$138,750	\$	17,164	\$	383,111	\$ 47,023	\$ 1,465,560 <sup>(2)</sup>		

- (1) The amount reflected assumes bonus payout at 1x of target.
- (2) Also includes employer contributions to the Retirement Savings Plan and Company credits to the Supplemental Savings Plan that will become fully vested upon an involuntary termination of employment (other than for cause), death or disability or a change in control termination for Mr. Trudeau (\$15,300 and \$65,797), Mr. Watkins (\$17,302 and \$1,638) and Mr. Merrick (\$12,325 and \$0). All other named executive officers are fully vested in employer contributions and Company credits.

## Cash Severance (Column B)

*Involuntary Termination (other than for cause).* For all named executive officers other than Mr. Trudeau, the cash severance amount in this scenario represents continuation of the named executive officer s base salary, as of September 27, 2013, for an 18-month severance period, plus an amount equal to 1.5 times the average of the named executive officer s annual incentive cash awards for the previous three fiscal years (i.e., fiscal 2012, 2011 and 2010), payable during the 18-month severance period and on our normal payroll schedule. For Mr. Trudeau, the amount represents continuation of his base salary, as of September 27, 2013, for a 24-month severance period, plus an amount equal to two times the average of his annual incentive cash awards for the

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previous three fiscal years, payable during the 24-month severance period and on our normal payroll schedule. For Messrs. Harbaugh and Edwards, the cash severance amount includes the termination bonus under their respective retention agreements.

*Change in Control Termination.* For all named executive officers, we assume that such executive officers experience an involuntary termination of employment (other than for cause) after the change in control which renders them eligible for benefits under the Mallinckrodt Change in Control Plan. Accordingly, the cash severance amount for all named executive officers other than Mr. Trudeau represents a lump-sum payment equal to 1.5 times the named executive officer s base salary, as of September 27, 2013, plus an amount equal to 1.5 times the average of the named executive officer s annual incentive cash awards for the previous three fiscal years (i.e., fiscal 2012, 2011, and 2010). For Mr. Trudeau, the amount represents a lump-sum payment equal to two times his base salary, as of September 27, 2013, plus an amount equal to two times his base salary, as of September 27, 2013, plus an amount equal to two times his base salary, as of September 27, 2013, plus an amount equal to two times the average of his annual incentive cash awards for the previous three fiscal years (i.e., fiscal 2012, 2011, and 2010).

Applicable to both the cash severance termination scenarios, in situations where the named executive officer did not have a full three year history of annual incentive cash awards due to not having commenced employment prior to fiscal 2010, the average calculated represents a prorated average calculated as the sum of the annual incentive cash awards divided by the length of service provided during the prior three fiscal years.

## Bonus (Column C)

*Involuntary Termination (other than for cause).* In the case of an involuntary termination (other than for cause), executive officers are entitled to a pro-rata payment of the annual incentive cash award based on the number of days they were employed by the Company during the fiscal year. Because we have assumed that the applicable terminations of employment occurred on the last day of our 2013 fiscal year, the amounts reported in Column C for this scenario represent the full annual incentive cash award payable to each named executive officer for fiscal 2013.

*Death or Disability and Change in Control Termination.* The bonus amount represents the pro-rata payment of the annual incentive cash award based on the number of days that the named executive officer was employed by the Company during the fiscal year. Because we have assumed that the applicable termination of employment occurred on the last day of our 2013 fiscal year, the amounts reported in Column C for this scenario represent the full annual incentive cash award payable to each named executive officer for fiscal 2013.

## **Option Awards (Column D)**

*Involuntary Termination (other than for cause).* For all named executive officers, the option award amount represents the value as of September 27, 2013 of outstanding options held by the named executive officer that would have vested during the 12-month period that immediately follows September 27, 2013 (i.e., from September 28, 2013 to September 26, 2014).

*Death or Disability and Change in Control Termination.* The option award amount represents the full vesting of unvested stock options held by the named executive officer as of September 27, 2013.

## Stock Awards (Column E)

*Involuntary Termination (other than for cause).* For all named executive officers other than Mr. Trudeau, the amounts reported in Column E for this scenario represent the value of the performance unit award issued in December 2010 which vested on December 1, 2013 and which the executive officer would have been entitled to receive upon an

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involuntary termination of employment on the last day of the fiscal year. For purposes of this scenario, the amount reported for the December 2010 performance unit award is based on the actual number of shares that vested after the conclusion of the FY11-FY13 performance cycle.

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*Death or Disability and Change in Control Termination.* The amounts reported in Column E for this scenario represent the value that would have been attained upon the full vesting of all unvested restricted unit and performance unit awards held by the named executive officer as of September 27, 2013. For purposes of this scenario, amounts attributable to performance unit awards are based on the following: (1) for the December 2010 award, the ending date for the performance period was accelerated to the date of separation and the amounts reported in this column are based on the achievement of 200%; and (2) for the December 2011 awards, the ending date for the performance shares was accelerated to the date of the separation and the amounts reported in this column are based on the achievement of the separation and the amounts reported in this column are based on the separation date of 168%.

## Welfare Benefits and Outplacement Services (Column F)

The welfare benefits amount represents the employer portion of the premium paid on behalf of the named executive officer for continued coverage under the Company s medical, dental and vision plans during the applicable severance period. Amounts for calendar year 2013 and 2014 are based on actual rates determined by the Company for the respective plan in such years, while the rates for subsequent years, where applicable, are assumed based on the historic percentage increase in rates for such coverage. Although payable in our discretion, for purposes of this column we assume that we would pay \$25,000 on behalf of each named executive officer for outplacement services upon an involuntary termination (other than for cause) and a change in control termination.

## **Separation Agreements**

Under Mr. Carchedi s Separation Agreement, Mr. Carchedi s employment with Mallinckrodt ceased as of October 10, 2013. Following termination, Mr. Carchedi became entitled to receive cash payments totaling \$1,044,306. These payments represent 18 months of Mr. Carchedi s base salary (\$637,500), his annual bonus multiplied by 1.5 (\$406,806). All unvested stock options which would have vested during the 12-month period following his termination also vested immediately as of September 28, 2013, with the stock options remaining exercisable for a limited period of time following termination. Any unvested portion of Mr. Carchedi s account in the Supplemental Savings and Retirement Plan also vested fully on September 28, 2013. Outplacement services will be provided for up to 12 months and the Company will reimburse Mr. Carchedi for certain housing and moving expenses. In consideration for these benefits, Mr. Carchedi executed a general release in favor of the Company and also agreed to confidentiality and non-disparagement provisions.

Under Mr. Silver s Separation Agreement, Mr. Silver s employment with Mallinckrodt ceased as of June 28, 2013. Following termination, Mr. Silver became entitled to receive cash payments totaling \$1,440,840. These payments represent 12 months of Mr. Silver s base salary (\$308,024), his annual bonus multiplied by 1.5 (\$132,806) and payment of a termination bonus due as part of his retention agreement (\$1,000,000). All unvested stock options which would have vested during the 12-month period following his termination also vested immediately as of June 28, 2013, with the stock options remaining exercisable for a limited period of time following termination. Any unvested portion of Mr. Silver s account in the Supplemental Savings and Retirement Plan also vested fully on June 28, 2013. Outplacement services will be provided for up to 12 months. In consideration for these benefits, Mr. Silver executed a general release in favor of the Company and also agreed to confidentiality and non-disparagement provisions.

### DESCRIPTION OF CERTAIN INDEBTEDNESS

At December 27, 2013, total debt was \$919.4 million compared with total debt at December 28, 2012 of \$9.9 million, both of which were directly incurred with third parties as Covidien s debt had not been allocated to us in historical periods.

### **Revolving Credit Facility**

Prior to the offering of the outstanding notes, MIFSA entered into a 5-year revolving credit facility with a borrowing capacity of up to \$250 million. Mallinckrodt guaranteed the credit facility upon the completion of the distribution. Indebtedness under the credit facility is treated as a general unsecured obligation of MIFSA and Mallinckrodt, and will rank pari passu in right of payment with the notes. Borrowings under the credit facility will bear interest at LIBOR plus 2.375% per annum (subject to adjustment based upon a ratings-based pricing grid). The credit facility provides for customary fees, including facility fees and other fees.

The credit facility contains customary affirmative and negative covenants, that among other things, will limit or restrict the ability of non-guarantor subsidiaries to incur indebtedness, our ability to incur liens, our ability to consolidate, merge or sell all or substantially all of our assets or the assets of the Specialty Pharmaceuticals segment or the Global Medical Imaging segment, our ability to pay dividends or make other distributions on or repurchase or redeem our capital stock, our ability to enter into transactions with affiliates, our ability to engage in sale and leaseback transactions, and our ability to enter into agreements restricting the ability of MIFSA s subsidiaries to pay dividends. The credit facility also contains financial maintenance covenants, including a leverage ratio covenant and interest coverage ratio covenant.

### **Other Ludlow Corporation Indebtedness**

Our subsidiary, Ludlow Corporation, is the obligor in respect of (i) approximately \$10.4 million of 9.5% notes due 2022 issued pursuant to an indenture between Ludlow Corporation and U.S. Bank National Association, as trustee, and (ii) approximately \$8.0 million of 8.0% notes due 2023 issued pursuant to an indenture between Lulow Corporation and U.S. Bank National Association, as trustee. The indenture governing such indebtedness includes customary covenants, that, among other things, limit or restrict the ability of Ludlow Corporation and its subsidiaries to incur liens, enter into sale and leaseback transactions and consolidate, merge or sell all or substantially all of their assets. See Capitalization.

### Our Pending Acquisition of Cadence Pharmaceuticals, Inc.

We expect to incur significant additional indebtedness in connection with our pending acquisition of Cadence. See Risk Factors Risks Related to Our Pending Acquisition of Cadence Pharmaceuticals, Inc.

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## **DESCRIPTION OF NOTES**

## General

The terms of the exchange notes and the outstanding notes are identical in all material respects, except:

the exchange notes will have been registered under the Securities Act;

the exchange notes will not contain transfer restrictions and registration rights that relate to the outstanding notes; and

the exchange notes will not contain provisions relating to the payment of additional interest to the holders of the outstanding notes under the circumstances related to the timing of the exchange offer. Any outstanding notes that remain outstanding after the exchange offer, together with the exchange notes issued in the exchange offer, will be treated as a single class of securities for voting purposes under the indenture.

In this Description of Notes, (i) the term MIFSA refers to Mallinckrodt International Finance S.A., (ii) the term CIFSA refers to Covidien International Finance S.A., (iii) the term Mallinckrodt plc refers to Mallinckrodt plc, (iv) the term Covidien plc refers to Covidien plc, (v) the term separation refers to the separation of the Pharmaceuticals business from Covidien plc s other businesses, the transfer of the assets and liabilities associated with such Pharmaceuticals business to Mallinckrodt plc and the creation, as a result of the distribution, of an independent, publicly-traded company, Mallinckrodt plc, which holds the assets and liabilities formerly associated with Covidien s Pharmaceuticals business after the distribution, (vi) the term distribution refers to Mallinckrodt plc s issuance of its ordinary shares to holders of record of Covidien plc s ordinary shares on the record date for the distribution on a pro rata basis, which occurred on June 28, 2013, and (vii) references to the 2018 notes refer to the outstanding 2018 notes and registered 2023 notes, in each case, unless the context requires otherwise.

On April 11, 2013 (the Issue Date ), MIFSA issued \$300,000,000 aggregate principal amount of the outstanding 3.500% senior notes due 2018 (the outstanding 2018 notes ) and \$600,000,000 million aggregate principal amount of the outstanding 4.750% senior notes due 2023 (the outstanding 2023 notes and, together with the 2018 notes, the outstanding notes ) under an indenture dated as of the Issue Date, among MIFSA, CIFSA, as guarantor, and Deutsche Bank Trust Company Americas, as trustee (the trustee ). The terms of the notes include those expressly set forth in the indenture and those made part of the indenture by reference to the Trust Indenture Act of 1939, as amended (the Trust Indenture Act ).

The following is a summary of the material provisions of the indenture. Because this is a summary, it may not contain all of the information that is important to you. You should read the indenture in its entirety because it, and not this description, defines MIFSA s and the Guarantor s obligations and your rights as holders of the notes. Copies of the indenture are available as described under Available Information.

References herein to the notes include the 2018 notes and the 2023 notes. However, the 2018 notes and the 2023 notes are two separate series of notes under the indenture for purposes of, among other things, payments of principal and interest and consenting to certain amendments to the indenture and the notes.

The 2018 notes bear interest at an annual rate of 3.500% per year. The 2023 notes bear interest at an annual rate of 4.750% per year. Each series of outstanding notes bears interest from the Issue Date. The first interest payment date on the outstanding notes was October 15, 2013. Interest is payable on each series of notes semi-annually on April 15 and October 15 to holders of record at the close of business on April 1 and October 1 (whether or not that date is a business day), as the case may be, immediately preceding such interest payment date, and on the maturity date. Interest on the notes will be computed on the basis of a 360-day year composed of twelve 30-day months. The 2018 notes mature on April 15, 2018, and the 2023 notes mature on April 15, 2023. The notes are not subject to any sinking fund or mandatory redemption.

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If any interest payment date would otherwise be a day that is not a business day, the related payment of interest will be postponed to the next date that is a business day and no interest will accrue on the amounts so payable for the period from and after that interest payment date to the next date that is a business day. If the maturity date of the notes falls on a day that is not a business day, the related payment of principal and interest will be made on the next business day as if it were made on the date such payment was due, and no interest will accrue on the amounts so payable for the period from and after such date to the next business day. The term business day means any day other than a Saturday, a Sunday or a day on which federal or state banking institutions or trust companies in New York City, or in the city where the office or agency for payment on the notes is maintained, are authorized or required by law, regulation or executive order to close.

Each series of registered notes will be issued only in registered form in denominations of \$2,000 and integral multiples of \$1,000 in excess thereof. Each series of registered notes will be represented by one or more global notes registered in the name of DTC.

We may redeem some or all of the notes at any time and from time to time at the redemption price described under

Optional Redemption. Additionally, we may, subject to applicable law, at any time purchase notes in the open market or otherwise.

## Guarantee

The outstanding notes initially were guaranteed (the CIFSA Guarantee ) on an unsecured basis by CIFSA. Pursuant to the indenture, the CIFSA Guarantee was automatically and unconditionally released and discharged on June 28, 2013, which was the date that the conditions for the release of the CIFSA Guarantee were satisfied (the Completion Date ). Upon the satisfaction of the conditions for the release of the CIFSA Guarantee, the outstanding notes were guaranteed on an unsecured and unsubordinated basis by Mallinckrodt plc (the Mallinckrodt Guarantee ). Under the Mallinckrodt Guarantee, Mallinckrodt plc fully and unconditionally guarantees to each holder of notes and the trustee, on an unsecured basis, the full and prompt payment of principal of, premium, if any, and interest on the notes, when and as the same become due and payable, whether at stated maturity, upon redemption, by declaration of acceleration or otherwise, including all fees and expenses due and owing to the trustee. The term Guarantor refers to CIFSA as guarantor of the outstanding notes prior to the Completion Date and to Mallinckrodt plc as guarantor of the notes on the Completion Date and thereafter, and the term Guarantee refers to the CIFSA Guarantee or Mallinckrodt Guarantee, as the case may be.

The Mallinckrodt Guarantee will terminate and Mallinckrodt plc will be deemed released from all of its obligations under the indenture upon covenant defeasance as provided below under Defeasance of Covenants Under Certain Circumstances or satisfaction and discharge of the indenture as provided below under Satisfaction and Discharge. Any release described in this paragraph may be evidenced by a supplemental indenture or other instrument, which may be entered into without the consent of any holders of notes.

## Ranking

The notes are unsecured and unsubordinated obligations of MIFSA and rank equally in right of payment with all of MIFSA s other existing and future unsecured and unsubordinated obligations, including any indebtedness under the credit facility entered into in connection with the separation. The notes are effectively junior to all of MIFSA s existing and future secured indebtedness to the extent of the assets securing such indebtedness.

MIFSA derives substantially all of its operating income from, and holds substantially all of its assets through, its subsidiaries. MIFSA depends on distributions of cash flow and earnings from its subsidiaries in order to meet its

payment obligations under the notes and its other obligations, including its obligations under the credit facility. MIFSA s subsidiaries are separate and distinct legal entities and have no obligation to pay any amounts due on MIFSA s debt securities, including the notes, or to provide MIFSA with funds for the payment of its

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obligations, whether by dividends, distributions, loans or otherwise. As a result, the notes are structurally subordinated to the liabilities of MIFSA s subsidiaries, including liabilities to trade creditors and preferred stockholders, if any. In addition, provisions of applicable law, such as those limiting the legal sources of dividends, could limit the ability of MIFSA s subsidiaries to make payments or other distributions to MIFSA and MIFSA s subsidiaries could agree to contractual restrictions on their ability to make distributions. As of December 27, 2013, MIFSA had approximately \$906.5 million of liabilities, excluding intercompany liabilities. In addition, in connection with the separation, MIFSA entered into a credit facility with a borrowing capacity of up to \$250 million, which is currently undrawn. See Risk Factors The notes will be structurally subordinated to all obligations of the Issuer s existing and future subsidiaries.

The Mallinckrodt Guarantee is the unsecured and unsubordinated obligation of Mallinckrodt plc and ranks equally in right of payment with all of Mallinckrodt plc s other existing and future unsecured and unsubordinated obligations, including Mallinckrodt plc s guarantee of the credit facility entered into in connection with the separation. The notes are effectively junior to all of Mallinckrodt plc s existing and future secured indebtedness to the extent of the assets securing such indebtedness. The notes are not guaranteed by any of Mallinckrodt plc s subsidiaries and are therefore effectively subordinated to all existing and future indebtedness and other obligations, including obligations to trade creditors and preferred stockholders, if any, of Mallinckrodt plc s subsidiaries (other than MIFSA). Mallinckrodt plc derives its income from continuing operations and cash flow primarily through distributions from its subsidiaries. Claims of creditors and preferred stockholders of such subsidiaries generally have priority with respect to the assets and earnings of such subsidiaries over the claims of creditors of Mallinckrodt plc or MIFSA, as the case may be, including holders of the notes. Accordingly, the notes are effectively subordinated to creditors, including trade creditors and preferred stockholders, if any, of Mallinckrodt plc s subsidiaries (other than MIFSA).

## **Negative Covenants**

The indenture contains the following negative covenants:

## Limitation on Liens

The indenture provides that, so long as any of the notes of either series remain outstanding (but subject to defeasance, as provided in the indenture), MIFSA, and Mallinckrodt plc on and after the Completion Date, will not, and will not permit any Restricted Subsidiary (as defined below) to, issue, assume or guarantee any Indebtedness that is secured by a mortgage, pledge, security interest, lien or encumbrance (each a lien ) upon any property that at the time of such issuance, assumption or guarantee constitutes a Principal Property, or any shares of stock of or Indebtedness issued by any Restricted Subsidiary, whether now owned or hereafter acquired, without effectively providing that, for so long as such lien shall continue in existence with respect to such secured Indebtedness, each series of notes (together with, if MIFSA, and Mallinckrodt plc on and after the Completion Date, determine, any other Indebtedness of MIFSA (or Mallinckrodt plc on and after the Completion Date) ranking equally with the notes, it being understood that for purposes hereof, Indebtedness which is secured by a lien and Indebtedness which is not so secured shall not, solely by reason of such lien, be deemed to be of different ranking) shall be equally and ratably secured by a lien ranking ratably with or equal to (or at MIFSA s or Mallinckrodt plc s option, as applicable, prior to) such secured Indebtedness. The foregoing covenant shall not apply to:

liens existing on the Issue Date;

liens on the stock, assets or Indebtedness of a person existing at the time such person becomes a Restricted Subsidiary unless created in contemplation of such person becoming a Restricted Subsidiary;

liens on any assets or Indebtedness of a person existing at the time such person is merged with or into or consolidated with or acquired by MIFSA, Mallinckrodt plc or a Restricted Subsidiary or at the time of a purchase, lease or other acquisition of the assets of a corporation or firm as an entirety or substantially as an entirety by MIFSA, Mallinckrodt plc or any Restricted Subsidiary;

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liens on any stock, assets or Indebtedness existing at the time of acquisition thereof by MIFSA, Mallinckrodt plc or any Restricted Subsidiary of such stock, assets or Indebtedness (which may include property previously leased by MIFSA, Mallinckrodt plc or any Restricted Subsidiary and leasehold interests on such property; *provided* that the lease terminates prior to or upon the acquisition), or liens on stock, assets or Indebtedness to secure the payment of all or any part of the purchase price of such stock, assets or Indebtedness to secure any Indebtedness incurred, assumed or guaranteed prior to, at the time of, or within 18 months after, the latest of the acquisition of such stock, assets or Indebtedness or, in the case of property, the completion of such property for the purpose of financing all or any part of the purchase price of the purchase price of substantial commercial operation or the making of the improvements;

liens securing Indebtedness owing by any Restricted Subsidiary to MIFSA or a Guarantor or by MIFSA to a Guarantor;

liens securing the notes;

liens in favor of the United States or any state thereof, or any department, agency or instrumentality or political subdivision of the United States or any state thereof, or in favor of any other country or any political subdivision thereof, to secure partial, progress, advance or other payments pursuant to any contract, statute, rule or regulation or to secure any Indebtedness incurred or guaranteed for the purpose of financing all or any part of the purchase price (or, in the case of real property, the cost of construction or improvement) of the Principal Property subject to such liens (including liens incurred in connection with pollution control, industrial revenue or similar financings);

pledges, liens or deposits under workers compensation or similar legislation, and liens thereunder that are not currently dischargeable, or in connection with bids, tenders, contracts (other than for the payment of money) or leases to which MIFSA, Mallinckrodt plc or any Restricted Subsidiary is a party, or to secure the public or statutory obligations of MIFSA, Mallinckrodt plc or any Restricted Subsidiary, or in connection with obtaining or maintaining self-insurance, or to obtain the benefits of any law, regulation or arrangement pertaining to unemployment insurance, old-age pensions, social security or similar matters, or to secure surety, performance, appeal or customs bonds to which MIFSA, Mallinckrodt plc or any Restricted Subsidiary is a party, or in litigation or other proceedings in connection with the matters heretofore referred to in this bullet point, such as interpleader proceedings, and other similar pledges, liens or deposits made or incurred in the ordinary course of business;

liens created by or resulting from any litigation or other proceeding that is being contested in good faith by appropriate proceedings, including liens arising out of judgments or awards against MIFSA, Mallinckrodt plc or any Restricted Subsidiary with respect to which MIFSA, Mallinckrodt plc or such Restricted Subsidiary in good faith is prosecuting an appeal or proceedings for review or for which the time to make an appeal has not yet expired; or final unappealable judgment liens which are satisfied within 15 days of the date of judgment; or liens incurred by MIFSA, Mallinckrodt plc or any Restricted Subsidiary for the purpose of obtaining a stay or discharge in the course of any litigation or other proceeding to which MIFSA,

Mallinckrodt plc or such Restricted Subsidiary is a party;

liens for taxes or assessments or governmental charges or levies not yet due or delinquent or that can thereafter be paid without penalty, or that are being contested in good faith by appropriate proceedings; landlords liens on property held under lease; and any other liens or charges incidental to the conduct of the business of MIFSA, Mallinckrodt plc or any Restricted Subsidiary, or the ownership of their respective assets, that were not incurred in connection with the borrowing of money or the obtaining of advances or credit and that, in the opinion of the board of directors of MIFSA or Mallinckrodt plc, as the case may be, do not materially impair the use of such assets in the operation of the business of MIFSA, Mallinckrodt plc or such Restricted Subsidiary or the value of such Principal Property for the purposes of such business;

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liens to secure MIFSA s, Mallinckrodt plc s or any Restricted Subsidiary s obligations under agreements with respect to spot, forward, future and option transactions, entered into in the ordinary course of business;

liens not permitted by the foregoing bullet points, if at the time of, and after giving effect to, the creation or assumption of any such lien, the aggregate amount of all outstanding Indebtedness of MIFSA, Mallinckrodt plc and the Restricted Subsidiaries (without duplication) secured by liens not so permitted by the foregoing bullet points, together with the Attributable Debt in respect of Sale and Lease-Back Transactions permitted by the second bullet point under Limitation on Sale and Lease-Back Transactions below, does not exceed the greater of \$125 million and 10% of Consolidated Net Worth; and

any extension, renewal or replacement (or successive extensions, renewals or replacements), in whole or in part, of any lien referred to in the foregoing bullet points if the principal amount of Indebtedness secured thereby unless otherwise excepted under the above bullet points does not exceed the principal amount of Indebtedness so secured at the time of such extension, renewal or replacement and that such extension, renewal or replacement is limited to all or a part of the assets (or any replacement assets therefor) that secured the lien so extended, renewed or replaced (plus improvements and construction on real property).
Although this covenant limits MIFSA s and any Restricted Subsidiary s (and Mallinckrodt plc s on and after the Completion Date) ability to incur Indebtedness that is secured by liens on Principal Properties or on the shares of stock of or Indebtedness issued by any Restricted Subsidiary, it would not prevent our subsidiaries that are not Restricted Subsidiaries from incurring Indebtedness secured by liens on shares of stock of or Indebtedness issued by

### Limitation on Sale and Lease-Back Transactions

Restricted Subsidiaries.

The indenture provides that so long as any of the notes of either series remain outstanding (but subject to defeasance, as provided in the indenture), MIFSA, and Mallinckrodt plc on and after the Completion Date, will not, and will not permit any Restricted Subsidiary to, enter into any Sale and Lease-Back Transaction unless:

such transaction was entered into prior to the Issue Date;

MIFSA, Mallinckrodt plc or such Restricted Subsidiary, at the time of entering into a Sale and Lease-Back Transaction, would be entitled to incur Indebtedness secured by a lien on the Principal Property to be leased in an amount at least equal to the Attributable Debt in respect of such Sale and Lease-Back Transaction, without equally and ratably securing the notes pursuant to the covenant described under Limitation on Liens ; or

the direct or indirect proceeds of the sale of the Principal Property to be leased are at least equal to the fair value of such Principal Property (as determined by MIFSA s board of directors) and an amount equal to the net proceeds from the sale of the property or assets so leased is applied, within 180 days of the effective date of any such Sale and Lease-Back Transaction, to the purchase or acquisition (or, in the case of real property, commencement of the construction) of property or assets or to the retirement (other than at maturity or pursuant to a mandatory sinking fund or mandatory redemption provision) of notes, or of Funded

Indebtedness of MIFSA or a consolidated subsidiary ranking on a parity with or senior to the notes; *provided* that there shall be credited to the amount of net proceeds required to be applied pursuant to this bullet point an amount equal to the sum of (i) the principal amount of notes delivered within 180 days of the effective date of such Sale and Lease-Back Transaction to the trustee for retirement and cancellation and (ii) the principal amount of other Funded Indebtedness voluntarily retired by MIFSA within such 180-day period, excluding retirements of notes and other Funded Indebtedness as a result of conversions or pursuant to mandatory sinking fund or mandatory prepayment provisions.

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For purposes of this Description of Notes, the following terms have the following meanings:

Attributable Debt, in connection with a Sale and Lease-Back Transaction, as of any particular time, means the aggregate of present values (discounted at a rate that, at the inception of the lease, represents the effective interest rate that the lessee would have incurred to borrow over a similar term the funds necessary to purchase the leased assets) of the obligations of MIFSA, Mallinckrodt plc or any Restricted Subsidiary for net rental payments during the remaining term of the applicable lease, including any period for which such lease has been extended or, at the option of the lessor, may be extended. The term net rental payments under any lease of any period shall mean the sum of the rental and other payments required to be paid in such period by the lessee thereunder, not including any amounts required to be paid by such lessee, whether or not designated as rental payments or additional rental payments, on account of maintenance and repairs, reconstruction, insurance, taxes, assessments, water rates or similar charges required to be paid by such lessee thereunder or any amounts required to be paid by such lessee thereunder contingent upon the amount of sales, maintenance and repairs, reconstruction, insurance, taxes, assessments, water rates or similar charges.

Consolidated Net Worth at any date means total assets less total liabilities, in each case appearing on the most recently prepared consolidated balance sheet of (i) prior to the Completion Date, CIFSA and its subsidiaries as of the end of a fiscal quarter of CIFSA and (ii) on or after the Completion Date, Mallinckrodt plc and its subsidiaries as of the end of a fiscal quarter of Mallinckrodt plc, in each case, prepared in accordance with GAAP as in effect on the date of the consolidated balance sheet.

Consolidated Tangible Assets at any date means total assets less all intangible assets appearing on the most recently prepared consolidated balance sheet of (i) prior to the Completion Date, CIFSA and its subsidiaries as of the end of a fiscal quarter of CIFSA and (ii) on or after the Completion Date, Mallinckrodt plc and its subsidiaries as of the end of a fiscal quarter of Mallinckrodt plc, in each case, prepared in accordance with GAAP as in effect on the date of the consolidated balance sheet. Intangible assets means the amount (if any) stated under the heading Goodwill and Other Intangible Assets, Net or under any other heading of intangible assets separately listed, in each case on the face of such consolidated balance sheet.

Funded Indebtedness means any Indebtedness maturing by its terms more than one year from the date of the determination thereof, including any Indebtedness renewable or extendible at the option of the obligor to a date later than one year from the date of the determination thereof.

GAAP means generally accepted accounting principles set forth in the FASB Accounting Standards Codification or in such other statements by such other entity as may be approved by a significant segment of the accounting profession of the United States, as in effect from time to time. At any time after the initial date of issuance of the notes, MIFSA may elect (by providing written notice to the trustee) to apply International Financial Reporting Standards (IFRS) in lieu of GAAP and, upon any such election, references herein to GAAP shall thereafter be construed to mean IFRS (except as otherwise provided herein); *provided* that any such election, once made, shall be irrevocable.

Indebtedness means, without duplication, the principal amount (such amount being the face amount or, with respect to original issue discount bonds or zero coupon notes, bonds or debentures or similar securities, determined based on the accreted amount as of the date of the most recently prepared consolidated balance sheet of (i) prior to the Completion Date, CIFSA and its subsidiaries as of the end of a fiscal quarter of CIFSA and (ii) on or after the Completion Date, Mallinckrodt plc and its subsidiaries as of the end of a fiscal quarter of Mallinckrodt plc, in each case, prepared in accordance with GAAP as in effect on the date of such consolidated balance sheet) of (i) all obligations for borrowed money, (ii) all obligations evidenced by debentures, notes or other similar instruments, (iii) all obligations in respect of letters of credit or bankers acceptances or similar instruments or reimbursement obligations with respect thereto (such instruments to constitute Indebtedness only to the extent that they are drawn and unreimbursed), (iv) all

obligations to pay the deferred purchase price of property or services, except (A) trade and similar accounts payable and accrued expenses, (B) employee compensation, deferred compensation and pension obligations,

and other obligations arising from employee benefit programs and agreements or other similar employment arrangements, (C) obligations in respect of customer advances received and (D) obligations in connection with earnout and holdback agreements, in each case in the ordinary course of business, (v) all obligations as lessee to the extent capitalized in accordance with GAAP, and (vi) all Indebtedness of others consolidated in such balance sheet that is guaranteed by MIFSA or any of its subsidiaries or for which MIFSA or any of its subsidiaries is legally responsible or liable (whether by agreement to purchase indebtedness of, or to supply funds or to invest in, others).

Principal Property means (i) prior to the Completion Date, any U.S. manufacturing, processing or assembly plant or any U.S. warehouse or distribution facility of CIFSA or any of its subsidiaries and (A) is owned by CIFSA or any subsidiary of CIFSA on the Issue Date, (B) the initial construction of which has been completed after the Issue Date or (C) is acquired after the Issue Date, in each case other than any such plants, facilities, warehouses or portions thereof, that in the opinion of the board of directors of CIFSA, are not collectively of material importance to the total business conducted by CIFSA and its subsidiaries as an entirety, or that has a net book value (excluding any capitalized interest expense) on the Issue Date in the case of clause (A) of this definition, on the date of completion of the initial construction in the case of clause (B) of this definition or on the date of acquisition in the case of clause (C) of this definition, of less than 2.0% of Consolidated Tangible Assets on the consolidated balance sheet of CIFSA and its subsidiaries as of the applicable date and (ii) on or after the Completion Date, any U.S. manufacturing, processing or assembly plant or any U.S. warehouse or distribution facility of Mallinckrodt plc or any of its subsidiaries and (A) is owned by Mallinckrodt plc or any subsidiary of Mallinckrodt plc on the Issue Date and after giving effect to the separation, (B) the initial construction of which has been completed after the Issue Date or (C) is acquired after the Issue Date, in each case other than any such plants, facilities, warehouses or portions thereof, that in the opinion of the board of directors of MIFSA, are not collectively of material importance to the total business conducted by Mallinckrodt plc and its subsidiaries as an entirety, or that has a net book value (excluding any capitalized interest expense) on the Issue Date in the case of clause (A) of this definition, on the date of completion of the initial construction in the case of clause (B) of this definition or on the date of acquisition in the case of clause (C) of this definition, of less than 2.0% of Consolidated Tangible Assets on the consolidated balance sheet of Mallinckrodt plc and its subsidiaries as of the applicable date.

Restricted Subsidiary means any subsidiary of MIFSA, or Mallinckrodt plc on or after the Completion Date, that owns or leases a Principal Property.

Sale and Lease-Back Transaction means an arrangement with any person providing for the leasing by MIFSA, Mallinckrodt plc on or after the Completion Date, or a Restricted Subsidiary of any Principal Property whereby such Principal Property has been or is to be sold or transferred by MIFSA, Mallinckrodt plc or a Restricted Subsidiary to such person other than Mallinckrodt plc, MIFSA or any of their respective subsidiaries; *provided*, *however*, that the foregoing shall not apply to any such arrangement involving a lease for a term, including renewal rights, for not more than three years.

## Limitations on Consolidations, Mergers and Sales of Assets

The indenture provides that none of the Guarantors or MIFSA will merge or consolidate with any other person and will not sell or convey all or substantially all of its assets to any person, unless:

either the applicable Guarantor or MIFSA, as the case may be, shall be the continuing entity, or the successor entity or the person which acquires by sale or conveyance of all or substantially all the assets of such Guarantor or MIFSA, as the case may be (if other than a Guarantor or MIFSA, as the case may be),

(A) shall expressly assume the due and punctual payment of the principal of, premium, if any, and interest on each series of notes or the obligations under the applicable Guarantee, as the case may be, according to their tenor, and the due and punctual performance and observance of all of the covenants and agreements of the indenture to be performed or observed by such Guarantor or MIFSA, as the case may be, by supplemental indenture satisfactory to the trustee, executed and delivered to the trustee by

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such person, and (B) shall be organized and existing under the laws of the United States of America or any State thereof or the District of Columbia, any member state of the European Union or Switzerland as in effect on the Issue Date;

no Event of Default and no event that, after notice or lapse of time or both, would become an Event of Default shall be continuing immediately after such merger or consolidation, or such sale or conveyance; and

the applicable Guarantor, or MIFSA, as the case may be, shall have delivered to the trustee an officer s certificate and an opinion of counsel stating that the proposed transaction and related supplemental indenture, if any, comply with the indenture.

Upon any consolidation or merger, or any sale, lease, conveyance or other disposition of all or substantially all of the assets of a Guarantor or MIFSA, as the case may be, effected in accordance with these provisions, the successor person formed by such consolidation or into or with which such Guarantor or MIFSA, as the case may be, is merged or to which such sale, lease, conveyance or other disposition is made shall succeed to, and be substituted for, and may exercise every right and power of, such Guarantor or MIFSA, as the case may be, under the indenture with the same effect as if such successor person had been named as such Guarantor or MIFSA, as the case may be, herein. In the event of any such sale or conveyance (other than a conveyance by way of lease), such Guarantor or MIFSA, as the case may be, or any successor entity which shall theretofore have become such in the manner described herein, shall be discharged from all obligations and covenants under the indenture, the notes and the guarantees and may be liquidated and dissolved.

### **Events of Default**

The indenture provides that the term Event of Default means with respect to a series of notes any one or more of the following events that has occurred and is continuing:

default in the payment of interest on a note of such series as and when the same shall become due and payable, and continuance of such default for a period of 30 days; or

default in the payment of all or any part of the principal of or premium, if any, on a note of such series as and when the same shall become due and payable either at maturity, upon redemption, upon acceleration or otherwise; or

default in the performance, or breach, of any covenant or agreement of MIFSA or a Guarantor in respect of the notes of such series or the applicable Guarantee (other than (x) the failure to comply with any covenant or agreement contained in Section 314(a)(1) of the Trust Indenture Act, (y) the failure to file with the trustee the information that may be required to be filed with the Commission or (z) a default or breach that is specifically dealt with elsewhere), and continuance of such default or breach for a period of 90 days after the date on which there has been given, by registered or certified mail, to MIFSA and such Guarantor by the trustee or to MIFSA, such Guarantor and the trustee by the holders of at least 25% in principal amount of the outstanding notes of such series affected thereby, a written notice specifying such default or breach and requiring it to be remedied and stating that such notice is a Notice of Default under the indenture; or

a Guarantee of the notes of such series shall for any reason cease to be, or shall for any reason be asserted in writing by MIFSA or the applicable Guarantor not to be, in full force and effect and enforceable in accordance with its terms except to the extent contemplated by the indenture and such Guarantee; or

a court having jurisdiction in the premises shall enter a decree or order for relief in respect of MIFSA or a Guarantor in an involuntary case under any applicable bankruptcy, insolvency or other similar law now or hereafter in effect, or appointing a receiver, liquidator, assignee, custodian, trustee or sequestrator (or similar official) of MIFSA or such Guarantor or for any substantial part of its property or ordering the winding up or liquidation of its affairs, and such decree or order shall remain unstayed and in effect for a period of 90 consecutive days; or

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MIFSA or a Guarantor shall commence a voluntary case under any applicable bankruptcy, insolvency or other similar law now or hereafter in effect, or consent to the entry of an order for relief in an involuntary case under any such law, or consent to the appointment of or taking possession by a receiver, liquidator, assignee, custodian, trustee or sequestrator (or similar official) of MIFSA or such Guarantor or for any substantial part of its property, or make any general assignment for the benefit of creditors, except, in each case, where such action is taken or such person is appointed in the context of a solvent scheme of arrangement or similar or analogous proceedings or process in any jurisdiction; or

an event of default shall occur and be continuing with respect to MIFSA s or a Guarantor s indebtedness for borrowed money (other than Non-Recourse Indebtedness) under any indenture or other instrument evidencing or under which MIFSA or such Guarantor shall have a principal amount outstanding (such amount with respect to original issue discount bonds or zero coupon notes, bonds or debentures or similar securities based on the accreted amount determined in accordance with GAAP and as of the date of the most recently prepared consolidated balance sheet of MIFSA or such Guarantor, as the case may be) in excess of \$100,000,000, and such event of default shall involve the failure to pay the principal of such indebtedness on the final maturity date thereof after the expiration of any applicable grace period with respect thereto, or such indebtedness shall have been accelerated so that the same shall have become due and payable prior to the date on which the same would otherwise have become due and payable, and such acceleration shall not be rescinded or annulled within 30 days after notice thereof shall have been given to MIFSA and such Guarantor by the trustee, or to MIFSA, such Guarantor and the trustee by the holders of at least 25% in aggregate principal amount of a series of notes; provided that, if such event of default under such indenture or instrument shall be remedied or cured by MIFSA or such Guarantor or waived by the requisite holders of such indebtedness, then the Event of Default under the indenture by reason thereof shall be deemed likewise to have been thereupon remedied, cured or waived without further action upon the part of either the trustee or any of the holders of the notes.

For purposes of this Events of Default section, the following terms have the following meanings:

Indebtedness has the definition given to it under Negative Covenants Limitation on Sale and Lease-Back Transactions above.

Non-Recourse Indebtedness means Indebtedness upon the enforcement of which recourse may be had by the holder(s) thereof only to identified assets of MIFSA or a Guarantor or any subsidiary of MIFSA or a Guarantor and not to MIFSA or a Guarantor or any subsidiary of MIFSA or a Guarantor or any subsidiary of MIFSA or a Guarantor personally (subject to, for the avoidance of doubt, customary exceptions contained in non-recourse financings to the non-recourse nature of the obligations thereunder).

In the case of any Event of Default with respect to a series of notes, unless the principal of all the notes of such series shall have already become due and payable, either the trustee or the holders of at least 25% in aggregate principal amount of the outstanding notes of such series, by notice in writing to MIFSA and the Guarantor, and to the trustee if notice is given by such holders, may declare the unpaid principal of all such notes of such series to be due and payable immediately.

The holders of a majority in principal amount of the outstanding notes of a series may waive any Events of Default in the performance of any of the covenants contained in the indenture with respect to such series, except an Event of Default regarding payment of principal, premium, if any, or interest. Any such waiver shall cure such Event of Default.

Subject to the terms of the indenture, if an Event of Default with respect to a series of notes under the indenture shall occur and be continuing, the trustee is under no obligation to exercise any of its rights or powers under the indenture at the request or direction of any of the holders of the notes of such series if the trustee determines in good faith that the proceeding could result in personal liability. The holders of a majority in

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principal amount of the outstanding notes of such series will have the right to direct in writing the time, method and place of conducting any proceeding for any remedy available to the trustee or exercising any trust or power conferred on the trustee, with respect to the notes of such series, *provided* that such direction is not in conflict with any law or the indenture.

A holder of the notes only has the right to institute a proceeding under the indenture or to appoint a receiver or trustee, or to seek other remedies if:

the holder has given written notice to the trustee of a continuing Event of Default with respect to such holder s series of notes;

the holders of at least 25% in aggregate principal amount of the notes of such series have made a written request, and such holders have offered indemnity and security satisfactory, to the trustee to institute such proceeding as trustee; and

the trustee does not institute such action, suit or proceeding, and does not receive from the holders of a majority in aggregate principal amount of the outstanding notes of such series other conflicting directions within 60 days after such notice, request and offer.

The right of any holder to receive payment of principal, premium, if any, or interest or to institute a suit for such payment shall not be impaired without the consent of such holder.

#### **Issuance of Additional Notes**

MIFSA may issue additional notes of each series in any amount having the same terms as the notes of such series in all respects, except for the issue date, the issue price, the initial interest payment date and rights under the registration rights agreement. The notes of each series issued hereby and any such additional notes of such series subsequently issued, together with any exchange notes of such series, will be treated as a single class of such series for all purposes of the indenture, including for purposes of voting and redemptions; *provided* that if such additional notes are not fungible with the notes of such series issued hereby for U.S. federal income tax purposes such additional notes shall have a separate CUSIP number.

### **Optional Redemption**

Each series of notes is redeemable, in whole or in part (in integral multiples of \$1,000, with any portion of a holder s notes not redeemed to be in a minimum denomination of \$2,000 and integral multiples in excess thereof), solely at MIFSA s option, at any time and from time to time in accordance with the conditions described below, on not less than 30 nor more than 60 days prior written notice mailed to the holders of the notes to be redeemed and upon 45 days prior written notice to the trustee (or such shorter period as agreed by the trustee) at a redemption price equal to the greater of:

100% of the principal amount of the notes to be redeemed; and

an amount as determined by the Quotation Agent and delivered to the trustee in writing, equal to the sum of the present values of the remaining scheduled payments of principal and interest thereon due on any date after the redemption date (excluding the portion of interest that will be accrued and unpaid to and including the redemption date) discounted from their scheduled date of payment to the redemption date (assuming a 360-day year consisting of twelve 30-day months) at the Adjusted Redemption Treasury Rate *plus* (i) 45 basis points in the case of the 2018 notes and (ii) 50 basis points in the case of the 2023 notes,

plus, in each case, accrued and unpaid interest, if any, to, but excluding, the redemption date.

For purposes of this Optional Redemption section:

Adjusted Redemption Treasury Rate with respect to any redemption date means the rate equal to the semiannual equivalent yield to maturity or interpolated (on a 30/360 day count basis) yield to maturity of the

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Comparable Redemption Treasury Issue, assuming a price for the Comparable Redemption Treasury Issue (expressed as a percentage of its principal amount) equal to the Comparable Redemption Treasury Price for such redemption date.

Comparable Redemption Treasury Issue means the United States Treasury security selected by the Quotation Agent as having a maturity comparable to the remaining term of the notes to be redeemed that will be utilized at the time of selection and in accordance with customary financial practice in pricing new issues of corporate debt securities of comparable maturity to the remaining term of such notes.

Comparable Redemption Treasury Price with respect to any redemption date means:

the average of the Redemption Reference Treasury Dealer Quotations for such redemption date, after excluding the highest and lowest such Redemption Reference Treasury Dealer Quotations (unless there is more than one highest or lowest quotation, in which case only one such highest and/or lowest quotation shall be excluded); or

if the Quotation Agent obtains fewer than four such Redemption Reference Treasury Dealer Quotations, the average of all such Redemption Reference Treasury Dealer Quotations. Quotation Agent means a Redemption Reference Treasury Dealer appointed as such agent by MIFSA.

Redemption Reference Treasury Dealer means (a) each of J.P. Morgan Securities LLC, Goldman, Sachs & Co., Citigroup Global Markets Inc. and Deutsche Bank Securities Inc. or their respective affiliates which are primary U.S. government securities dealers, and their respective successors; *provided*, *however*, that if any of the foregoing shall cease to be a primary U.S. government securities dealer (a Primary Treasury Dealer ), MIFSA will substitute therefor another Primary Treasury Dealer selected by MIFSA and (b) any other Primary Treasury Dealer selected by MIFSA.

Redemption Reference Treasury Dealer Quotations with respect to each Redemption Reference Treasury Dealer and any redemption date means the average, as determined by the Quotation Agent, of the bid and offer prices at 11:00 a.m., New York City time, for the Comparable Redemption Treasury Issue (expressed in each case as a percentage of its principal amount) for settlement on the redemption date quoted in writing to the Quotation Agent by such Redemption Reference Treasury Dealer on the third business day preceding such redemption date.

### **Repurchase Upon Change of Control Triggering Event**

If a Change of Control Triggering Event (as defined below) occurs with respect to a series of notes, unless MIFSA has exercised its right to redeem such notes as described under Optional Redemption or Redemption Upon Changes in Withholding Taxes, each holder of such notes has the right to require that MIFSA repurchase all or a portion of such holder s notes (in integral multiples of \$1,000, with any portion of such holder s notes not repurchased to be in a minimum denomination of \$2,000 and integral multiples in excess thereof) pursuant to the offer described below (the

Change of Control Offer ), at a repurchase price equal to 101% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the repurchase date.

Within 30 days following the date upon which the Change of Control Triggering Event occurred, or at MIFSA s option, prior to any Change of Control, but after the first public announcement of such pending Change of Control, MIFSA is required to send, by first class mail, a notice to each holder of the applicable series of notes, with a copy to

the trustee, which notice shall govern the terms of the Change of Control Offer. Such notice shall state, among other things, the repurchase date, which must be no earlier than 30 days nor later than 60 days from the date such notice is mailed, other than as may be required by law (the Change of Control Payment Date ). The notice, if mailed prior to the date of consummation of the Change of Control, shall state that the

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Change of Control Offer is conditioned on the Change of Control Triggering Event occurring on or prior to the Change of Control Payment Date. Holders of notes electing to have notes repurchased pursuant to a Change of Control Offer will be required to surrender their notes, with the form entitled Option of Holder to Elect Repurchase on the reverse of the note, or such other customary documents of surrender and transfer as MIFSA may reasonably request, duly completed, or transfer their notes by book-entry transfer, to the paying agent at the address specified in the notice prior to the close of business on the third business day prior to the Change of Control Payment Date.

MIFSA is not be required to make a Change of Control Offer if a third party makes such an offer in the manner, at the times and otherwise in compliance with the requirements for such an offer made by MIFSA and such third party purchases all notes properly tendered and not withdrawn under its offer.

MIFSA will comply with the requirements of Rule 14e-1 under the Exchange Act and any other securities laws and regulations thereunder to the extent such laws and regulations are applicable in connection with the repurchase of notes pursuant to a Change of Control Offer. To the extent that any securities laws or regulations conflict with the Change of Control provisions of the indenture, MIFSA will comply with the applicable securities laws and regulations and shall be deemed not to have breached its obligations under the Change of Control provisions of the indenture by virtue thereof.

The Change of Control Triggering Event purchase feature of the notes may in certain circumstances make more difficult or discourage a sale or takeover of Mallinckrodt plc and, thus, the removal of incumbent management. The Change of Control Triggering Event purchase feature is a result of negotiations between MIFSA and the initial purchasers. Mallinckrodt plc could, in the future, enter into certain transactions, including acquisitions, refinancings or other recapitalizations, that would not constitute a Change of Control under the indenture, but that could increase the amount of indebtedness outstanding at such time or otherwise affect its capital structure or credit ratings. The indenture does not contain any restrictions on MIFSA s or any Guarantor s ability to incur additional indebtedness, other than the restrictions on the incurrence of indebtedness secured by liens contained in the covenants described under Negative Covenants Limitation on Liens and Negative Covenants Limitation on Sale and Lease-back Transactions. Such restrictions can only be waived with the consent of the holders of a majority in principal amount of the notes of a series then outstanding. Except for the limitations contained in such covenants, however, the indenture does not contain covenants or provisions that may afford holders of the notes protections in the event of a highly leveraged transaction.

MIFSA s and the applicable Guarantor s ability to pay cash to holders of notes following the occurrence of a Change of Control Triggering Event may be limited by MIFSA s and the applicable Guarantor s then existing financial resources. There can be no assurance that sufficient funds will be available when necessary to make any required repurchases.

The definition of Change of Control includes a phrase relating to the direct or indirect sale, lease, transfer, conveyance or other disposition of all or substantially all of Mallinckrodt plc s properties or assets and those of its subsidiaries taken as a whole. Although there is a limited body of case law interpreting the phrase substantially all, there is no precise established definition of the phrase under applicable law. Accordingly, the ability of a holder of notes to require MIFSA to repurchase its notes as a result of a sale, lease, transfer, conveyance or other disposition of less than all of Mallinckrodt plc s assets and those of its subsidiaries, taken as a whole, to another person or group may be uncertain. In such case, holders of the notes may not be able to resolve this uncertainty without resorting to legal action. The provisions under the indenture relative to MIFSA s obligation to make an offer to repurchase the notes of any series as a result of a Change of Control Triggering Event may be waived or modified with the written consent of the holders of at least a majority in aggregate principal amount of the notes of such series at the time outstanding.

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For purposes of this Change of Control Triggering Event section, the following terms have the following meanings:

Change of Control means the occurrence of any of the following after the Completion Date:

the direct or indirect sale, transfer, conveyance or other disposition (other than by way of merger or consolidation), in one or a series of related transactions, of all or substantially all of the assets of Mallinckrodt plc and its subsidiaries taken as a whole to any person or group of persons (as that term is used in Section 13(d)(3) of the Exchange Act) other than to Mallinckrodt plc or one of its subsidiaries;

the consummation of any transaction (including, without limitation, any merger or consolidation) the result of which is that any person (as that term is used in Section 13(d)(3) of the Exchange Act) becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 under the Exchange Act), directly or indirectly, of more than 50% of the outstanding Voting Stock (measured by voting power rather than number of shares) of Mallinckrodt plc;

at any time after the Completion Date, the first day on which the majority of the members of the board of directors of Mallinckrodt plc cease to be Continuing Directors;

Mallinckrodt plc consolidates with, or merges with or into, any person, or any person consolidates with, or merges with or into, Mallinckrodt plc, in any such event pursuant to a transaction in which any of the outstanding Voting Stock of Mallinckrodt plc or such other person is converted into or exchanged for cash, securities or other property, other than any such transaction where the shares of the Voting Stock of Mallinckrodt plc or such transaction constitute, or are converted into or exchanged for, a majority of the Voting Stock of the surviving person immediately after giving effect to such transaction; or

the adoption of a plan relating to the liquidation or dissolution of Mallinckrodt plc. Notwithstanding the foregoing, a transaction effected to create a holding company for Mallinckrodt plc will not be deemed to involve a Change of Control if: (1) pursuant to such transaction, Mallinckrodt plc becomes a 100% owned subsidiary of such holding company and (2) the holders of the Voting Stock of such holding company immediately following that transaction are substantially the same as the holders of Voting Stock of Mallinckrodt plc immediately prior to that transaction.

Change of Control Triggering Event means the occurrence of both a Change of Control and a Ratings Event.

Continuing Directors means, as of any date of determination, any member of the board of directors of Mallinckrodt plc who:

was a member of such board of directors on the Completion Date; or

was nominated for election, co-opted or elected to such board of directors with the approval of a majority of the Continuing Directors who were members of such board of directors at the time of such nomination, co-option or election (either by a specific vote or by approval of the proxy statement in which such member was named as a nominee for election as a director).

Investment Grade means a rating equal to or better than Baa3 (or the equivalent under any successor ratings category of Moody s) by Moody s and BBB- (or the equivalent under any successor ratings category of S&P) by S&P.

Moody s means Moody s Investors Service, Inc., and its successors.

Rating Agencies means (1) each of Moody s and S&P and (2) if either Moody s or S&P ceases to rate the applicable series of notes or fails to make a rating of such notes publicly available for reasons outside of

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MIFSA s control, a nationally recognized statistical rating organization within the meaning of Rule 15c3-1(c)(2)(vi)(F) under the Exchange Act, selected by MIFSA as a replacement agency for Moody s or S&P, or both of them, as the case may be.

Ratings Event means the applicable series of notes are rated below Investment Grade by both Rating Agencies on any date during the period (the Trigger Period ) commencing on the first public announcement of any Change of Control (or pending Change of Control) and ending 60 days following consummation of such Change of Control (which Trigger Period will be extended following consummation of a Change of Control for so long as either of the Rating Agencies has publicly announced that it is considering a possible change). If a Rating Agency does not provide a rating for the applicable series of notes at the commencement of any Trigger Period, such notes will be deemed to be rated below Investment Grade by such Rating Agency during that Trigger Period.

S&P means Standard & Poor s Rating Services, a division of The McGraw-Hill Companies, Inc., and its successors.

Voting Stock of any specified person as of any date means the capital stock of such person that is at the time entitled to vote generally in the election of the board of directors of such person.

### **Payment of Additional Amounts**

All payments made by MIFSA under or with respect to the notes or by a Guarantor with respect to a Guarantee, will be made free and clear of and without withholding or deduction for, or on account of, any present or future tax, duty, levy, assessment or other governmental charge, including any related interest, penalties or additions to tax ( Taxes ) unless the withholding or deduction of such Taxes is then required by law or by interpretation or administration of law. If any deduction or withholding for, or on account of, any Taxes imposed or levied by or on behalf of (1) any jurisdiction in which MIFSA, or the applicable Guarantor, is then incorporated, organized or resident for tax purposes or any political subdivision thereof or therein (each, a Company Tax Jurisdiction ) or (2) any jurisdiction from or through which payment is made by or on behalf of MIFSA, or a Guarantor (including the jurisdiction of any paying agent for the applicable series of notes) or any political subdivision thereof or therein (each, together with each Company Tax Jurisdiction, a Tax Jurisdiction ) will at any time be required to be made from any payments made by MIFSA under or with respect to the applicable series of notes or a Guarantor under or with respect to the applicable Guarantee, including payments of principal, redemption price, interest or premium, MIFSA or such Guarantor, as applicable, will pay such additional amounts (the Additional Amounts ) as may be necessary in order that the net amounts received in respect of such payments by each holder of the notes of such series after such withholding, deduction or imposition (including any such withholding, deduction or imposition from such Additional Amounts) will equal the respective amounts that would have been received in respect of such payments in the absence of such withholding or deduction; provided, however, that no Additional Amounts will be payable with respect to:

(1) any Taxes, to the extent such Taxes would not have been imposed but for the existence of any actual or deemed present or former connection between the holder or the beneficial owner of the notes of a series and the relevant Tax Jurisdiction (including, without limitation, being or having been a national, resident or citizen of, being or having been engaged in a trade or business in, being or having been physically present in, or having or having had a permanent establishment in, such jurisdiction for Tax purposes), other than the holding of such notes, the enforcement of rights under such notes or under a Guarantee or the receipt of any payments in respect of such note or a Guarantee;

- (2) any Taxes, to the extent such Taxes were imposed as a result of the presentation of such notes for payment (where presentation is required) more than 30 days after the relevant payment is first made available for payment to the holder (except to the extent that the holder would have been entitled to Additional Amounts had the notes been presented on the last day of such 30-day period);
- (3) any estate, inheritance, gift, sales, transfer, personal property or similar Taxes;

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- (4) any Taxes withheld, deducted or imposed on a payment to an individual that are required to be made pursuant to European Council Directive 2003/48/EC or any other directive implementing the conclusions of the ECOFIN Council meeting of November 26 and 27, 2000 on the taxation of savings income, or any law implementing or complying with or introduced in order to conform to, such directive;
- (5) Taxes imposed on or with respect to a payment made to a holder of notes who would have been able to avoid such withholding or deduction by presenting such notes (where presentation is required) to another paying agent;
- (6) any Taxes payable other than by deduction or withholding from payments under, or with respect to, such notes or the applicable Guarantee;
- (7) any Taxes to the extent such Taxes are imposed or withheld by reason of the failure of the holder or beneficial owner of such notes, to comply with any written request of MIFSA or a Guarantor addressed to the holder to satisfy any certification, identification, information or other reporting requirements, whether required by statute, treaty, regulation or administrative practice of a relevant Tax Jurisdiction, as a precondition to exemption from, or reduction in the rate of deduction or withholding of, Taxes imposed by the relevant Tax Jurisdiction (including, without limitation, a certification that the holder or beneficial owner is not resident in such Tax Jurisdiction), but in each case, only to the extent the holder or beneficial owner is legally entitled to provide such certification or documentation;
- (8) any withholding or deduction required pursuant to Section 1471(b) of the Code, or otherwise imposed pursuant to Sections 1471 through 1474 of the Code, any regulations or agreements thereunder, official interpretations thereof, or any law implementing an intergovernmental approach thereto;
- (9) any Taxes that are imposed or withheld solely because the beneficial owner of such notes, or a fiduciary, settler, beneficiary, or member of the beneficial owner if the beneficial owner is an estate, trust, partnership, limited liability company or other fiscally transparent entity, or a person holding a power over an estate or trust administered by a fiduciary holder owns or owned 10% or more of the total voting power of all classes of stock of MIFSA or the applicable Guarantor; or

## (10) any combination of items (1) through (9) above.

Nor will Additional Amounts be paid with respect to any payment on a note to a holder who is a fiduciary, a partnership or other entity treated as a partnership for U.S. federal income tax purposes, a limited liability company or other entity that is not the sole beneficial owner of such payment to the extent such payment would be required by the laws of a relevant Tax Jurisdiction (or any political subdivision thereof) to be included in the income, for tax purposes, of a beneficiary or settlor with respect to such fiduciary, a partner of such partnership or other entity treated as a partnership for U.S. federal income tax purposes, a member of such limited liability company or such other beneficial owner, in each case, who would not have been entitled to the Additional Amounts had that beneficiary, settlor, member or beneficial owner been the holder.

In addition to the foregoing, MIFSA and the applicable Guarantor, as the case may be, will also pay and indemnify the holder for any present or future stamp, issue, registration, court or documentary Taxes, or any other excise or property Taxes, charges or similar levies (including penalties, interest and any other reasonable expenses related thereto) which are levied by a relevant Tax Jurisdiction on the execution, delivery, issuance, or registration of the notes of either series, or the indenture, the applicable Guarantee or any other document or instrument referred to therein in connection with a transfer of such notes at the time of the initial resale by the Initial Purchasers.

If MIFSA or a Guarantor, as the case may be, becomes aware that it will be obligated to pay Additional Amounts with respect to any payment under or with respect to the notes of either series, or a Guarantee, MIFSA or such Guarantor, as the case may be, will deliver to the trustee on a date that is at least 30 days prior to the date of that payment (unless the obligation to pay Additional Amounts arises fewer than 45 days prior to that payment

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date, in which case MIFSA or such Guarantor shall notify the trustee in writing promptly thereafter) an officer s certificate stating the fact that Additional Amounts will be payable and the amount estimated to be so payable. The officer s certificate(s) must also set forth any other information reasonably necessary to enable the paying agent to pay such Additional Amounts to holders of such notes on the relevant payment date. The trustee shall be entitled to rely solely on such officer s certificate (as supplemented, updated or revised by any subsequent officer s certificates) as conclusive proof that such payments are necessary.

MIFSA or a Guarantor, as the case may be, will make all withholdings and deductions required by law in respect of the notes, and will remit the full amount deducted or withheld to the relevant Tax authority in accordance with applicable law. MIFSA or such Guarantor will use its reasonable efforts to obtain Tax receipts from each Tax authority evidencing the payment of any Taxes so deducted or withheld. Upon reasonable written request, MIFSA or such Guarantor will furnish to the trustee (or to a holder or beneficial owner upon written request), within a reasonable time after the date the payment of any Taxes so deducted or withheld is made, certified copies of Tax receipts evidencing payment by MIFSA or such Guarantor, as the case may be, or if, notwithstanding such entity s efforts to obtain receipts, receipts are not obtained, other evidence of payments (reasonably satisfactory to the trustee) by such entity.

Whenever in the indenture or in this Description of the Notes there is mentioned, in any context, the payment of amounts based upon the principal amount of the notes of a series or of principal, interest or of any other amount payable under, or with respect to, such notes or a Guarantee, such mention shall be deemed to include mention of the payment of Additional Amounts to the extent that, in such context, Additional Amounts are, were or would be payable in respect thereof.

The above obligations will survive any termination, defeasance or discharge of the indenture and any transfer by a holder or beneficial owner of either series of notes, and will apply, mutatis mutandis, to any jurisdiction in which any successor person to MIFSA or a Guarantor is incorporated, organized or resident for tax purposes or any jurisdiction from or through which payment is made by or on behalf of such person on such notes (or any Guarantee) and any political subdivision thereof or therein.

# **Redemption Upon Changes in Withholding Taxes**

MIFSA or a Guarantor, as applicable, may redeem either series of notes, in whole but not in part, at its discretion at any time upon giving not less than 30 nor more than 60 days prior written notice to the holders of such notes (which notice will be irrevocable) and upon 45 days prior written notice to the trustee (or such shorter period as agreed by the trustee), at a redemption price equal to 100% of the aggregate principal amount thereof, together with accrued and unpaid interest, if any, to the date fixed for redemption (a Tax Redemption Date ) and all Additional Amounts (if any) then due and which will become due on the Tax Redemption Date as a result of the redemption or otherwise (subject to the right of holders of the applicable series of notes on the relevant record date to receive interest due on the relevant interest payment date and Additional Amounts (if any) in respect thereof), if on the next date on which any amount would be payable in respect of such notes, MIFSA or a Guarantor is or would be required to pay Additional Amounts, and MIFSA or such Guarantor cannot avoid any such payment obligation by taking reasonable measures available to it, and the requirement arises as a result of:

 any amendment to, or change in, the laws (or any regulations or rulings promulgated thereunder) of a relevant Tax Jurisdiction which change or amendment becomes effective on or after the Issue Date (or, if the applicable Company Tax Jurisdiction became a Company Tax Jurisdiction on a date after the Issue Date, such later date), or

(2) any amendment to, or change in, an official interpretation or application of such laws, regulations or rulings (including by virtue of a holding, judgment, order by a court of competent jurisdiction or a change in published administrative practice) which amendment or change becomes effective on or after the Issue Date (or, if the applicable Company Tax Jurisdiction became a Company Tax Jurisdiction on a date after the Issue Date, such later date).

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Neither MIFSA nor a Guarantor will give any such notice of redemption earlier than 90 days prior to the earliest date on which MIFSA or such Guarantor, as applicable, would be obligated to make such payment or withholding if a payment in respect of the notes was then due, and the obligation to pay Additional Amounts must be in effect at the time such notice is given. Prior to the publication or, where relevant, mailing of any notice of redemption of the applicable series of notes pursuant to the foregoing, MIFSA or a Guarantor, as applicable, will deliver to the trustee an opinion of independent tax counsel to the effect that there has been such amendment or change which would entitle MIFSA or such Guarantor to redeem such notes. In addition, before MIFSA or such Guarantor, as applicable, publishes or mails notice of redemption of such notes, it will deliver to the trustee an officer s certificate to the effect that MIFSA or such Guarantor cannot avoid its obligation to pay Additional Amounts with respect to such notes by taking reasonable measures available to it.

The trustee will accept and shall be entitled to conclusively rely on such officer s certificate and opinion of counsel as evidence of the existence and satisfaction of the conditions precedent as described above, in which event it will be conclusive and binding on the holders of the applicable series of notes.

The foregoing will apply mutatis mutandis to any jurisdiction in which any successor person to MIFSA or a Guarantor is incorporated or organized, or any jurisdiction from or through which payment is made by or on behalf of such person on either series of notes (or any Guarantee) and any political subdivision thereof or therein.

## **Modification of the Indenture**

MIFSA, a Guarantor and the trustee, at any time and from time to time, may enter into one or more supplemental indentures without the consent of any holders of the notes for any of the following purposes:

to cure any ambiguity, defect or inconsistency in the indenture or either series of notes, including making any such changes as are required for the indenture to comply with the Trust Indenture Act, or to make such other provisions in regard to matters or questions arising under the indenture as the board of directors of MIFSA or a Guarantor may deem necessary or desirable, and which shall not in either case adversely affect the interests of the holders of notes of either series in any material respect;

to evidence the succession of another person to MIFSA or a Guarantor, or successive successions, and the assumption by the successor person of the covenants, agreements and obligations of MIFSA or a Guarantor, as the case may be, pursuant to provisions in the indenture concerning consolidation, merger, the sale of assets or successor entities;

to provide for uncertificated notes in addition to or in place of certificated notes;

to add to the covenants of MIFSA or a Guarantor for the benefit of the holders of either series of notes or to surrender any of MIFSA s or a Guarantor s rights or powers;

to add any additional Events of Default for the benefit of the holders of either series of notes;

to secure either series of notes;

to add one or more guarantees for the benefit of the holders of the notes;

to evidence the release of any guarantee of the notes pursuant to and in accordance with the terms of the indenture;

to make any other change that does not adversely affect the rights of any holder of either series of notes in any material respect;

to issue additional notes of either series in accordance with the limitations set forth in the indenture;

to establish the form of the notes of either series;

to comply with the rules of any applicable securities depository;

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to provide for the issuance of the exchange notes of either series, which will have terms substantially identical in all material respects to the notes of such series (except that the transfer restrictions contained in such notes will be modified or eliminated, as appropriate, and there will be no registration rights (and no increases in annual interest rate) and CIFSA will not guarantee such notes), and which will be treated, together with any outstanding notes of such series, as a single issuance of securities;

to evidence and provide for the acceptance of appointment by a successor trustee with respect to the notes of either series and to add to or change any provision of the indenture as shall be necessary to provide for or facilitate the administration of the trust by more than one trustee; and

to conform the text of the indenture, either of the guarantee or the notes of either series to any provision of this Description of Notes to the extent that such provision in this Description of Notes was intended to be a verbatim recitation of a provision of such indenture, guarantee or notes, as evidenced by an officer s certificate.

In addition, under the indenture, the rights of holders may be changed by MIFSA, a Guarantor and the trustee with the written consent of the holders of at least a majority in aggregate principal amount of the notes of each series at the time outstanding that are affected. However, the following changes may only be made with the consent of each holder of outstanding notes of such series affected:

extend the fixed maturity or reduce the principal amount of the notes of either series;

reduce the rate of or extend the time for payment of interest on the notes of either series;

reduce the premium payable upon the redemption of the notes of either series;

make the notes of either series payable in currency other than that stated therein;

impair the right to institute suit for the enforcement of any payment on or after the fixed maturity thereof or, in the case of redemption, on or after the redemption date;

reduce the percentage of notes of either series the holders of which are required to consent to any such supplemental indenture or indentures;

expressly subordinate in right of payment the notes of either series or a Guarantee thereof;

except as expressly permitted by the indenture, modify a Guarantee in any manner adverse to the holders of the notes of either series issued thereunder; or

make any change in these amendment and waiver provisions.

It will not be necessary for the consent of the holders of either series to approve the particular form of any proposed supplement, amendment or waiver, but it shall be sufficient if the consent approves the substance of it.

# Satisfaction and Discharge

MIFSA s obligations with respect to a series of notes and, upon the satisfaction and discharge of all series of notes, the indenture will be discharged upon MIFSA s or a Guarantor s (i) delivery to the trustee of an officer s certificate and opinion of counsel, each stating that all conditions precedent specified in the indenture relating to satisfaction and discharge have been complied with and (ii) irrevocable deposit with the trustee, in trust, of funds or governmental obligations sufficient to pay at maturity within one year or upon redemption within one year all of the notes of such series which have not already been delivered to the trustee for cancellation, including:

principal;

premium, if any;

unpaid interest; and

all other payments due under the terms of the indenture with respect to the notes of such series.

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Notwithstanding the foregoing, neither MIFSA nor a Guarantor may be discharged from the following obligations, which will survive until such notes mature:

to make any interest or principal payments that may be required;

to register the transfer or exchange of such notes;

to replace stolen, lost or mutilated notes;

to maintain a paying agent; and

to appoint a new trustee as required.

Neither MIFSA nor a Guarantor may be discharged from the following obligations, which will survive the satisfaction and discharge of such series of notes:

to compensate, reimburse and indemnify the trustee in accordance with the terms of the indenture; and

to receive unclaimed payments held by the trustee for at least one year and remit such payments to the holders, if required.

## **Defeasance of Covenants Under Certain Circumstances**

Upon compliance with specified conditions with respect to a series of notes, MIFSA will not be required to comply with some covenants contained in the indenture, and any omission to comply with the obligations will not constitute a default or an Event of Default relating to such notes, or, if applicable, MIFSA s obligations with respect to such notes will be discharged. These conditions include:

the irrevocable deposit, in trust with the trustee for the benefit of the holders of such notes, of funds or of governmental obligations, in each case, sufficient in the opinion of a nationally recognized firm of independent public accountants to pay all the principal of, premium, if any, and interest on such notes to maturity or redemption, as the case may be, and all other amounts payable by MIFSA under the indenture;

the delivery to such trustee of an officer s certificate signed by authorized persons and an opinion of counsel, each stating that all conditions precedent specified in the indenture relating to covenant defeasance have been complied with;

an Event of Default under the indenture described in the first, second, sixth or seventh bullet points in the first paragraph under the caption Events of Default has not occurred and is not continuing, and an event which with notice or lapse of time or both would become such an Event of Default with respect to such notes has not occurred and is not continuing, on the date of such deposit;

the delivery to the trustee of an opinion of counsel or a ruling received from the IRS to the effect that the holders of such notes will not recognize income, gain or loss for federal income tax purposes as a result of the exercise of such covenant defeasance and will be subject to federal income tax in the same amount and in the same manner and at the same times as would have been the case absent such exercise;

the trustee will not have a conflicting interest for the purposes of the Trust Indenture Act with respect to such notes due to the defeasance; and

such covenant defeasance will not result in the trust arising from such deposit constituting, unless it is qualified, a regulated investment company under the Investment Company Act of 1940.

# **Governing Law**

The indenture and each series of notes will be governed by and construed in accordance with the internal laws of the State of New York without regard for conflicts of laws principles that would require the application

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of any other law. The indenture will be subject to the provisions of the Trust Indenture Act that are required to be part of the indenture and shall, to the extent applicable, be governed by such provisions. Articles 86 to 94-8 and 98 of the Luxembourg act dated 10 August 1915 on commercial companies, as amended, shall not apply in respect of the notes.

# **Regarding the Trustee**

Deutsche Bank Trust Company Americas is the trustee under the indenture and also has been appointed by MIFSA to act as registrar, transfer agent and paying agent for the notes. From time to time, the trustee and its affiliates perform various other services for MIFSA and its affiliates. In particular, an affiliate of the trustee acts as a lender under MIFSA s credit facility.

The indenture contains limitations on the rights of the trustee, if it becomes a creditor of MIFSA or a Guarantor, to obtain payment of claims in some cases, or to realize on property received in respect of any of these claims as security or otherwise. The trustee is permitted to engage in other transactions. However, if the trustee acquires any conflicting interest, it must either eliminate its conflict within 90 days, apply to the SEC for permission to continue or resign.

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## **EXCHANGE OFFER**

In connection with the issuance of the outstanding notes, MIFSA entered into a registration rights agreement dated April 11, 2013 with J.P. Morgan Securities LLC and Goldman, Sachs & Co., acting as the representative of the initial purchasers of the outstanding notes. Pursuant to the registration rights agreement, MIFSA agreed to use commercially reasonable efforts to (i) file a registration statement to exchange the outstanding notes for new notes registered under the Securities Act having substantially the same terms as the outstanding notes and evidencing the same indebtedness as the notes and (ii) cause the registration statement to be declared effective under the Securities Act. MIFSA also agreed to file and keep effective a shelf registration statement to cover resales of the outstanding notes under certain circumstances.

MIFSA has agreed to use commercially reasonable efforts to cause the exchange to be completed within 365 days after the issuance of the notes. If MIFSA fails to satisfy its registration obligations under the registration rights agreement, it will be required to pay additional interest to the holders of the notes under certain circumstances. In the event that the exchange offer has not been consummated on or prior to April 11, 2014, the interest rate on the outstanding notes will be increased by 0.25% per annum for the first 90 days immediately following the respective due date, and by an additional 0.25% per annum at the beginning of each subsequent 90-day period, until the applicable requirement has been met or the outstanding notes become freely tradable under the Securities Act, *provided* that the additional interest rate on the notes may not exceed at any one time in the aggregate 1.00% per annum. Following the cure of all such registration defaults, the accrual of additional interest shall cease.

Our obligations to register the exchange notes will terminate upon the completion of the exchange offer. However, under certain circumstances specified in the registration rights agreement, we may be required to file a shelf registration statement for a continuous offer in connection with the outstanding notes.

The following summary of certain provisions of the registration rights agreement does not purport to be complete and is subject to, and is qualified in its entirety by reference to, all the provisions of the registration rights agreement. You should refer to the exhibits that are a part of the registration statement of which this prospectus forms a part for a copy of the registration rights agreement.

The exchange offer will permit eligible holders of notes to exchange the outstanding notes for the exchange notes that are substantially identical in all material respects with the outstanding notes, except that:

the offer and sale of the exchange notes will have been registered under the Securities Act, and thus the exchange notes generally will not be subject to the restrictions on transfer applicable to the outstanding notes or bear restrictive legends;

the exchange notes bear a different CUSIP number from the outstanding notes;

the exchange notes will not be entitled to registration rights, and

the exchange notes will not have the right to earn additional interest under circumstances relating to our registration obligations.

The exchange notes will evidence the same debt as the outstanding notes. Holders of exchange notes will be entitled to the benefits of the indenture.

# General

We will issue exchange notes for tendered and accepted outstanding notes promptly after expiration of the exchange offer. For each old note surrendered to us pursuant to the exchange offer, the holder of such old note will receive an exchange note having a principal amount equal to that of the surrendered old note. Interest on each exchange note will accrue from the last interest payment date on which interest was paid on the old note surrendered in exchange therefor.

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In connection with the issuance of the outstanding notes, we have arranged for the outstanding notes to be issued in the form of global notes through the facilities of DTC acting as depositary. The exchange notes will also be issued in the form of global notes registered in the name of DTC or its nominee and each beneficial owner s interest in it will be transferable in book-entry form through DTC.

Holders of outstanding notes do not have any appraisal or dissenters rights in connection with the exchange offer. Outstanding notes which are not tendered for exchange or are tendered but not accepted in connection with the exchange offer will remain outstanding and be entitled to the benefits of the indenture under which they were issued, including accrual of interest, but, subject to a limited exception, will not be entitled to any registration rights under the applicable registration rights agreement. See Consequences of Failure to Tender.

We will be deemed to have accepted validly tendered outstanding notes when and if we have given written notice to the exchange agent of our acceptance. The exchange agent will act as agent for the tendering holders for the purpose of receiving the exchange notes from MIFSA. If any tendered outstanding notes are not accepted for exchange because of an invalid tender, the occurrence of other events described in this prospectus or otherwise, we will return the certificates for any unaccepted outstanding notes, at our expense, to the tendering holder promptly upon the expiration or termination of the exchange offer.

The exchange offer is not being made to, nor will we accept tenders for exchange from, holders of the outstanding notes in any jurisdiction in which the exchange offer or the acceptance of it would not be in compliance with the securities or blue sky laws of that jurisdiction.

## Eligibility; Transferability

Under existing interpretations of the Securities Act by the staff of the SEC contained in several no-action letters to third parties, and subject to the immediately following sentence, we believe that the exchange notes will generally be freely transferable by holders after the exchange offer without further compliance with the registration and prospectus delivery requirements of the Securities Act (subject to certain representations required to be made by each holder of outstanding notes, as set forth under Procedures for Tendering ). However, any holder of outstanding notes who:

is one of Mallinckrodt plc s or MIFSA s affiliates (as defined in Rule 405 under the Securities Act),

does not acquire the exchange notes in the ordinary course of business,

distributes, intends to distribute, or has an arrangement or understanding with any person to distribute the exchange notes as part of the exchange offer, or

is a broker-dealer who purchased outstanding notes from us in the initial offering of the outstanding notes for resale pursuant to Rule 144A or any other available exemption under the Securities Act,

will not be able to rely on the interpretations of the staff of the SEC, will not be permitted to tender outstanding notes in the exchange offer and, in the absence of any exemption, must comply with the registration and prospectus delivery requirements of the Securities Act in connection with any resale of the exchange notes.

Our belief that transfers of exchange notes would be permitted without registration or prospectus delivery under the conditions described above is based on SEC interpretations given to other, unrelated issuers in similar exchange offers. We cannot assure you that the SEC would make a similar interpretation with respect to our exchange offer. We will not be responsible for or indemnify you against any liability you may incur under the Securities Act.

Each broker-dealer that receives exchange notes for its own account under the exchange offer in exchange for outstanding notes that were acquired by the broker-dealer as a result of market-making or other trading activity must acknowledge that it will deliver a prospectus in connection with any resale of the exchange notes. See Plan of Distribution.

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## Expiration of the Exchange Offer; Extensions; Amendments

The exchange offer will expire at 5:00 p.m., New York City time, on , 2014, which we refer to as the expiration date, unless we extend the exchange offer. To extend the exchange offer, we will notify the exchange agent and each registered holder of any extension before 9:00 a.m., New York City time, on the next business day after the previously scheduled expiration date. We reserve the right to extend the exchange offer, delay accepting any tendered outstanding notes or, if any of the conditions described below under the heading Conditions have not been satisfied, to terminate the exchange offer. We do not currently intend to extend the expiration of the exchange offer. We will delay acceptance only due to an extension of the exchange offer. We also reserve the right to amend the terms of the exchange agent. If we amend the exchange offer in a manner that we consider material, we will disclose such amendment by means of a prospectus supplement, and we will extend the exchange offer for a period of five to ten business days.

Any extension, delay, termination, waiver or amendment of the exchange offer will be followed promptly by public announcement thereof, such announcement in the case of an extension to be made no later than 9:00 a.m., New York City time, on the next business day after the previously scheduled expiration date.

If we delay accepting any outstanding notes or terminate the exchange offer, we promptly will pay the consideration offered, or return any outstanding notes deposited, pursuant to the exchange offer as required by Rule 14e-1(c) under the Exchange Act.

### Conditions

Notwithstanding any other term of the exchange offer, we will not be required to accept for exchange, or issue any exchange notes for, any outstanding notes, and may terminate or amend the exchange offer before the expiration of the exchange offer, if:

we determine that the exchange offer violates any law, statute, rule, regulation or interpretation by the staff of the SEC or any order of any governmental agency or court of competent jurisdiction; or

any action or proceeding is instituted or threatened in any court or by or before any governmental agency relating to the exchange offer which, in our judgment, could reasonably be expected to impair our ability to proceed with the exchange offer.

The conditions listed above are for our sole benefit and may be asserted by us regardless of the circumstances giving rise to any of these conditions. We may waive these conditions in our reasonable discretion in whole or in part at any time and from time to time prior to the expiration date. The failure by us at any time to exercise any of the above rights shall not be considered a waiver of such right, and such right shall be considered an ongoing right which may be asserted at any time and from time to time.

In addition, we will not accept for exchange any outstanding notes tendered, and no exchange notes will be issued in exchange for those outstanding notes, if at any time any stop order is threatened or issued with respect to the registration statement for the exchange offer and the exchange notes or the qualification of the indenture under the Trust Indenture Act of 1939. In any such event, we must use commercially reasonable best efforts to obtain the withdrawal of any stop order as soon as practicable.

In addition, we will not be obligated to accept for exchange the outstanding notes of any holder that has not made to us the representations described under Eligibility; Transferability and Plan of Distribution.

## **Procedures for Tendering**

### Delivery of Letter of Transmittal and Outstanding Notes

Only a holder of record of outstanding notes may tender outstanding notes in the exchange offer. In order to tender outstanding notes in the exchange offer, a holder of outstanding notes must deliver a letter of transmittal and deliver the outstanding notes to the exchange agent. Delivery of the outstanding notes may be made by book-entry transfer to the exchange agent s account at DTC.

Specifically, to accept the exchange offer by delivery of a letter of transmittal and outstanding notes, a holder must:

complete, sign and date the letter of transmittal, or a facsimile of the letter of transmittal, have the signature on the letter of transmittal guaranteed if the letter of transmittal so requires and deliver the letter of transmittal or facsimile to the exchange agent, including all other required documents at the address set forth below under Exchange Agent, prior to the expiration of the exchange offer; and

deliver the outstanding notes to the exchange agent by one of the following methods, as further described under Methods of Delivering Outstanding Notes below:

if a holder holds outstanding notes in book-entry form, the exchange agent must receive, before expiration of the exchange offer, timely confirmation of book-entry transfer of outstanding notes into the exchange agent s account at DTC; or

if a holder is unable to effect book-entry transfer of book-entry notes before the expiration of the exchange offer, the holder must comply with the guaranteed delivery procedures.

If the applicable letter of transmittal is signed by the record holder(s) of the outstanding notes tendered, the signature must correspond with the name(s) written on the face of the outstanding notes without alteration, enlargement or any change whatsoever. If the applicable letter of transmittal is signed by a participant in DTC, the signature must correspond with the name as it appears on the security position listing as the holder of the outstanding notes.

A signature on a letter of transmittal or a notice of withdrawal must be guaranteed by an eligible guarantor institution. Eligible guarantor institutions include banks, brokers, dealers, municipal securities dealers, municipal securities brokers, government securities dealers, government securities brokers, credit unions, national securities exchanges, registered securities associations, clearing agencies and savings associations. The signature need not be guaranteed by an eligible guarantor institution if the outstanding notes are tendered:

by a registered holder who has not completed the box entitled Special Issuance Instructions or Special Delivery Instructions on the letter of transmittal; or

for the account of an eligible institution.

If the letter of transmittal is signed by a person other than the registered holder of any outstanding notes, the outstanding notes must be endorsed or accompanied by a properly completed bond power. The bond power must be signed by the registered holder as the registered holder s name appears on the outstanding notes, and an eligible guarantor institution must guarantee the signature on the bond power.

If the letter of transmittal or any outstanding notes or bond powers are signed by trustees, executors, administrators, guardians, attorneys-in-fact, officers of corporations or others acting in a fiduciary or representative capacity, these persons should so indicate when signing. Unless we waive this requirement, they should also submit evidence satisfactory to us of their authority to deliver the letter of transmittal.

## Automated Tender Offer Program

If a holder is a participant in DTC and is transferring its outstanding notes in book-entry form through DTC, then the exchange agent and DTC have confirmed that such a holder may utilize the DTC ATOP procedures to tender outstanding notes in lieu of delivering a letter of transmittal.

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To use this alternative procedure:

a holder may instruct DTC, in accordance with the ATOP system, to transmit on its behalf a computer-generated message to the exchange agent in which the holder of the outstanding notes acknowledges and agrees to be bound by the terms of the letter of transmittal, which computer-generated message must be received by the exchange agent prior to 5:00 p.m., New York City time, on the expiration date; and

the exchange agent must receive, before expiration of the exchange offer, timely confirmation of book-entry transfer of outstanding notes into the exchange agent s account at DTC, according to the procedure for book-entry transfer described below.

However, the exchange for any outstanding notes tendered through the ATOP system will only be made after a book-entry confirmation of a book-entry transfer of outstanding notes into the exchange agent s account and timely receipt by the exchange agent of an agent s message and any other documents required by the letter of transmittal. The term agent s message means a message, transmitted by DTC and received by the exchange agent and forming part of a book-entry confirmation, which states that DTC has received an express acknowledgment from a participant tendering outstanding notes that are the subject of the book-entry confirmation that the participant has received and agrees to be bound by the terms of the letter of transmittal, and that we may enforce that agreement against the participant.

### Additional Terms and Procedures

Regardless of whether a holder delivers a letter of transmittal or uses the ATOP system, the tender by a holder that is not withdrawn before expiration of the exchange offer will constitute an agreement between that holder and us in accordance with the terms and subject to the conditions set forth in this prospectus and in the letter of transmittal. If a holder completing a letter of transmittal tenders less than all of the outstanding notes held by this holder, this tendering holder should fill in the applicable box of the letter of transmittal. The amount of outstanding notes delivered to the exchange agent will be deemed to have been tendered unless otherwise indicated.

The method of delivery of outstanding notes and the letter of transmittal and all other required documents to the exchange agent is at the election and sole risk of the holder. Instead of delivery by mail, a holder should use an overnight or hand delivery service. In all cases, a holder should allow for sufficient time to ensure delivery to the exchange agent before the expiration of the exchange offer. A holder may request its broker, dealer, commercial bank, trust company or nominee to effect these transactions for the holder. A holder should send any note, letter of transmittal or other required document only to the exchange agent and not directly to us.

Any beneficial owner whose outstanding notes are registered in the name of a broker, dealer, commercial bank, trust company or other nominee and who wishes to tender should contact the registered holder promptly and instruct it to tender on the owner s behalf. If the beneficial owner wishes to tender on its own behalf, it must, prior to completing and executing the letter of transmittal and delivering its outstanding notes, either:

make appropriate arrangements to register ownership of the outstanding notes in the owner s name; or

obtain a properly completed bond power from the registered holder of outstanding notes. The transfer of registered ownership may take considerable time and may not be completed prior to the expiration of the exchange offer.

We will determine in our sole discretion all questions as to the validity, form, eligibility, including time of receipt, acceptance and withdrawal of the tendered outstanding notes. Our determination will be final and binding. We reserve the absolute right to reject any outstanding notes not properly tendered or any outstanding notes the acceptance of which would, in the opinion of our counsel, be unlawful. We also reserve the right to

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waive any defects, irregularities or conditions of tender as to particular outstanding notes. Our interpretation of the terms and conditions of the exchange offer, including the instructions in the letter of transmittal, will be final and binding on all parties.

Unless waived, any defects or irregularities in connection with tenders of outstanding notes must be cured within the time that we determine. Although we intend to notify holders of defects or irregularities with respect to tenders of outstanding notes, neither we, the exchange agent nor any other person will incur any liability for failure to give such notification. Tenders of outstanding notes will not be deemed made until those defects or irregularities have been cured or waived. Any outstanding notes received by the exchange agent that are not properly tendered and as to which the defects or irregularities have not been cured or waived will be returned by the exchange agent without cost to the tendering holder, unless otherwise provided in the letter of transmittal, as soon as practicable following the expiration date.

In all cases, we will issue exchange notes for outstanding notes that we have accepted for exchange under the exchange offer only after the exchange agent timely receives:

a properly completed and duly executed letter of transmittal and all other required documents or a properly transmitted agent s message through the ATOP system; and

the outstanding notes or a book-entry confirmation that the outstanding notes have been transferred into the exchange agent s account at DTC.

Holders should receive copies of the applicable letter of transmittal with the prospectus. A holder may obtain copies of the applicable letter of transmittal for the outstanding notes from the exchange agent at its offices listed under Exchange Agent.

By signing the letter of transmittal, or causing DTC to transmit an agent s message to the exchange agent through the ATOP system, each tendering holder of outstanding notes will, among other things, make the representations in the letter of transmittal described under Eligibility; Transferability.

## Methods of Delivering Outstanding Notes

## Book-Entry Transfer

The exchange agent will make a request to establish an account with respect to the outstanding notes at DTC for purposes of the exchange offer within three business days after the date of this prospectus. A holder whose notes are not held in certificated form must deliver the notes by making a book-entry transfer of the notes into this account, which must be received before the expiration of the exchange offer.

#### **Guaranteed Delivery Procedures**

Holders wishing to tender their outstanding notes but whose outstanding notes are not immediately available or who otherwise cannot deliver their outstanding notes, the letter of transmittal or any other required documents to the exchange agent or cannot comply with the applicable procedures described above before expiration of the exchange offer may nonetheless tender if:

the tender is made through an eligible guarantor institution, which is defined above under Procedures for Tendering Delivery of Letter of Transmittal and Outstanding Notes;

before expiration of the exchange offer, the exchange agent receives from the eligible guarantor institution either a properly completed and duly executed notice of guaranteed delivery, by facsimile transmission, mail or hand delivery, or a properly transmitted agent s message and notice of guaranteed delivery, in each case:

setting forth the name and address of the holder and the registered number(s) and the principal amount of outstanding notes tendered;

stating that the tender is being made by guaranteed delivery; and

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guaranteeing that, within three New York Stock Exchange trading days after expiration of the exchange offer, the letter of transmittal, or facsimile thereof, together with the outstanding notes or a book-entry transfer confirmation, and any other documents required by the letter of transmittal will be deposited by the eligible guarantor institution with the exchange agent; and

the exchange agent receives the properly completed and executed letter of transmittal, or facsimile thereof, as well as all tendered outstanding notes in proper form for transfer or a book-entry transfer confirmation, and all other documents required by the letter of transmittal, within three New York Stock Exchange trading days after expiration of the exchange offer.

Upon request to the exchange agent, a notice of guaranteed delivery will be sent to holders who wish to tender their outstanding notes according to the guaranteed delivery procedures set forth above.

#### Withdrawal of Tenders

Except as otherwise provided in this prospectus, holders of outstanding notes may withdraw their tenders at any time before expiration of the exchange offer.

For a withdrawal to be effective, the exchange agent must receive a computer-generated notice of withdrawal transmitted by DTC on behalf of the holder in accordance with the standard operating procedures of DTC, or a written notice of withdrawal, which may be by telegram, telex, facsimile transmission or letter, at one of the addresses set forth below under Exchange Agent.

Any notice of withdrawal must:

specify the name of the person having tendered the outstanding notes to be withdrawn;

identify the outstanding notes to be withdrawn (including the certificate number(s) of the outstanding notes physically delivered) and principal amount of such notes, or, in the case of notes transferred by book-entry transfer, the name of the account at DTC; and

be signed by the holder in the same manner as the original signature on the letter of transmittal by which such outstanding notes were tendered, with any required signature guarantees, or be accompanied by documents of transfer sufficient to have the trustee with respect to the outstanding notes register the transfer of such outstanding notes into the name of the person withdrawing the tender.

If outstanding notes have been tendered pursuant to the procedure for book-entry transfer described above, any notice of withdrawal must specify the name and number of the account at DTC to be credited with the withdrawn outstanding notes and otherwise comply with the procedures of the facility.

We will determine all questions as to the validity, form and eligibility, including time of receipt, of notices of withdrawal, and our determination shall be final and binding on all parties. We will deem any outstanding notes so withdrawn not to have been validly tendered for exchange for purposes of the exchange offer. We will return any outstanding notes that have been tendered for exchange but that are not exchanged for any reason to their holder without cost to the holder. In the case of outstanding notes tendered by book-entry transfer into the exchange agent s

account at DTC, according to the procedures described above, those outstanding notes will be credited to an account maintained with DTC, for outstanding notes, as soon as practicable after withdrawal, rejection of tender or termination of the exchange offer. You may retender properly withdrawn outstanding notes by following one of the procedures described under Procedures for Tendering above at any time on or before expiration of the exchange offer.

A holder may obtain a form of the notice of withdrawal from the exchange agent at its offices listed under Exchange Agent.

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## **Exchange Agent**

Deutsche Bank Trust Company Americas has been appointed as exchange agent for the exchange offer. You should direct questions and requests for assistance, requests for additional copies of this prospectus or of the letter of transmittal and requests for the notice of guaranteed delivery or the notice of withdrawal to the exchange agent addressed as follows:

To: Deutsche Bank Trust Company Americas

By Mail:

c/o DB Services Americas, Inc.

MS JCK01-0218

5022 Gate Parkway, Suite 200

Jacksonville, FL 32256

Attn: REORG Department

By Overnight Mail or Courier:

c/o DB Services Americas, Inc.

MS JCK01-0218

5022 Gate Parkway, Suite 200

Jacksonville, FL 32256

Attn: REORG Department

Telephone: (877) 843-9767

Email: DB.Reorg@db.com

By Facsimile Transmission (for Eligible Institutions Only):

(615) 866-3889

Confirm by Telephone: (877) 843-9767

DELIVERY OF THE LETTER OF TRANSMITTAL TO AN ADDRESS OTHER THAN AS SHOWN ABOVE OR TRANSMISSION VIA FACSIMILE OTHER THAN AS SET FORTH ABOVE DOES NOT CONSTITUTE A VALID DELIVERY OF THE LETTER OF TRANSMITTAL.

**Fees and Expenses** 

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We will bear the expenses of soliciting tenders. The principal solicitation is being made by mail. However, we may make additional solicitations by telegraph, telephone or in person by our officers and regular employees and those of our affiliates.

We have not retained any dealer-manager in connection with the exchange offer and will not make any payments to broker-dealers or others soliciting acceptances of the exchange offer. We shall, however, pay the exchange agent reasonable and customary fees for its services and reimburse it for its related reasonable out-of-pocket expenses.

We will pay the cash expenses to be incurred in connection with the exchange offer, including the following:

SEC registration fees;

fees and expenses of the exchange agent and trustee;

our accounting and legal fees; and

our printing and mailing costs.

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## **Transfer Taxes**

We will pay all transfer taxes, if any, applicable to the exchange of outstanding notes under the exchange offer, except as follows. The tendering holder will be required to pay any transfer taxes, whether imposed on the registered holder or any other person, if:

exchange notes are to be delivered to, or issued in the name of, any person other than the registered holder of the outstanding notes so exchanged;

tendered outstanding notes are registered in the name of any person other than the person signing the letter of transmittal; or

a transfer tax is imposed for any reason other than the exchange of outstanding notes under the exchange offer.

If satisfactory evidence of payment of transfer taxes is not submitted with the letter of transmittal, the amount of any transfer taxes will be billed to the tendering holder.

#### **Accounting Treatment**

We will record the exchange notes at the same carrying value as the outstanding notes as reflected in our accounting records on the date of the exchange. Accordingly, we will not recognize any gain or loss for accounting purposes upon completion of the exchange offer.

#### **Consequences of Failure to Tender**

All untendered outstanding notes will remain subject to the restrictions on transfer provided for in the outstanding notes and in the Indenture. Generally, the outstanding notes that are not exchanged for exchange notes pursuant to the exchange offer will remain restricted securities. Accordingly, such outstanding notes may be resold only:

to us (upon redemption thereof or otherwise);

pursuant to a registration statement which has been declared effective under the Securities Act;

for so long as the outstanding notes are eligible for resale pursuant to Rule 144A, to a person the holder of the outstanding notes and any person acting on its behalf reasonably believes is a qualified institutional buyer as defined in Rule 144A, that purchases for its own account or for the account of another qualified institutional buyer, in each case to whom notice is given that the transfer is being made in reliance on Rule 144A; or

pursuant to any other available exemption from the registration requirements of the Securities Act (in which case we and the trustee shall have the right to require the delivery of an opinion of counsel, certifications and/or other information satisfactory to us and the trustee),

in each case subject to compliance with any applicable foreign, state or other securities laws.

Upon completion of the exchange offer, due to the restrictions on transfer of the outstanding notes and the absence of such restrictions applicable to the exchange notes, it is likely that the market, if any, for outstanding notes will be relatively less liquid than the market for exchange notes. Consequently, holders of outstanding notes who do not participate in the exchange offer could experience significant diminution in the value of their outstanding notes, compared to the value of the exchange notes. The holders of outstanding notes not tendered will have no further registration rights, except that, under limited circumstances, we may be required to file a shelf registration statement for a continuous offer of outstanding notes.

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## SECURITY OWNERSHIP AND REPORTING

## Security Ownership of Management and Certain Beneficial Owners

The following table shows the number of ordinary shares beneficially owned by (i) each current director, each executive officer named in the Summary Compensation Table and our directors and executive officers as a group, as of February 28, 2014; and (ii) each person who we know or have reason to believe is the beneficial owner of more than 5% of our outstanding ordinary shares as of February 28, 2014, based on statements filed by such persons pursuant to Section 13(d) or 13(g) of the Exchange Act and notices delivered to the Company pursuant to the Irish Companies Act.

A person is deemed to be a beneficial owner of ordinary shares if he or she, either alone or with others, has the power to vote or to dispose of those ordinary shares or the right to acquire such power within 60 days of the date of the table. Ordinary shares subject to stock options presently exercisable or exercisable within 60 days of February 28, 2014 and restricted units are deemed to be outstanding and beneficially owned by the person holding the securities for the purpose of computing the percentage ownership of that person, but are not treated as outstanding for the purpose of computing the percentage of any other person. There were 58,355,617 Mallinckrodt ordinary shares outstanding as of February 28, 2014 and the calculations of percentage ownership below are based on such number of outstanding shares regardless of the date of the information regarding beneficial ownership reported below.

## Directors and Executive Officers

Name of Beneficial Owner	Number of Mallinckrodt Ordinary Shares Beneficially Owned	Percentage Ownership
Directors and Named Executive Officers		
Melvin D. Booth <sup>(1)</sup>	9,551	*
Mark C. Trudeau <sup>(2)</sup>	136,027	*
David R. Carlucci <sup>(3)</sup>	3,034	*
J. Martin Carroll <sup>(3)</sup>	5,034	*
Diane H. Gulyas <sup>(3)</sup>	4,184	*
Nancy S. Lurker <sup>(3)</sup>	3,034	*
JoAnn A. Reed <sup>(3)</sup>	3,034	*
Kneeland C. Youngblood, M.D. <sup>(3)</sup>	3,034	*
Joseph A. Zaccagnino <sup>(3)</sup>	4,599	*
Matthew Harbaugh <sup>(4)</sup>	72,911	*
Ian Watkins <sup>(5)</sup>	14,732	*
Peter Edwards <sup>(6)</sup>	29,853	*
Stephen Merrick <sup>(7)</sup>	13,432	*
Stefano Carchedi <sup>(8)</sup>	3,515	*
David Silver <sup>(9)</sup>	0	*
All directors and executive officers as a group (18		
persons) <sup>(10)</sup>	339,062	*

### **Other Beneficial Owners**

Artisan Partners Limited Partnership		
875 East Wisconsin Avenue, Suite 800		
Milwaukee, Wisconsin 53202	4,302,734 <sup>(11)</sup>	7.4%
BlackRock, Inc.		
40 East 52 <sup>nd</sup> Street		
New York, New York 10022	5,228,383 <sup>(12)</sup>	9.0%
JANA Partners LLC		
767 Fifth Avenue, 8th Floor		
New York, New York 10153	3,312,546 <sup>(13)</sup>	5.7%
Paulson & Co., Inc.		
1251 Avenue of the Americas		
New York, New York 10020	5,640,000 <sup>(14)</sup>	9.7%
The Vanguard Group		
100 Vanguard Blvd.		
Malvern, Pennsylvania 19355	3,162,847 <sup>(15)</sup>	5.4%
Lord, Abbett & Co. LLC		
90 Hudson Street		
Jersey City, New Jersey 07302	3,016,695 <sup>(16)</sup>	5.2%

- \* Represents less than 1% of outstanding ordinary shares.
- (1) Includes 4,551 restricted units.
- <sup>(2)</sup> Includes 119,955 restricted units and 17,904 ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 2, 2014.
- <sup>(3)</sup> Includes 3,034 restricted units.
- <sup>(4)</sup> Includes 23,724 restricted units and 42,901 ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 2, 2014.
- <sup>(5)</sup> Includes 10,044 restricted units and 4,075 ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 2, 2014.
- <sup>(6)</sup> Includes 15,294 restricted units and 11,369 ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 2, 2014.
- <sup>(7)</sup> Includes 11,099 restricted units and 2,332 ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 2, 2014.

(8)

Consists of ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 2, 2014. The information reported for Mr. Carchedi is based on information available to the Company as of his termination date and may not reflect current beneficial ownership.

- <sup>(9)</sup> The information reported for Mr. Silver is based on information available to the Company as of his termination date and may not reflect current beneficial ownership.
- (10) Includes, for executive officers not specifically named in the table, an aggregate of 3,211 ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 2, 2014. Messrs. Carchedi and Silver are not included in the calculation for all directors and executive officers as a group.
- (11) Based on information contained in a Schedule 13G filed by Artisan Partners Limited Partnership with the SEC January 30, 2014. Artisan Partners Limited Partnership reports that it has shared voting power with respect to 4,041,456 of these shares and shared dispositive power with respect to all of these shares.
- (12) Based on information contained in a Schedule 13G filed by Blackrock, Inc. with the SEC on February 3, 2014. Blackrock, Inc. reports that it has sole voting power with respect to 4,930,686 shares and sole dispositive power with respect to all these shares.
- (13) Based on information contained in a Schedule 13G filed by Jana Partners LLC with the SEC on February 14, 2014. JANA Partners LLC reports that it has sole voting power and sole dispositive power with respect to all these shares.

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- <sup>(14)</sup> Based on information contained in a Schedule 13G filed by Paulson & Co., Inc. with the SEC on February 14, 2014. Paulson & Co., Inc. reports that it has sole voting power and sole dispositive power with respect to all these shares.
- (15) Based on information contained in a Schedule 13G filed by the Vanguard Group with the SEC on February 11, 2014. The Vanguard Group reports that it has sole voting power with respect to 36,250 of these shares, sole dispositive power with respect to 3,130,397 of these shares and shared dispositive power with respect to 32,450 of these shares.
- <sup>(16)</sup> Based on information contained in a notice pursuant to section 67 of the Irish Companies Act sent by Lord, Abbett & Co. LLC to the Company, which notice discloses the number of shares in which Lord, Abbett & Co. LLC is interested as of February 24, 2014.

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## OUR RELATIONSHIP WITH COVIDIEN FOLLOWING THE DISTRIBUTION

Since the separation on June 28, 2013, we and Covidien have operated as separate, independent public companies. In connection with the separation, we and Covidien entered into certain agreements that provide a framework for our relationship with Covidien after the separation and provide for the allocation between us and Covidien of Covidien s assets, employees, liabilities and obligations (including its property, employee benefits, environmental liabilities and tax liabilities) attributable to periods prior to, at and after our separation from Covidien. The following is a summary of the terms of the material agreements that we entered into with Covidien in connection with the separation.

The material agreements described below are filed as exhibits to the registration statement of which this prospectus forms a part. The summaries of each of these agreements set forth the terms of the agreements that we believe are material. These summaries are qualified in their entireties by reference to the full text of the applicable agreements, which are incorporated by reference into this prospectus.

#### **Separation and Distribution Agreement**

The separation and distribution agreement sets forth the agreements between us and Covidien regarding the principal corporate transactions required to effect our separation from Covidien and other agreements governing our relationship with Covidien.

The separation and distribution agreement identified assets to be transferred, liabilities to be assumed and contracts to be assigned to each of us and Covidien as part of the separation, and it provided for when and how these transfers, assumptions and assignments will occur. In particular, the separation and distribution agreement provided, among other things, that, subject to the terms and conditions contained therein:

certain assets related to the businesses and operations of Covidien s Pharmaceuticals business (and certain legacy businesses and operations of Mallinckrodt entities), which we refer to as the Mallinckrodt Assets, were transferred to us or one of our subsidiaries;

certain liabilities (including whether accrued, contingent or otherwise) arising out of or resulting from the Mallinckrodt Assets, and other liabilities related to the businesses and operations of Covidien s Pharmaceuticals business (and certain legacy businesses and operations of Mallinckrodt entities), which we refer to as the Mallinckrodt Liabilities, were retained by or transferred to us or one of our subsidiaries;

all of the assets and liabilities (including whether accrued, contingent or otherwise) other than the Mallinckrodt Assets and Mallinckrodt Liabilities (such assets and liabilities, other than the Mallinckrodt Assets and the Mallinckrodt Liabilities, are referred to as the Excluded Assets and Excluded Liabilities, respectively) were retained by or transferred to Covidien or one of its subsidiaries; and

certain shared contracts were assigned, in part to us or our applicable subsidiaries or were appropriately amended.

Except as may expressly be set forth in the separation and distribution agreement or any other transaction agreements, all assets were transferred on an as is, where is basis and the respective transferees agreed to bear the economic and

legal risks that (1) any conveyance will prove to be insufficient to vest in the transferee good title, free and clear of any security interest, and (2) any necessary consents or governmental approvals are not obtained or any requirements of laws or judgments are not complied with. In general, each party to the separation and distribution agreement assumed liability for all pending, threatened and unasserted legal matters related to its own business or its assumed or retained liabilities and agreed to indemnify the other party for any liability to the extent arising out of or resulting from such assumed or retained legal matters. In addition, the separation and distribution agreement provides for cross-indemnities principally designed to place financial responsibility for the obligations and liabilities of our business with us and financial responsibility for the obligations and liabilities of Covidien s remaining business with Covidien, among other indemnities.

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Specifically, each of Covidien and Mallinckrodt will indemnify, defend and hold harmless the other party, its subsidiaries and their respective directors, officers, employees and agents against any losses arising out of or resulting from:

the liabilities that each such party assumed or retained pursuant to the separation and distribution agreement (which, in the case of Mallinckrodt, would include the Mallinckrodt Liabilities and, in the case of Covidien, would include the Excluded Liabilities); and

any breach by such party of the separation and distribution agreement or the other transaction agreements. Also, we will indemnify, defend and hold harmless Covidien, its subsidiaries and their respective directors, officers, employees and agents from and against any losses arising out of or resulting from:

the operation of our business;

except to the extent it relates to an Excluded Liability, any guarantee, indemnification obligation, letter of credit reimbursement obligation, surety bond or other credit support agreement, arrangement, commitment or understanding for the benefit of Mallinckrodt or its subsidiaries by Covidien or any of its subsidiaries that survives following the distribution; and

any untrue statement or alleged untrue statement of a material fact or omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, with respect to all information contained in the Form 10, the information statement mailed to Covidien shareholders in connection with the distribution, the offering memorandum for the April 2013 notes offering or any other disclosure document that describes the separation or the distribution or Mallinckrodt and its subsidiaries or primarily relates to the transactions contemplated by the separation and distribution agreement.

In addition, Covidien will indemnify, defend and hold harmless Mallinckrodt, its subsidiaries and their respective directors, officers, employees and agents from and against any losses arising out of or resulting from:

Covidien s business other than the Pharmaceuticals business (except to the extent it relates to a Mallinckrodt Liability and other than the conduct of business, operations or activities for the benefit of Mallinckrodt or its subsidiaries pursuant to the separation and distribution agreement, the transition services agreement, the tax matters agreement or the employee matters agreement); and

the investigation and remediation of sites in Orrington, Maine and Penobscot River and Bay (as described in Note 18 of the notes to our annual consolidated and combined financial statements included elsewhere in this prospectus).

The separation and distribution agreement also specifies procedures with respect to claims subject to indemnification and related matters.

To the extent that any transfers contemplated by the separation and distribution agreement have not been consummated on or prior to the distribution date, the parties agreed to cooperate to effect such transfers as promptly as practicable following the distribution date. In addition, each of the parties agreed to cooperate with the other party and use commercially reasonable efforts to take or to cause to be taken all actions, and to do, or to cause to be done, all things reasonably necessary under applicable law or contractual obligations to consummate and make effective the transactions contemplated by the separation and distribution agreement and the other transaction agreements.

Under the separation and distribution agreement, following the separation, we and Covidien are obligated to provide each other access to information in certain circumstances. The separation and distribution agreement also imposes obligations with respect to retention of information and confidentiality.

The separation and distribution agreement provides for the allocation among the parties of rights and obligations under existing insurance policies with respect to occurrences prior to completion of the separation

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and sets forth procedures for the administration of insured claims. In addition, the separation and distribution agreement allocates between the parties the right to proceeds and the obligation to incur certain deductibles under certain insurance policies.

## **Transition Services Agreement**

We and Covidien entered into a transition services agreement in connection with the separation pursuant to which we and Covidien and our respective affiliates agreed to provide each other, on an interim, transitional basis, various services, including, but not limited to, treasury administration, employee benefits administration, information technology services, non-exclusive distribution and importation services for our products in certain countries outside the United States, regulatory, general administrative services and other support services. The agreed-upon charges for such services are generally intended to allow the servicing party to recover all out-of-pocket costs and expenses and a predetermined profit equal to a mark-up of such out-of-pocket expenses. The party receiving each transition service will be provided with reasonable information that supports the charges for such transition service by the party providing the service.

The services generally commenced on the distribution date and will terminate up to 24 months following the distribution date. The receiving party may terminate certain specified services by giving prior written notice to the provider of such services and paying specified wind-down charges.

Subject to certain exceptions, the liabilities of each party providing services under the transition services agreement is generally limited to the aggregate charges (excluding any third-party costs and expenses included in such charges) actually paid to such party by the other party pursuant to the transition services agreement. The transition services agreement also provides that the provider of a service will not be liable to the recipient of such service for any special, indirect, incidental or consequential damages.

# **Tax Matters Agreement**

In connection with the separation, we entered into a tax matters agreement with Covidien that generally governs Covidien s and our respective rights, responsibilities and obligations after the distribution with respect to certain taxes, including ordinary course of business taxes and taxes, if any, incurred as a result of any failure of the distribution of our shares to qualify as a tax-free distribution for U.S. federal income tax purposes within the meaning of Section 355 of the Code or other applicable tax law or any failure of certain internal transactions undertaken in anticipation of the distribution to qualify for tax-free or tax-favored treatment under the applicable tax law. The agreement also assigns rights and responsibilities for administrative matters, such as the filing of returns, payment of taxes due, retention of records, tax reporting practices and conduct of audits, examinations or similar proceedings. In addition, the agreement provides for cooperation and information sharing with respect to tax matters.

Under the tax matters agreement, with certain exceptions, we are generally responsible for the payment of: