Mallinckrodt International Finance SA
Form S-4
January 16, 2014
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As filed with the Securities and Exchange Commission on January 16, 2014

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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	**Ireland**
(State or other jurisdiction of incorporation or organization)	**(State or other jurisdiction of incorporation or organization)**

2834 **(Primary Standard Industrial** **Classification Number)**	**2834** **(Primary Standard Industrial** **Classification Number)**
98-1094609 **(I.R.S. Employer** **Identification Number)**	**98-1088325** **(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)**	**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 filer ¨	Accelerated filer ¨
Non-accelerated filer x (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 transaction:

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price per Unit	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee[1]
3.500% Senior Notes due 2018	$300,000,000	100%	$300,000,000	$38,640.00
4.750% Senior Notes due 2023	$600,000,000	100%	$600,000,000	$77,280.00
Guarantee of the 3.500% Senior Notes due 2018	$300,000,000	N/A	N/A	(2)
Guarantee of the 4.750% Senior Notes due 2023	$600,000,000	N/A	N/A	(2)

(1) Calculated pursuant to Rule 457(f)(2) under the Securities Act.
(2) No separate consideration will be received for the guarantee, and pursuant to Rule 457(n) under the Securities Act, no additional registration fee is due for the guarantee.

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.

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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 JANUARY 16, 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, the exchange notes), respectively, each of whose exchange 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 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

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 Risk Factors beginning on page 15 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 ac-knowledge 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.

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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, we, us, our, our Company and the Company refe Mallinckrodt plc, an Irish public limited company, and its combined 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 2013, fiscal 2012, fiscal 2011, fiscal 2010 and fiscal 2009 are to Mallinckrodt s fiscal years ended 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 or® 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 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.

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WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-4 (Registration No. 333-) 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, plan, intend, project, anticipate, estimate, predict, potential, continue, ma 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.

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 15.

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). In the fourth quarter of fiscal 2013, the FDA accepted for filing our NDA for the drug filed as MNK-395, which the FDA has granted conditional approval for the brand name PENNSAID® (diclofenac sodium topical solution) 2% w/w (Pennsaid 2%). 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; and Meredith Fischer, our Senior Vice President, Communications and Public Affairs; 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). 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 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 1.50% 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.

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.**

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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 outstanding 2018 notes and the registered 2018 notes collectively as the 2018 notes and the outstanding 2023 notes and the registered 2023 notes collectively as the 2023 notes. We refer to outstanding notes and the exchange notes collectively as the 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.

Use of Proceeds

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

Exchange Agent

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.

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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	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	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.
Further Issuances	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 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, 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.

	Fiscal Year[1]		
(Dollars in Millions)	**2013[2]**	**2012[3]**	**2011[4]**
Consolidated and Combined Statement of Income Data:			
Net sales	$ 2,204.5	$ 2,056.2	$ 2,021.8
Gross profit	1,024.9	964.8	914.9
Operating income[5]	144.8	235.2	240.7
Income from continuing operations before income taxes	126.4	236.1	243.2
Income from continuing operations	57.8	141.3	157.0
Other Financial Data:			
Adjusted EBITDA[6]	$ 396.7	$ 402.8	$ 371.8

	September 27, 2013	**September 28, 2012**	**September 30, 2011**
Consolidated and Combined Balance Sheet Data:			
Total assets	$ 3,556.6	$ 2,898.9	$ 2,832.2
Long-term debt	918.3	8.9	10.4
Shareholders equity	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) 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.

(3) 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.

(4) 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.

(5) 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. 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.

(6) 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 six groups: risks related to the exchange offer, risks related to the notes, 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 September 27, 2013, we had $919.8 million of total debt. We may also incur 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 in the future for working capital, capital expenditures and acquisitions;
- Limiting our ability to refinance our indebtedness on terms acceptable to us or at all;
- Imposing restrictive covenants on our operations;

Requiring us to dedicate a significant portion of our cash flows from operations to paying the principal of and interest on our indebtedness, thereby reducing funds available for other corporate purposes; and

Making us more vulnerable to economic downturns and limiting our ability to withstand competitive pressures.

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. 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 other 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 September 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.

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.

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 because it may not have sufficient financial resources to repurchase all of the debt securities that are tendered 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 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.

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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, 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 downgrade by either S&P or Moody s could decrease earnings and may result in higher borrowing costs.

Any future lowering of our ratings likely would make it more difficult or more expensive for us to obtain additional debt financing. If any credit rating initially assigned to the notes is subsequently lowered or withdrawn for any reason, 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 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

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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. 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

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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. Until these facilities resume normal production, we expect to fulfill customer orders through procurement of Mo-99 from alternative sources at higher than historical 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

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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;

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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;

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

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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.

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 to 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.

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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

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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® (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 expects to issue its formal recommendation to the DHHS in December 2013. This recommendation will begin a process that will lead to a final decision by the DEA on the scheduling of these products. 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 systemic impact of potential long-term and wide-spread recession (including concerns that certain European

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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 September 27, 2013, it was probable that we would incur remedial costs in the range of $46.4 million to $81.5 million. We also concluded that, as of September 27, 2013, the best estimate within this range was $46.4 million. For further information on our environmental obligations, refer to Business Legal Proceedings and Note 18 of the notes to our consolidated and combined financial statements included elsewhere

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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, or the failure to recruit additional key scientific, 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 services effectively and efficiently, could disrupt our business 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.

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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 indemnities. 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.

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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 from Tyco International or TE Connectivity Ltd. pursuant to the Tyco Tax Sharing 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

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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 or hear actions against us or those persons based on those 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

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. 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

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under Irish insolvency laws, if a company goes into liquidation, a liquidator may apply to the court to have 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 cancelled 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 September 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)		September 27, 2013
Cash and Cash Equivalents	$	275.5
Debt:		
Current maturities of long-term debt:		
Capital lease obligation		1.4
Loan payable		0.1
Total current debt		1.5
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		1.8
Total long-term debt		918.3
Total debt		919.8
Equity:		
Total equity		1,255.6
Total capitalization	$	2,175.4

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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. 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.

	Fiscal				
	2013	**2012**	**2011**	**2010**	**2009**
Ratio of earnings to fixed charges	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 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 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 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)	Fiscal Year[1]				
	2013	2012	2011	2010	2009
Consolidated and Combined Statement of Income Data:					
Net sales[2]	$ 2,204.5	$ 2,056.2	$ 2,021.8	$ 2,047.6	$ 2,429.5
Gross profit	1,024.9	964.8	914.9	932.4	1,296.3
Research and development expenses[3]	165.7	144.1	141.5	119.1	155.2
Operating income[4][5]	144.8	235.2	240.7	240.4	508.5
Income from continuing operations before income taxes	126.4	236.1	243.2	243.2	512.0
Income from continuing operations	57.8	141.3	157.0	145.9	315.5
Share Data:[6]					
Basic income from continuing operations per share	$ 1.00	$ 2.45	$ 2.72	$ 2.53	$ 5.47
Diluted income from continuing operations per share	1.00	2.45	2.72	2.53	5.47
Cash dividends per ordinary share					

	September 27, 2013	September 28, 2012	September 30, 2011	September 24, 2010	September 25, 2009
Consolidated and Combined Balance Sheet Data:					

Total assets	$ 3,556.6	$ 2,898.9	$ 2,832.2	$ 2,892.6	$ 3,167.4
Long-term debt	918.3	8.9	10.4	11.6	13.6
Shareholders equity	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.

(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.

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(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. Fiscal 2013, 2012 and 2011 include separation related costs of $74.2 million, $25.5 million and $2.9 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. 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, 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. Management considers the bases on which the expenses have been

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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 (baclofen injection) 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® 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® (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.

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Also in fiscal 2009, we entered into a licensing agreement to utilize Depomed Inc. s (Depomed) Acuform™ gastric 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 the Netherlands also experienced a shutdown. Until these facilities resume normal production, we expect to fulfill customer orders through procurement of Mo-99 from alternative sources at higher than historical 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 dosages. We held a 180-day exclusivity period for each of the 27 mg, 36 mg and 54 mg dosage strengths, which began upon the commercial launch of each dosage strength. We launched the 27 mg dosage strength upon FDA approval during the first quarter of fiscal 2013 and launched the 36 mg and 54 mg dosage strengths during the second quarter of fiscal 2013. In February 2013, we submitted a supplement to our approved ANDA for an 18 mg dosage strength, which the FDA has accepted and granted priority review. Net sales of Methylphenidate ER were $148.3 million in fiscal 2013; however, we expect that sales of these products may subsequently decline in fiscal 2014 due to a number of factors, including expiration of the exclusivity periods. In July 2013, a competitor received 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.

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 has the right, pursuant to agreements with us, to sell a generic version of Exalgo; however, their entrance to 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 dosages expire in July 2014.

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 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 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 September 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 first

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half of fiscal 2014. Our NDA for MNK-395 was submitted in June 2012 and, after repeating a pharmacokinetic study and submitting the results to the FDA, the application was accepted for filing in August 2013. The FDA has granted conditional approval of the name Pennsaid 2% for the MNK-395 NDA. If approved, we expect to launch this product in the second half 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 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 September 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 dosage strength of Methylphenidate ER. The FDA has accepted this supplement and granted it priority review. If accepted, we will have all four dosage strengths available on the market, as we currently offer the 27 mg, 36 mg and 54 mg dosage 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

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 Year		
	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

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

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 in the Global Medical Imaging segment.

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.

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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 Year		
	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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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):

	Fiscal Year		
	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[(1)]	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):

	Fiscal Year		
	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

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

	Fiscal Year		
	2013	2012	Percentage 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

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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):

	Fiscal Year		
	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):

	Fiscal Year		
	2013	2012	Percentage Change
Optiray	$ 318.5	$ 352.2	(9.6)%
Optimark	44.8	48.0	(6.7)
Other	134.8	141.8	(4.9)
Contrast Media and Delivery Systems	498.1	542.0	(8.1)
Ultra-Technekow DTE	188.8	202.5	(6.8)
Octreoscan	82.8	78.7	5.2
Other	166.0	173.6	(4.4)
Nuclear Imaging	437.6	454.8	(3.8)
Global Medical Imaging	$ 935.7	$ 996.8	(6.1)

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[(1)]	(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.

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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		
	2012	2011	Percentage 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[(1)]	54.2	52.4	3.4
Net sales	$ 2,056.2	$ 2,021.8	1.7

(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):

	Fiscal Year		
	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

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

	Fiscal Year		
	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):

	Fiscal Year		
	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)

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

	Fiscal Year	
	2012	2011

			Percentage Change
Optiray	$ 352.2	$ 374.9	(6.1)%
Optimark	48.0	50.3	(4.6)
Other	141.8	170.3	(16.7)
Contrast Media and Delivery Systems	542.0	595.5	(9.0)
Ultra-Technekow DTE	202.5	200.3	1.1
Octreoscan	78.7	76.9	2.3
Other	173.6	187.3	(7.3)
Nuclear Imaging	454.8	464.5	(2.1)
Global Medical Imaging	$ 996.8	$ 1,060.0	(6.0)

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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):

	Fiscal Year			
	2013		2012	
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[(1)]	(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.

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.

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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):

	Fiscal Year		
	2013	**2012**	**2011**
Net cash provided by (used in):			
Operating activities	$ 135.9	$ 255.8	$ 370.2
Investing activities	(234.7)	(152.2)	(112.6)
Financing activities	373.0	(103.6)	(257.6)
Effect of currency exchange rate changes on cash and cash equivalents	1.3		
Net increase in cash and cash equivalents	$ 275.5	$	$

Operating Activities

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 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 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

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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

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.

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

Debt and Capitalization

At September 27, 2013, total debt was $919.8 million compared with total debt at September 28, 2012 of $10.2 million, both of which were directly incurred with third parties as Covidien s debt had not been allocated to us in historical periods.

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 1.50% 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 0.25%, 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, to interest expense to exceed certain thresholds. Other nonfinancial covenants restrict, among other things, our ability to create liens, 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 outstanding under the credit facility as of September 27, 2013.

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 September 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.

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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 than 1 year	1-3 years	3-5 years	More than 5 years
Long-term debt obligations[1]	$ 1,270.8	$ 40.7	$ 81.2	$ 381.2	$ 767.7
Capital lease obligations[1]	3.4	1.5	1.9		
Operating lease obligations	66.7	19.3	23.7	13.5	10.2
Purchase obligations[2]	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 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 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. The Company assesses the probability of potential liabilities related to such representations, warranties and indemnities and adjusts potential liabilities as a result of changes in facts and circumstances. The Company has no reason to believe that these uncertainties would have a material adverse effect on its 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 consolidated balance sheet at September 27, 2013 was $20.1 million, of which $17.2 million related to environmental, health and safety matters. The value of the environmental, health and safety indemnity 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 September 27, 2013. As of September 27, 2013, the maximum future payments we could be required to make under these indemnification obligations was $75.5 million. We were required to pay $30.0 million into an escrow account as collateral to the purchaser, of which $23.5 million remained in other assets on the consolidated balance sheet at September 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 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 September 27, 2013, we had a $21.1 million letter of credit to guarantee decommissioning costs associated with our Saint Louis, Missouri plant. As of September 27, 2013, we had various other letters of credit and guarantee and surety bonds totaling $38.1 million.

We exchanged title to $11.3 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 2022, 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 consolidated and combined 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, managed care organizations and group purchasing organizations that provide for rebates, sales incentives, distribution service 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

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 asset 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

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

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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 the single level rate that produces the same result as the spot rate curve. For our non-U.S. plans, the discount rate is generally determined by reviewing country- and region-specific government and corporate bond interest rates. 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. 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 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 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

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

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Interest Rate Risk

As of September 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 September 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 September 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 consolidated statement of income is 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 September 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 $34.2 million as of September 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 September 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 $47.5 million as of September 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.

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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® 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.